DRUG USE AND OPIOID SUBSTITUTION TREATMENT IN PREGNANCY: EVIDENCE FROM ELECTRONIC HEALTH RECORDS

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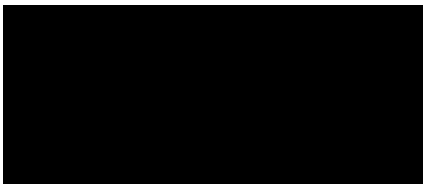
DECLARATION

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

Statement of Authorship

I carried out all the work presented in this thesis. Parts of chapters 4 and 6 have also been published as journal articles. The journal articles references are included in Appendix 11.



ABSTRACT

Background: Misuse of drugs is a public health problem which can lead to poor health outcomes. Drug use during pregnancy could potentially harm the unborn baby. Pregnancy usually triggers women to visit their general practitioner (GP) which may provide an opportunity for drug use to be raised and recorded. To date, there are no UK studies with large sample sizes to estimate the burden of drug use during pregnancy. Therefore, my aim was to describe and understand drug use and opioid substitution treatment in and around pregnancy using electronic health records.

Methods: Using a mixed methods design, I firstly, utilized The Health Improvement Network (THIN) to estimate GP recording rates of individuals who use drugs and/or are prescribed opioid substitution treatment in the general population, of women in and around pregnancy and infants with neonatal abstinence syndrome (NAS). Next, I compared rates with national surveys and hospital birth data. Finally, I conducted qualitative interviews to gain GPs' perspectives regarding their decisions about recording drug-use.

Results: GP recording trends for the general population were in keeping with national surveys, but with lower rates. Recording was relatively low in and around pregnancy. GP recording of NAS was similar to hospital data, however rates were lower. Finally, qualitative interview analysis identified that influences on recording drug use were complex and related to pressures at the individual as well as organisational (general practices, Clinical Commissioning Groups) and governmental levels in the shape of government policies.

Conclusion: In conclusion, evidence from the thesis supports the use of THIN as a suitable tool for monitoring trends but not rates of problem drug use in the general population. Electronic primary health records could potentially be used to monitor the impact of problematic drug use in and around pregnancy. The thesis also supports utilising THIN for researching drug use and opioid substitution treatment in the general population.

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ABBREVIATIONS

ACU	Acceptable Computer Usage
AMR	Acceptable Mortality Ratio
ALSPAC	Avon Longitudinal Study of Parents and Children
BNF	British National Formulary
CI	Confidence Interval
CCGs	Clinical Commissioning Groups
CPRD	Clinical Practice Research Datalink
CSEW	Crime Survey for England and Wales
DSM	Diagnostic and Statistical Manual for Mental disorders
Denom	Denominator
EMCDDA	The European Monitoring Centre for Drugs and Drug Addiction
GP	General Practitioner
GPRD	General Practitioner Research Database
HES	Hospital Episode Statistics
HESID	Hospital Episode Statistics Identity Number
ICD	International Classification of Disease
ICPC	International Classification of Primary Care
LES	Local Enhanced Service
LSD	Lysergic Acid Diethylamide
NDTMS	National Drug Treatment Monitoring System

NTA	National Treatment Agency
NAS/NWS	Neonatal Abstinence Syndrome/Neonatal Withdrawal Syndrome
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
NTA	National Treatment Agency
ONS	Office for National Statistics
OR	Odds Ratio
OST	Opioid Substitution Treatment
OXMIS	Oxford Medical Information System
PHE	Public Health England
PR	Prevalence Ratio
QOF	Quality Outcome Framework
RCGP	Royal College of General Practitioners
RDMD	Regional Drug Misuse Database
RR	Rate Ratio
SHA	Strategic Health Authority
SMMGP	Substance Misuse Management in General Practice
UK	United Kingdom
USA	United States of America
THIN	The Health Improvement Network

CHAPTER 1 INTRODUCTION AND LITERATURE REVIEW

1.1 Content and Structure of Chapter 1

In this chapter, I firstly present an overview of the thesis, followed by the background of the dissertation which is based on previous literature and policy documents. The chapter ends with a review of literature that has previously explored recording of drug use and opioid substitution treatment in electronic health records and drug use during pregnancy.

1.2 Overview of Thesis

The main focus of the PhD was to explore the level of burden of drug use in and around pregnancy in England and Wales by examining General Practitioner (GP) recording of drug use and opioid substitution treatment in individuals' electronic health records. The two main research questions of the thesis were to establish if a primary care database could be used as i) a surveillance and ii) a research tool for drug use and opioid substitution treatment in and around pregnancy. In order to increase my understanding of pregnant women who use drugs and/or opioid substitution treatment, I first examined electronic health records of the general population and subsequently focused on women in and around pregnancy and infants with neonatal abstinence syndrome (a symptom of maternal drug use). I used a mixed methods approach to answer the research questions, consequently the first three studies are quantitative and the fourth qualitative.

The thesis comprises of nine chapters, which all begin with the content and structure of each chapter and conclude with how the chapter supports the thesis. The first chapter begins with descriptions and definitions of drug use, opioid substitution treatment and recording in electronic health records. I then evaluate the burden of drug use globally and describe the history of drug policy in the UK. After which, I review previous literature examining recording of drug use and opioid substitution treatment in primary care and conclude this chapter with the rationale for undertaking my PhD. In the second chapter I describe the overall

aim, objectives and research questions of the thesis, followed by short summaries of chapters 3-8. The third chapter includes a description of the two large databases that I used for my epidemiological studies (The Health Improvement Network (used in studies 1-3) and Hospital Episode Statistics (used in study 3)) and I discuss qualitative methodologies (used in study 4). The fourth chapter covers the first quantitative study in which I focus on GP recording of those in the general population who use drugs and/or opioid substitution treatment. This leads onto the fifth chapter, which examines women identified in chapter 4 who are also pregnant. The focus of this chapter is on GP recording of women who use drugs and/or opioid substitution treatment in and around pregnancy. Following this, chapter six presents the third and final quantitative study, which concentrates on GP recording of neonatal abstinence syndrome in infants. The seventh chapter describes the analysis and findings of the qualitative study in which I interviewed GPs to gain a deeper understanding of factors that influence recording of drugs use and/or opioid substitution treatment in electronic health records. The penultimate chapter synthesises the results from both the quantitative and qualitative studies. Finally, in the last chapter, I present and overview of the thesis and discuss how the thesis brings new knowledge and improves method, I discuss the reason for choosing the Crime Survey for England and Wales over the Offending Crime and Justice Survey, I present the overarching strengths and limitations, support the argument for the thesis, discuss the contribution of the thesis to the field of research, the clinical and research implications and the overall conclusion of the thesis.

1.3 Background

1.3.1 Classification of controlled drugs in the United Kingdom

A drug is defined as controlled if it has the potential for abuse or addiction (Drugscope, 2015a). This can include both illicit drugs and prescribed medications under the United Kingdom Misuse of drugs Act, passed in 1971 *(see section 1.3.8 for details)* (Drugscope, 2015a). There are four categories of controlled drugs; sedatives, stimulants, opioids and hallucinogens which are categorised into classes and schedules (Home office, 2013). Penalties for production, supply and possession are highest for Class A drugs and lowest for Class C drugs (Table 1.1) (Drugscope, 2015a; Home office, 2013). Each drug is

also classified into a schedule, which relates to the control of supply of the drug (Drugscope, 2015a; Home office, 2013). Schedule 1 is the most rigorous and these drugs can only be administered under exceptional circumstances with a license from the home office (Drugscope, 2015a; Home office, 2013). Whilst schedule 5 can be bought over the counter but the drug has to be supplied by a pharmacist (Table 1.1) (Drugscope, 2015a; Home office, 2013).

Table 1.1: Classes and schedules of the most common drugs used in the United Kingdom (Drugscope, 2015a; Home office, 2013)

Drug	Class	Schedule	Type
Amphetamine	A	2	Stimulant
Benzodiazepine	C	3/4	Sedative
Buprenorphine	C	3	Opiate
Cannabis	B	1	Sedative
Cocaine/ Crack cocaine	A	2	Stimulant
Ecstasy/MDMA*	A	1	Stimulant
Heroin	A	2	Opiate
Lysergic Acid Diethylamide/LSD	A	1	Hallucinogenic
Methadone	C	2	Opiate

*MDMA=methylenedioxy methamphetamine

1.3.2 Definitions of individuals who use drugs

In the next section, I define drug dependence, addiction, recreational drug use, problematic drug use, substance use disorder, people who use drugs and diagnosis of substance misuse disorder

1.3.2.1 Drug dependence

Drug dependence is defined as a physical dependence to a drug (National Institute of Drug Abuse, 2015). An individual adapts to the drug both physiologically and psychologically leading to them developing a tolerance to the

drug (National Institute of Drug Abuse, 2015). Consequently, if the same individual stops taking the drug, withdrawal symptoms can occur (National Institute of Drug Abuse, 2015). A person is not necessarily addicted to a drug if they are physically dependant, however, a person who is addicted, is usually physically dependant on the drug (National Institute of Drug Abuse, 2015).

1.3.2.2 Drug addiction

Drug addiction is defined as a condition where an individual develops a compulsive craving for the pleasurable effects induced by a specific drug (National Institute of Drug Abuse, 2015). This harmful behaviour can interfere with normal life responsibilities, and despite the negative consequences of the behaviour, the individual continues to take the drug (National Institute of Drug Abuse, 2015).

1.3.2.3 Recreational drug use

Recreational drug use is when an individual uses a drug to alter their state of consciousness rather than for medical reasons (Drugscope, 2015b). The individual uses the drug occasionally and usually perceives that the drug is not addictive (Drugscope, 2015b). However, recreational drug use can lead to problem drug use (Drugscope, 2015b).

1.3.2.4 Problem drug use

Problem drug use can arise in those individuals who become dependent on or addicted to the recreational drug (Drugscope, 2015c). Drugs induce different effects on the user and these effects are seen as more problematic than how often the drug is used (Drugscope, 2015c). Consequences of problematic drug use can include difficulties with relationships, financial and legal problems and imbalance with physical and mental health (Drugscope, 2015c).

An individual can seek specific treatment (*see sections 1.3.3 for details*) for problem drug use. However, both recreational drug users and problem drug users may also seek help for other symptoms and co-morbidities occurring due to the drug use.

1.3.2.5 People who use drugs

People who use drugs are defined as individuals who use illegal drugs , other "club-drugs" or abuse prescription drugs (National Institute of Drug Abuse, 2014). It is difficult to distinguish between recreational and problem drug users when looking at primary care records and I will therefore be using the term, ***'people who use drugs'*** (*see section 1.3.2.5 for details*) when describing the individuals who have a recording for any illicit drug use, controlled drug dependence and ***"opioid substitution treatment"*** if they have a prescription or Read code for treatment.

1.3.2.6 Clinical diagnosis of Substance Use Disorder

The Diagnostic and Statistical Manual for Mental disorders (DSM) is available for clinicians to diagnose and classify mental disorders (American Psychiatric Association, 2013). The DSM-V was published, in April 2013 and changes were made to the Substance-Related and Addictive Disorders chapter (*See Appendix 1*) (American Psychiatric Association, 2013). One of the main changes was that the chapter in the DSM-IV was divided into two parts; "substance abuse" and "substance dependence" (American Psychiatric Association, 2013). Whereas, the DSM-V has incorporated these two and relabelled them "substance use disorder" (American Psychiatric Association, 2013). Another of the main changes was that in the DSM-V, an individual had to have a threshold of at least two criteria to be diagnosed with "substance use disorder" as opposed to at least one and two criteria for "substance abuse" and "substance dependence" respectively in the DSM-IV. The criteria for diagnosis are laid out in Table 1.2.

Table 1.2: DSM-V Substance use disorder chapter (American Psychiatric Association, 2013)

DSM-V- Substance use disorders (2 or more criteria in the last year)
Impaired control over substance use (1-4)
A. the individual may take the substance in larger amounts or over a longer period than was originally intended
B. the individual may express a persistent desire to cut down or regulate substance use and may report multiple unsuccessful efforts to decrease or discontinue use
C. the individual may spend a great deal of time obtaining the substance, using the substance, or recovering from its effects
D. craving, or a strong desire or urge to use the substance
Social impairment (5-8)
E. recurrent substance use may result in a failure to fulfil major role obligations at work, school, or home.
F. the individual may continue substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance
G. important social, occupational, or recreational activities may be given up or reduced because of substance use. The individual may withdraw from family activities and hobbies in order to use the substance
H. this may take the form of recurrent substance use in situations in which it is physically hazardous
Risky use of the substance (8-9)
I. the individual may continue substance use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance
Pharmacological grouping (10-11)
J. tolerance, as defined by either of the following: a) a need for markedly increased dose of the substance to achieve the desired effect or a markedly reduced effect when the usual dose is consumed. b) a markedly diminished effect with continued use of the same dose of the substance
K. withdrawal a) characteristic withdrawal syndrome for the substance b) the substance is taken to relieve or avoid withdrawal symptoms

There are different sections for each type of drug in the DSM-V, and the same 11 criteria seen in Table 1.2 are included in each of these sections (American Psychiatric Association, 2013). The DSM-V is used to ascertain if individuals have certain criteria to be formally diagnosed. I will be examining all records between 1994-2012 in the first study (Chapter 4) and I will therefore incorporate diagnoses from both the DSM-IV and DSM-V when looking for possible Read codes that GPs could be using to record drug use in electronic health records.

GPs may however not always adhere to the detail of the DSM-V diagnoses. For example Rait *et al* found that GPs increasingly record a mixture of symptoms and definitions for depression rather than a formal diagnosis in electronic health records (Rait *et al*., 2009). I therefore need to also include Read codes other than formal DSM diagnoses when examining electronic health records for drug use.

If an individual in the UK is diagnosed with one of the following; "substance dependence", "substance abuse" or "substance use disorder"; various treatments should be offered to the individual from either a general practice, a hospital inpatient setting or a community drug clinic. I will discuss the treatments available in the next section.

1.3.3 Treatments available in the UK

In this section I describe the different treatments available for both opioid and non-opioid dependence available in the UK

1.3.3.1 Treatments for problematic opioid use in the UK (see Appendix 2 for details of dose and cost of different treatments)

The National Institute for Health and Care Excellence (NICE), the Royal College of General Practitioners (RCGP) and the British Association for Psychopharmacology have published guidelines for pharmaceutical treatment for problematic opioid use (Lingford-Hughes *et al*., 2012; National Institute for Clinical Excellence, 2010a; Royal College of General Practitioners, 2011). Both methadone and buprenorphine are synthetic opioid derivatives and are the first line treatment for opioid addiction in the UK (Lingford-Hughes *et al*., 2012; National Institute for Clinical Excellence, 2010a; Royal College of General Practitioners, 2011).

Opioids produce pain relief and mood enhancing effects (Al-Hasani and Bruchas, 2011). Four opioid receptors are widely dispersed in the brain, spinal cord and digestive tract (Al-Hasani and Bruchas, 2011). These receptors are classified into four subtypes; delta (δ), kappa (κ), mu (μ) an opioid receptor like-1 (ORL 1) (Al-Hasani and Bruchas, 2011). Methadone is a full opioid agonist and it produces its effects until either it fills and activates all the μ opioid receptors (located on nerve synapses) or reaches its maximum effect and therefore induces a heightened state through the same mechanism as illicit opioids (Whelan and Remski, 2012). Methadone comes in various forms and it is up to the GP which form to prescribe (Ford *et al*., 2013; National Institute for Clinical Excellence, 2010a). Oral liquid methadone is most commonly prescribed, however injectable forms of methadone are also licenced for treatment (Ford *et al*., 2013; National Institute for Clinical Excellence, 2010a). Methadone alleviates cravings, withdrawal symptoms and blocks other opioids from entering the μ opioid receptors (Whelan and Remski, 2012).

Buprenorphine (Subutex®) was licensed in the UK in 1999 (Ford *et al*., 2013). It has both agonist and antagonist properties (Rothman *et al*., 2000). Its main effects are acting as a partial μ opioid receptor agonist and a κ opioid receptor antagonist (Rothman *et al*., 2000). It has a plateau effect which is reached at a moderate dose and increasing the dose should not increase the euphoric effect (Mégarbane *et al*., 2006; Rothman *et al*., 2000). Buprenorphine is not as potent as methadone and it has fewer side effects such as withdrawal, addiction, respiratory distress and risk of overdose. (Mégarbane *et al*., 2006; Whelan and Remski, 2012). However, buprenorphine does have a harmful interaction with benzodiazepine and other analgesics and it is more expensive than methadone (Appendix 2) (Whelan and Remski, 2012). Buprenorphine is usually prescribed as a sublingual table for opioid substitution treatment (Ford *et al*., 2013).

Naloxone is usually prescribed in combination with buprenorphine (Suboxone®1:4 ratio) (Ford *et al*., 2013). Suboxone® was licensed in the UK in 2007 and is also prescribed as a sublingual tablet (Ford *et al*., 2013). Naloxone

reduces the opioid-effects if an individual tries to inject the buprenorphine rather than taking it as sub-lingual tablet (Ford *et al*., 2013). There is evidence that patients can be safely changed from Subutex® to Suboxone® in a community setting (Bell *et al*., 2004; Daulouède *et al*., 2010). Naloxone is also used in high doses for individuals who have taken an opioid-overdose (Ford *et al*., 2013).

Naltrexone is an opioid antagonist which blocks opioid receptors (National Institute for Clinical Excellence, 2007a). It is licensed to be used for 7-10 days after completion of detox from methadone or buprenorphine (National Institute for Clinical Excellence, 2007a). It should be prescribed as oral tablets and should be combined with psychological support (Ford *et al*., 2013; National Institute for Clinical Excellence, 2007a).

Lofexidine is a non-opioid alpha-adrenergic agonist (Ford *et al*., 2013). It is rarely prescribed, however it can be used to manage opioid withdrawal and is usually prescribed to individuals who use smaller amounts of opioids (Gowing *et al*., 1996).

Dihydrocodeine is not licensed for opioid substitution treatment in the UK (Ford *et al*., 2013). However, some GPs do prescribe it in tablet form for opioid dependence and there is some evidence indicating that it is as effective as methadone (Ford *et al*., 2013; Robertson *et al*., 2006). It is shorter acting than methadone and therefore requires a higher dose (Ford *et al*., 2013).

There is ongoing discussion as to which medication is the most effective for individuals requiring treatment, and it is recommended that treatment is usually selected on a case-by-case basis (Lingford-Hughes *et al*., 2012; Whelan and Remski, 2012). As stated previously, GPs have recommended guidelines for prescribing opioid substitution treatment. When GPs prescribe a drug for substance misuse, they record it as a drug code (prescription) in the individual's

electronic health care record and should report it to the National Drug Treatment Monitoring System (Public Health England, 2013a). However, some people who use drugs, but do not receive treatment or who have been referred for treatment elsewhere, may still have some notes in their electronic health records. I will therefore be examining prescriptions and Read codes used by GPs for prescribing and recording opioid substitution treatment in the first study (Chapter 4).

1.3.3.2 Treatment for non-opioid drug dependence

There are no pharmacological treatments for non-opioid substance misuse (Public Health England, 2015). Patient-centred and evidence based psychosocial interventions, such as cognitive behavioural therapy are not commonly available at GP practices, but are available in some other NHS and voluntary services (National Institute for Clinical Excellence, 2007b). Day and residential rehabilitation treatment centres are available and charities and non-profit organizations (such as Cocaine and Narcotics Anonymous) offer informal treatment which have been recommended for recovery (Drugscope, 2015d; Public Health England, 2015). GPs can directly refer or guide individuals to self-refer to the appropriate treatment (Drugscope, 2015d; Public Health England, 2015). Unlike pharmacological treatment, it is not mandatory to record non-pharmacological treatment in a patient's electronic health record, nor is it mandatory to report the treatment to the National Drug Treatment Monitoring Agency (Public Health England, 2013a). I will however include referrals for drug use in the electronic health records in the first study (Chapter 4).

1.3.4 Health records in general practice

In this section I will describe health records and focus on electronic health records used in the UK

1.3.4.1 Electronic Health records

Health records play an important role in documenting an individual's clinical information (National Archives, 2015; Royal College of General Practitioners Informatics Group, 2009). There has been a staggered transition from paper records to electronic records in the UK (Freeman and Hughes, 2010). Electronic health records can contribute to a longitudinal view and help with continuous care of the individual, especially if the individual is not always seeing the same GP (Freeman and Hughes, 2010). The benefits of good record-keeping in general practice are summarised by the Department of Health's good practice guidelines for electronic patient records (Royal College of General Practitioners, 2011b).

"The primary purpose of the GP record is to aid the clinical care of individual patients by: assisting the health professional to structure their thoughts and make appropriate decisions; acting as an aide memoir during subsequent consultations; making information available to others with access to the record system who are involved in the care of the same patient (including electronic transfer of records when the patient moves practice); providing information for inclusion in other documents (e.g. case conference reports or referrals); and storing information received from other parties or organisations (e.g. discharge letters from maternity services). The records can also assist in the clinical care of the practice population by facilitating needs assessments of the population; identifying target groups; and supporting audit and improvement need to put in own words."

The primary purpose of the electronic health record is to support the care of the patient. In order to achieve this, recommendations in the guidelines include the following:

- All health professionals within the practice are responsible for ensuring complete, accurate and comprehensible record keeping.
- All records should be recorded electronically and the use of paper records should be discontinued in order to avoid confusion of patient care.
- Every clinical consultation with the patient should be recorded electronically.

- All prescriptions should be chronologically and correctly entered into the electronic records.
- All practices should have agreed coding standards. The general practices should agree as to which information is recorded in a systematic way, which codes or groups of codes are used to record and what is the best way to enter the data. The recording standards will be based on priorities, practice populations, special interests within the practices and secondary use of the electronic records.
- Practices are encouraged to use templates or recording protocols to standardise coding.
- Practices should update and refine their recording policies and should be able to use the electronic records to review their own data or external analysis by large electronic database.

Health professionals can utilize electronic health records to structure their thoughts and make suitable decisions in order to ensure patient-centred care (Freeman and Hughes, 2010). The electronic health record can be shared amongst other health professionals who are involved in the same patient's care and include other documentations such as discharge letters from the midwifery services (Freeman and Hughes, 2010). Although the primary purpose of the record is for patient care, they have also been used for clinical audit, research, education, service planning and contract delivery (Royal College of General Practitioners, 2011b).

Electronic health records are a more efficient way of sharing patient information compared to paper records (Royal College of General Practitioners Informatics Group, 2009). There may be a number of GPs and allied health professionals involved in an individual's care and the health records allow access to important information and continuity of care. Electronic health records can therefore be accessed in order to monitor, assess and treat an individual appropriately (Medical Protection Society, 2015). However, access to the health records can

sometimes be limited to the general practice and there may be variation within practices (Royal College of General Practitioners Informatics Group, 2009). Health records with removal of identities (such as name and address) can also be used for public health research, although patients can opt out of their records being used for research (Medical Protection Society, 2015; Royal College of General Practitioners Informatics Group, 2009). Since 1990, an individual has the right to request access to their records (National Archives, 2015; Royal College of General Practitioners Informatics Group, 2009). GPs can record medical symptoms, diagnoses, prescriptions, additional health records and referrals in the health records (Medical Protection Society, 2015). GPs use drug codes for prescriptions and Read codes and/or free-text for symptoms, diagnoses and care pathways (Davé and Petersen, 2009). I will describe these coding systems in more detail in the next section.

1.3.5 Coding in general practice

In this section, I will explain specific coding systems GPs use to record and document patient consultations.

A classification and coding system is important for recording and retrieving information for individual patients, analysing data for audit and research and electronic communication of data between computers (Chisholm, 1990). The first coding system used in the UK was Oxford Medical Information System codes (OXMIS codes) (Benson, 2011). OXMIS was developed by Dr J Perry and was based on the international classification of diseases Eighth Revision (ICD-8) (Benson, 2011). This coding system was used throughout the 1980s in general practice (Benson, 2011).

Read codes were subsequently developed as a thesaurus of medical terms by James Read between 1981 to 1986 (Benson, 2011). They are a hierarchical classification system mapped to the International Classification of Diseases Ninth Revision (ICD-9) (Benson, 2011; Chisholm, 1990; Davé and Petersen, 2009). Family, social and medical history, presenting medical symptoms, diagnoses,

additional health records, procedures referrals and administration (Benson, 2011; Chisholm, 1990; Davé and Petersen, 2009). The NHS introduced the Read codes in 1990 and implemented them as standard coding practice (Benson, 2011; Chisholm, 1990; Davé and Petersen, 2009). Read codes were originally designed for general practice, but the NHS has extended to all areas of clinical practice (Benson, 2011; Chisholm, 1990; Davé and Petersen, 2009). When a Read code is used, the code is flagged up on the computer screen when the individual's record is opened (Davé and Petersen, 2009; Medical Protection Society, 2015). GPs can also choose to use free-text when recording. I will explain Read codes in more detail in *section 3.4.1.*

Read codes are rarely used outside the UK, most other countries use the WHO International Classification of Primary Care (ICPC) (World Health Organisation, 2003). However, Chisholm argues that the Read code system is the most comprehensive coding system, as it also includes patient history, and occupation and social information (Chisholm, 1990).

1.3.6 Primary Care Databases

In this section, I will describe two of the primary care databases available in the UK; the General Practice Research Database (GPRD) and The Health Improvement Network (THIN). The majority of the UK population is registered with a GP (Lis *et al*., 1995) (*see section 3.4.2 for details*). General practices can choose to contribute electronic health records to different primary care databases. GPRD became the Clinical Practice Research Datalink (CPRD) in March 2012 (Clinical Practice Research Datalink, 2013). CPRD represents approximately 8% of the UK population and uses both OXMIS (restricted to older records) and Read codes (Clinical Practice Research Datalink, 2013). Whilst THIN represents about 6% of the UK population and only uses Read codes (CSD health research, 2015; Davé and Petersen, 2009). There is approximately an overlap of 60% of the general practices in both these primary care databases (CSD health research, 2015). Since 2013, the UK government have encouraged research in academia to use patient electronic health records in the form of

primary care databases (Callaway, 2013). I will describe THIN in more detail in *section 3.4*.

I will now describe and discuss the problem of drug use worldwide and compare this to the problem in the UK.

1.3.7 How big is the problem?

Illicit drug use and misuse of controlled drugs is a public-health problem with potentially serious impacts on both mental (depression, anxiety, psychosis and personality disorder) and physical health (liver and lung damage, cardiovascular disease, muscular and skeletal problems and poor vein health) (Madgula et al., 2011a; Public Health England, 2015). In 2012, between approximately 162-324 million people had used an illicit drug globally (United Nations Office on Drugs and Crime, 2014). Approximately 20 million disability adjusted life years is due to illicit drug dependence (Degenhardt *et al*., 2013). It is estimated that £2.50 could be saved in costs to society for every £1 invested in drug treatment (National Treatment Agency for Substance Misuse, 2012a). The prevalence of illicit drug use and misuse of controlled drugs is greater in high income countries, but this may reflect low ascertainment of data in low income countries (United Nations Office on Drugs and Crime, 2014). The UK, together with the USA, Russia and Australia had the highest rate of global disease burden due to illicit drug intake in 2010 (Degenhardt *et al*., 2013). The prevalence of illicit drug use in the UK is one of the highest in Europe with the UK also having the second highest number of illicit drug confiscations by police in Europe in 2012 (European Monitoring Centre for Drugs and Drug Addiction, 2014a). Table 1.3 illustrates the percentage of the adult population who reported using drugs in England, Wales, Scotland and Northern Ireland between 2002/03 to 2011/12.

Table 1.3: Percentage of adults using drugs ever, in the last year and last month in England, Wales, Scotland and Northern Ireland

	England and Wales* (Adults aged 16/59 years)		**Scotland** (Adults aged 16/59 years)**		**Northern Ireland*** (Adults aged 16/64 years)**	
% Adults	**2002/03**	**2011/12**	**2004**	**2010/11**	**2002/03**	**2010/11**
Ever used a drug	35.6	36.5	24.8	23.7	18.5	27.2
Used drugs in last year	12.3	8.9	8.0	6.6	5.6	7.0
Used drugs in last month	7.5	5.2	4.0	3.5	3.0	3.2

*British Crime Survey (2002/03), Crime Survey for England and Wales (2011/12)
**Scottish Crime Survey (2002/03), Scottish Crime and Justice Survey (2010/11) ***Northern Irish Crime Survey

The proportion of adults who used drugs in the last year and last month have decreased over a ten year period in England, Wales and Scotland (Condon and Smith, 2003; Office for National Statistics, 2012; Scottish Government, 2011, 2004). Whilst the proportions have risen in Northern Ireland between 2002/03 to 2010/11 (Northern Ireland Executive, 2013). Higgens *et al.* suggested that one of the reasons for the increase in Northern Ireland is due to the decrease in political conflict and therefore easier access to drugs. (Higgins *et al*., 2004). It may be difficult to directly compare the three crime surveys as the scope and timing is not consistent. For this reason, I will be focusing on drug use and treatment in England and Wales rather than for the whole of the UK in the thesis.

According to the Crime survey for England and Wales, there has been a reduction in reported drug use from 12.3% in 2002/03 to 8.9% (±3 million people) in 2011/12 (Office for National Statistics, 2012). Furthermore, there has also been a reduction in problem drug users in treatment from 210,815 in 2008/09 to 193,575 in 2012/13 and a reduction of heroin and crack cocaine users from 332,090 in 2005/06 to 298,752 in 2010/11 (Hay *et al*., 2013, 2011, 2006; Public Health England, 2015). These estimates are based on self-reports and hence may be subject to reporting bias. (Degenhardt *et al*., 2013; Health Protection Agency, 2012; Office for National Statistics, 2013a). Additionally, Frischer *et al.*

argued that the estimates of drug use from household surveys may be conservative (Frischer *et al.*, 2001). Moreover, they exclude population groups who may have a higher prevalence of drug use, these groups include; prisoners, homeless people and students living in halls of residence (Degenhardt *et al*., 2013; Health Protection Agency, 2012; Office for National Statistics, 2013a).

Although, overall declared drug use seems to have decreased in England and Wales, there has been a change in trend of particular drugs used between 1996 and 2013 (Figure 1:1). By 2012/13, the main illicit drugs that were used in the UK population (16-59 years old) were cannabis (6.4%), cocaine (1.9%), crack cocaine (0.2%), amphetamine (0.8%), ecstasy (1.3%) and heroin (0.12%) (Office for National Statistics, 2013a). The overall trend of recorded drug use has decreased with heroin remaining relatively stable whilst cannabis has routinely been the highest contributor for recorded drug use (Office for National Statistics, 2013a). Cannabis was classified as a class B drug until 2004, it was reclassified to a class C drug between 2004 and 2009 and then reverted back to class B. (*see section 1.3 for more details*). The increase of reported cannabis use in 2003/04 and the subsequent reduction in 2012/13 could be due to the change in class classification and the change in willingness of individuals to report cannabis use.

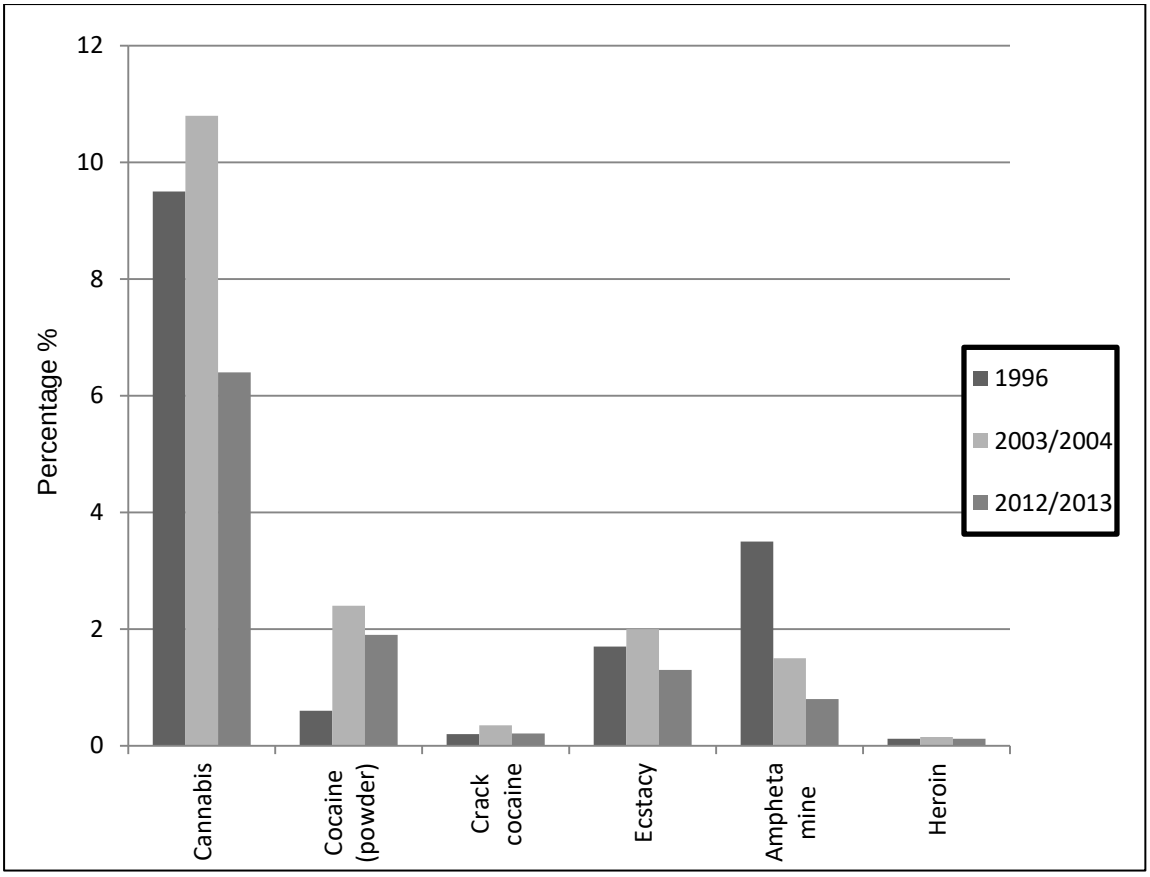


Figure 1:1: Trends in illicit drugs used among adults aged 16-59 years (1996, 2003/4, 2012/13) (Chivite-Matthew et al., 2005, Office for National Statistics, 2013a)

Men consistently have higher recording for drug use, however women of potential childbearing age contribute to the majority of recording in females (Office for National Statistics, 2013a). Drug use during pregnancy impacts the mother, foetus and the subsequent development of the child (Madgula et al., 2011a). Accurately estimating the prevalence of drug use during pregnancy is difficult as examining women during pregnancy can be complex (Gyarmathy *et al*., 2009; O'Donnell *et al*., 2009; Office for National Statistics, 2013a; Public Health England, 2015). Estimates of drug use during pregnancy vary by country ranging from 5-8% of pregnant women (Gyarmathy *et al*., 2009; O'Donnell *et al*., 2009; van Gelder *et al*., 2009). Information about drug use during pregnancy is collected as part of the National Drug Strategy Household Survey in Australia (every three years) and the annual National Survey on Drug Use and Health in the United States (Australian government, 2010; Substance Abuse and Mental Health Services Administration, 2012). The results from the surveys are subject

to limitations such as response bias which makes estimates of drug use during pregnancy more uncertain than in the general population. The prevalence of drug use during pregnancy has been difficult to ascertain in Europe, as data is not available for most European countries (European Monitoring Centre for Drugs and Drug Addiction, 2014b). Estimates reported by The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) are based on various approximations, rather than actual measures (European Monitoring Centre for Drugs and Drug Addiction, 2014b). The EMCDDA estimates that 20% of women entering drug treatment and 34% of opioid users are women, of which the majority are of child bearing age (Gyarmathy *et al*., 2009). They also suggested that there may be approximately 30,000 pregnant women using opioids in Europe and that a similar number of pregnant women are using drugs other than opioids (Gyarmathy *et al*., 2009). The EMCDDA estimates of drug use in the general UK population are based on the Crime Survey for England and Wales, the Scottish Crime and Justice Survey and the Northern Irish Crime Survey (*see section 1.3.8*), which currently do not include questions on drug use specifically during pregnancy (European Monitoring Centre for Drugs and Drug Addiction, 2013; Office for National Statistics, 2013b). Findings from Scottish hospital births reported that drug use during pregnancy had increased from 9 to 11 per 1000 women given birth between 2003 and 2010 (National Statistics Scotland, 2012). It was however suggested that caution should be taken when comparing prevalence over time as recording of drug use during pregnancy has improved over the last 5 years in Scotland (National Statistics Scotland, 2012). Based on the limited studies in England and Wales, approximately a third of people who use drugs are female, with 90% being of potential childbearing age (Ed Day and George, 2005). It is evident that large gaps still exist in epidemiological research regarding the prevalence and burden drug use during pregnancy in England and Wales (Madgula et al., 2011a).

1.3.8 Policies influencing recording of drug use and treatment of opioid substitution treatment

In this section, I will describe how present policy influences GP recording of drug use and opioid substitution treatment.

1.3.8.1 Quality Outcomes Framework and Payment-by-Results

The Quality and Outcomes Framework (QOF) which was implemented in 2004, remunerates general practices for providing clinical quality indicators of certain diseases and outcomes (Department of Health, 2003). Maisey *et al.* suggested that if a disease is included in QOF and the general practice receives a financial incentive for treating the individual it is more likely that the disease, treatment and outcome will be recorded systematically and regularly (Maisey *et al*., 2008). The general practice may also develop a recording protocol to ensure recording quality assurance (Maisey *et al*., 2008). Dixon *et al.* examined whether or not QOF helped reduce health inequalities using both quantitative and qualitative methods (Dixon *et al*., 2010). They conducted 33 semi-structured interviews with GPs and practice managers in primary care (Dixon *et al*., 2010). Their findings echoed the study by Maisey *et al.* as they found that practices responded to QOF incentive outcomes by re-organising and making their approach more systematic, however some GPs perceived that QOF was not addressing the challenges of serving individuals with complex and social needs (Dixon *et al*., 2010). Examples of challenging individuals were refugees, homeless, or drug-and alcohol-dependent patients (Dixon *et al*., 2010). The findings suggested that other pay-for-performance indicators may need to be developed to remunerate and incentivise practices who deliver care to challenging individuals (Dixon *et al*., 2010). Consequently a pilot study is investigating how a different incentive scheme, Payment-by-Results, could be used to incentivise delivery for recovery for drugs and alcohol in primary care (Department of Health, 2012). The pilot took place across eight sites for two years and started in April 2012, however the final results have not been published yet (Department of Health, 2012). The RCGP argued that although not everyone agrees with Payment-by-Results for the treatment of recovery for drugs and alcohol, Payment-by-Results may be incorporated into primary care in the future (Harris and Halliday, 2013).

There are currently no specific QOF indicators for recording drug use (NHS Employers, 2013). There are however general NICE guidelines recommending

that GPs should discuss drug use in conjunction with mental health and the implications of drug use should be discussed with the individual during pregnancy (National Institute for Clinical Excellence, 2014). Consequently, there are no financial incentives for recording drug use, unless a Local Enhanced Service (LES) has been commissioned in the area (*see section 1.3.8.2*) (NHS Commissioning Board, 2015)

1.3.8.2 Clinical Commissioning Groups, Local Enhanced Services and the Localism Act (2011)

Clinical Commissioning Groups (CCGs) became responsible for commissioning hospital and community services in their area in April 2013 (NHS Clinical Commissioners, 2015). CCGs determine which services are required in the area and are also responsible for providing these services, which includes drug and alcohol services (NHS Clinical Commissioners, 2015). General practices are incorporated into the applicable CCG (NHS Clinical Commissioners, 2015). Therefore decisions and services provided by the CCG could indirectly influence GP recording of drug use in electronic health records.

Local Enhanced Services are agreed by CCGs and local authorities in response to local needs and priorities in the specific area (Department of Health, 2003; NHS Commissioning Board, 2015). Furthermore, the Localism Act, 2011 is an Act of Parliament to facilitate the transfer of decision-making powers from central government to individuals and communities (Harris and Halliday, 2013; Localism Act, 2011). The General Medical Services (GMS) contract, introduced in 2003, is the contractual agreement between NHS England and General Practices stating the core requirements of GPs in General Practices (Department of Health, 2003). Whilst opioid substitution treatment and treatment for non-opioid problem drug use is not incorporated in this GMS contract, specific Local Enhanced Services have been commission in various areas to treat drug use (National Treatment Agency for Substance Misuse, 2006). Together with the Localism Act, 2011, the model of shared care has been implemented whereby general practices work together with statutory NHS and voluntary drug treatment services.(National

Treatment Agency for Substance Misuse, 2006). The individual can therefore either receive treatment at a specific general practice, be referred or they can self-refer to the drug treatment services (National Treatment Agency for Substance Misuse, 2006). As mentioned previously in *section 1.3.3.1*, if the individual receives opioid substitution treatment from the GP, it should be recorded in the electronic health record.

1.3.9 History of drug policy in the UK

In order to contextualise the role of GPs with people who use drugs, I describe the history of UK drug policies with a focus on how policy has impacted the involvement of GPs.

An increase in drug use for non-medical purposes in the late eighteenth and early nineteenth centuries was attributed to the improvement in production, increase in supply, promotion, distribution and reduced prices of drugs (Courtwright, 2012a, 2012b). In the early nineteenth century, the increase in drug use led to the concept of addiction (Courtwright, 2012a). Before 1916, there was little regulation over the use of drugs of dependence in the UK (Reuter and Stevens, 2007). However, the concept of addiction influenced the formation of the "temperance movement" which influenced a change in societal attitudes towards the regulation of drugs (Courtwright, 2012a). During 1870-1930, anti-vice activism rose in North America and Europe and campaigns for the prohibition of non-medical use of drugs and other substances such as alcohol, were launched (Courtwright, 2012a).

During and after World War I, there was an increase in the use of both cocaine and heroin which together with anti-vice activism, led to the criminalisation of these drugs by the UK government between 1916-1928 (Reuter and Stevens, 2007). During this time, GPs could legally prescribe illicit drugs to the relatively small and stable number of known addicts who were predominantly from a middle class background (Reuter and Stevens, 2007). In 1924, the Rolleston committee

was established to advise on the supply of morphine and heroin to addicts (Strang and Gossop, 2005). This led to the publication of the Rolleston report in 1926, which recommended that GPs gradually reduce the amount of addictive drugs prescribed (Strang and Gossop, 2005). The 'British system' of controlling illicit drugs was developed and GPs were still allowed to prescribe these addictive drugs in a controlled manner, but with the aim of weaning the individual off the drug or to maintain them on a small amount (Strang and Gossop, 2005).

During 1958, the Interdepartmental Committee on drug addiction (also known as the Brain Committee) was established by the Home Office (Reuter and Stevens, 2007). The Committee was responsible for assessing the potential harmful effects of certain drugs and whether or not some of the drugs needed to be prescribed for medicinal purposes (Reuter and Stevens, 2007). The first Brain report (published in 1961), stated that problem drug use was small in the UK, however by the time the second 'Brain' report was published in 1964, there was an increase in the use of cannabis, amphetamines and Lysergic Acid Diethylamide (LSD) and concurrently GP prescribing (Interdepartmental committe on drug addiction, 1965; Interdepartmental committee on drug addiction, 1961). This increase in drug use was the driving force for the establishment of the Dangerous Drugs Act, 1967 and the Home Office Addicts Index in 1968 (Reuter and Stevens, 2007). This legislative Act required doctors to notify the Home Office of any confirmed and suspected addicts (Corkery, 2002). It also restricted the prescription of heroin and cocaine by GPs and the first drug treatment centres were set up (Corkery, 2002). There was often a delay from dependence to notification, but individuals who became dependent were more likely to come into contact with a GP (Figure 1:2) (Millar *et al*., 2004).

The Misuse of Drugs Act was introduced in 1971, to classify drugs according to the potential harm they could cause and penalties for possession, producing and selling them (Misuse of Drugs Act, 1971) *(see section 1.3 for details).* More serious penalties were created for trafficking and supplying drugs (Reuter and Stevens, 2007). The Advisory Council on the Misuse of Drugs was created under

this Act and continues to advise the UK government on the control of illicit drugs (Figure 1:2) (Reuter and Stevens, 2007).

Monitoring of drug misuse has its challenges. The first British Crime Survey was conducted in 1983; it incorporated crimes that had not been reported to police and included drug misuse (Office for National Statistics, 2013b). The survey was replaced by the Crime Survey for Britain and Wales in 1993 and there are similar surveys conducted in Scotland and Northern Ireland (Department of Justice, 2014; Office for National Statistics, 2013b; The Scottish Government, 2013). As mentioned in the previous section, the crime surveys do not include information regarding drug use specifically during pregnancy. The European Monitoring Centre for Drugs and Drug Addiction argues that using population surveys for estimating problematic drug use may be underestimated as most surveys are self-reports and not representative of homeless and prisons (European Monitoring Centre for Drugs and Drug Addiction, 2007). However, in the UK the national surveys are the best population estimates for surveillance of drug use. As mentioned in the previous section I will be comparing results of recording drug use in general practice to the Crime Survey for England and Wales in the first study (Chapter 4)

Monitoring of opioid substitution treatment (*see section 1.3.3.1 for details*) for drug misuse is more accurate as recording of treatment is mandatory, initially the Home Office Addicts Index monitored individuals accessing services for drug misuse treatment. In 1997, the Regional Drug Misuse Database replaced the Addicts index. Subsequently, the National Treatment Agency and the Welsh National Database for Substance misuse replaced the Regional Drug Misuse Database in 2001 for recording treatment in England and Wales respectively. (Public Health England, 2015; Welsh Government, 2015).

The National Treatment Agency became part of Public Health England in 2013 (Public Health England, 2015). The National Drug Treatment Monitoring System

monitors over 1500 community treatment centres which includes inpatient, outpatient and GP practices in England (Public Health England, 2015). Most of the drug treatment services in England and Wales are accessed via self-referral and other referral sources including the NHS, the criminal justice system and GPs (Figure 1:2) (Public Health England, 2015; Welsh Government, 2015). The reports from the monitoring systems regarding treatment produce more reliable surveillance results compared to the national surveys for drug use and can be used more credibly to compare treatment occurring in general practice.

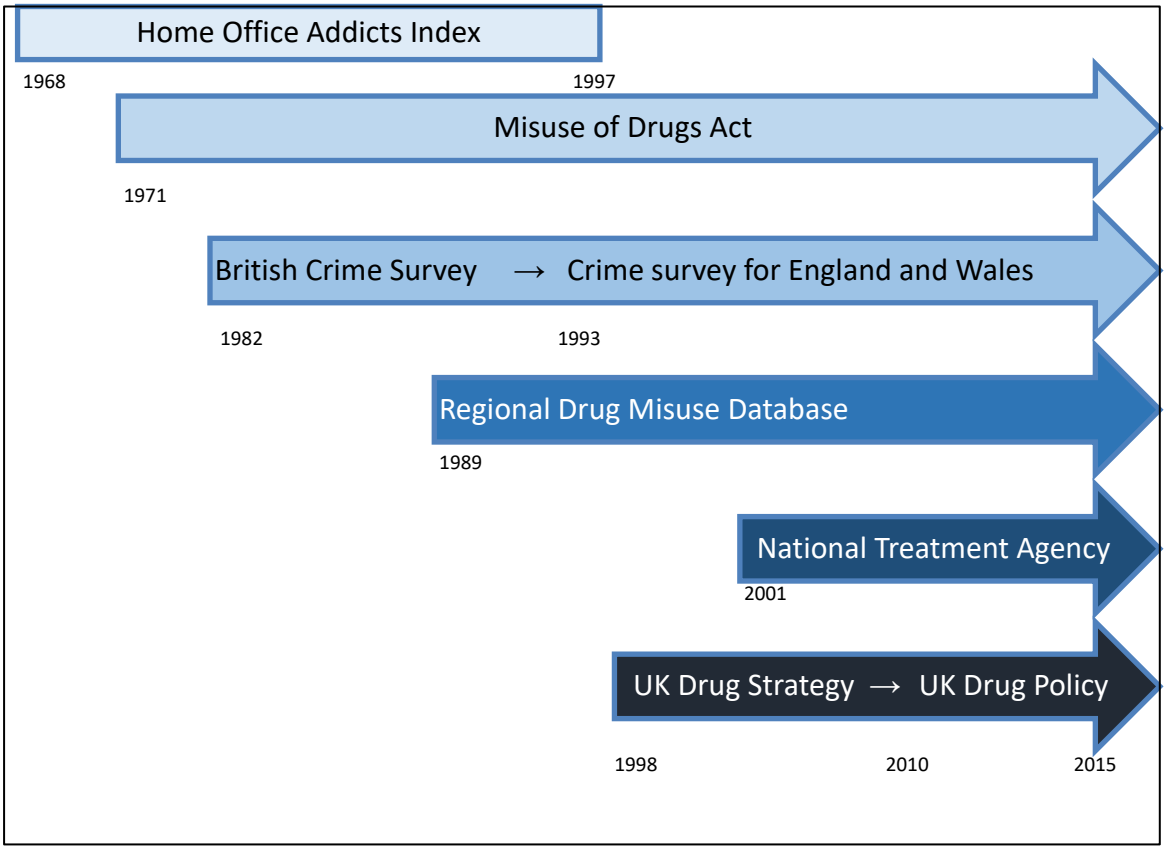


Figure 1:2: Graphical representation of the history of drug policy in the United Kingdom (1968-present)

In 1998, a 10 year Drug strategy (Tackling Drugs to Build a Better Britain) was implemented in the UK (Home office, 1998). The main focus of this strategy was on providing and improving treatment services, reducing drug-related crime, raising public awareness and engaging with the community (Howard, 2007). This strategy was revised in 2002 and 2008 (Howard, 2007). Coinciding with the change in government, a revised version was implemented in 2010 (Reducing

Demand, Restricting Supply, Building Recovery: Supporting People to Live a Drug-Free Life) (Home office, 2010). One of the main aims of this strategy was to help people to live a drug-free life and focus on complete withdrawal rather than maintenance (Home office, 2010). There are criticisms of the impact that the 1998 strategy made, which included the fact that not enough money was provided for the purpose of research (Howard, 2007). Policies were, therefore, developed without understanding of the underlying causes of the problem (Howard, 2007). However, prevention and recovery of drug dependency has been recently incorporated in one of the top five health priorities for Public Health England 2013/14 (Public Health England, 2013b).

I will now describe previous quantitative and qualitative studies that have examined GP recording of drug use and opioid substitution treatment.

1.3.10 Search methods for identification of studies

I used the following search engines to search for relevant primary, review and meta-analysis studies regarding recording of drug use in primary care up to April, 2013: PubMed, Web of Science, CINAHL, EMBASE (Search terms can be seen in Appendix 3). Once I found relevant studies, I also examined their reference lists in order to find additional relevant articles. I will briefly describe the various studies in this section and discuss them in more detail in Chapters 4-7.

1.3.11 Quantitative studies examining recording of drug use and opioid substitution treatment in primary care

Up to April, 2013, there were five studies that had used a primary care database to identify individuals with a recording of drug misuse and one study identifying individuals with prescriptions for opioid substitution treatment. I will describe the aims and main findings of these studies in this section, and I will describe and discuss the studies in more detail in *section 4.2*.

All five of the cohort studies by Frischer *et al*. used the General Practice Research Database (GPRD) to identify individuals recorded (using either Read or OXMIS codes) with drug misuse (Frischer et al., 2000; 2001, 2004, 2005, 2009). The first study's aim was to ascertain if the GPRD could be used as a surveillance tool for monitoring problematic drug use, whilst the second (pilot), third and fourth studies examined co-morbid psychiatric illness and substance misuse and the fourth focused on the time-trends of recorded drug misuse.

The main findings from the study published in 2000 were firstly that GPRD had a significantly higher number of individuals recorded with drug use (n=6574) (In the West Midlands, between 1993-1997) compared with an existing surveillance tool, the Regional Drug Misuse Database (n=3643). The authors suggested that the discrepancy could be attributed to the decrease in mandatory reported cases from GPs and other sources in RDMD and the increase in treatment in primary care (Frischer *et al*., 2000). Over half of the individuals with a recording for drug misuse also had a psychiatric co-morbidity (Frischer *et al*., 2000). The authors concluded that although GPs did not record the specific drug used, the GPRD may be a good contributor to overall drug misuse trends (Frischer *et al*., 2000).

The second study was a pilot study examining the prevalence of co-morbid mental illness and drug use recorded in GPRD (Frischer and Akram, 2001). A patient was defined as having a co-morbidity if they had both a mental illness and drug use diagnosis in their medical records between January 1993 until December 1997 in the West Midlands (Frischer and Akram, 2001). The main findings showed that 0.25% of the cohort had a recorded for drug use, 11.26% a recording for mental illness and 0.12% had a recording for both (Frischer and Akram, 2001). The authors concluded the GPRD may be suitable for identifying and analysing individuals with a co-morbidity of mental illness and drug misuse (Frischer and Akram, 2001).

The third study published in 2004, found that GPs were seeing more co-morbid (psychiatric illness and drug misuse) patients each year (1993-1998 in England and Wales), additionally the annual prevalence of recorded drug misuse increased in all age-groups except for individuals aged between 65-74 years. The ratio of males to females also increased from 1.1:1 to 1.37:1 (Frischer *et al*., 2004).

Findings from the fourth study published in 2005, indicated that 15.1% (936,128) of individuals had a code for psychiatric illness, 0.37% (22,904) had a code for substance misuse and 3969 individuals had codes for both (between 1993 and 1998 in England and Wales). They estimated that individuals who were coded with substance misuse first were 1.54 times more likely to develop a psychiatric illness, whilst those with a psychiatric illness were 2.09 times more likely to have a code for substance misuse (Frischer *et al*., 2005).

The main findings from the final study published in 2009, showed that the prevalence and incidence for drug misuse decreased for the 16-24 age-group and increased or remained the same for the older age-groups (between 1998 and 2005 in the UK) (Frischer *et al*., 2009). The authors suggested a decline in recording which could be due to a decrease in overall drug use especially in the 16-24 year age-group as a result of the 1998 drug policy *(see section 1.3.8 for details)* (Frischer *et al*., 2009). The authors suggested that individuals who had a diagnostic or prescription code had a serious enough problem to warrant a recording (Frischer *et al*., 2009).

GPRD has also been used to identify individuals who have been diagnosed with substance misuse and prescribed opioid substitution treatment. Cornish *et al.* examined prescribing patterns of opiate substitution treatment and the risk of death between 1990 and 2005 in the UK (Cornish *et al*., 2010). The main outcome of the study was comparing mortality rates with the timing of starting and discontinuing opioid substitution treatment (Cornish *et al*., 2010). The study highlighted that mortality risk of opioid users in treatment increased at the start of

treatment (14-28 days) and the month after treatment has discontinued (Cornish *et al*., 2010).

I will now describe the qualitative studies which have examined recording in primary care.

1.3.12 Qualitative studies examining recording in primary care

Up to April, 2013, there were no qualitative studies exploring GP recording of drug use and opioid substitution treatment in primary care in the UK in the general population or during pregnancy. There were however two UK studies exploring recording of two other sensitive issues; alcohol misuse and child maltreatment.

Firstly, the Alcohol Needs Assessment Research Project included the exploration of recording of alcohol misuse using both quantitative and qualitatively methods in England (Department of Health, 2005). Alcohol misuse recording was examined using GPRD (*see section 1.3.6*) and telephone interviews with GPs across the country, in addition six focus groups were conducted (Department of Health, 2005). Five times more individuals were reported with alcohol misuse in the telephone interviews compared with those recorded in GPRD (Department of Health, 2005). This indicated that GPs were aware of people who misused alcohol but did not record it (Department of Health, 2005). The following reasons for not recording and referring were highlighted in focus groups; GPs were reluctant to record and refer due to limited access of overstretched services and the lack of patient engagement with the services (Department of Health, 2005).

Secondly, Woodman *et al.* used both quantitative and qualitative methods to examine recording and responses to child maltreatment in primary care (Woodman *et al*., 2013, 2012). As with drug use, child maltreatment is an example of a stigmatised and sensitive issue managed in primary care. The

Health Improvement Network was firstly used to examine the variation of recording of child maltreatment in the UK (Woodman *et al*., 2012). The results showed that 1% of child maltreatment was recorded in primary care and they acknowledged that this was an underestimate (Woodman *et al*., 2012). Subsequently, they conducted in-depth qualitative interviews with GPs and practice nurses in England to understand the response and action taken by health professionals with regards to child maltreatment (Woodman *et al*., 2013). The findings suggested that GPs used core skills for long term management of families who prompted concerns about child maltreatment and that general practices who displayed exemplar practice (example: conducting regular practice meetings regarding vulnerable families) should be evaluated with a view to being rolled out nationally (Woodman *et al*., 2013). Woodman *et al.* did not explicitly explore GP recording of child maltreatment, however, they went a step further to ascertain an understanding of the response and actions of the health professionals regarding a very sensitive issue (Woodman *et al*., 2013).

Although both studies explored recording of other concerns, the issues of alcohol misuse and child maltreatment are also examples of stigmatised and sensitive issues that may have repercussions if recorded in the electronic health records, as with recording of drug use (Department of Health, 2005; Woodman *et al*., 2013, 2012).

1.3.13 Quantitative studies estimating drug use during pregnancy and outcomes of drug use during pregnancy

Up until April, 2013, there have been no studies examining the recording of drug use during pregnancy using primary care databases in England and Wales. Accurately estimating the burden of drug use during pregnancy is complex. Likely reasons for inaccurate data are underreporting due to the stigma of drug use during pregnancy, unawareness of the pregnancy due to amenorrhoea, fear of the newborn being taken away and no, late or default attendance to the GP and antenatal clinics (Centre for Maternal and Child Enquiries, 2011).

There have been four studies within the England, but none in Wales that have examined drug use during pregnancy. In this section I will describe these studies briefly and discuss them in more detail in *section 5.2*. The aims of all four studies were to ascertain an estimate of women who use drugs during pregnancy in secondary care.

The first two cross-sectional studies by Farkas *et al.* (n=1000) and Sherwood *et al. (n=807)*, were conducted in East and South London respectively and both tested anonymous urine samples of pregnant women during the first trimester for drug use. Ten percent (Farkas *et al*.) and 15.6% (Sherwood *et al*.) of the samples tested positively for drug use with cannabis being the most common drug used in both studies.

The third study involved analysis of the Avon Longitudinal Study of Parents and Children Study (ALSPAC) (Fergusson *et al*., 2002). Pregnant women (n=12,000) enrolled on the ALSPAC study were given a self-reported questionnaire which included questions on cannabis use between 18-20 weeks gestation and a question on whether or not the woman used drugs during pregnancy. The authors reported that 5% of women in their study smoked cannabis during pregnancy, whilst 6.8% reported using other hard drugs.

The final study was conducted by The Advisory Council on the Misuse of Drugs prevention working group in June, 2011, which produced the Hidden Harm report in response to the needs of children of problem drug users (Advisory Council on the Misuse of Drugs, 2011). The findings estimated that between 200,000-300,000 (2-3% of children under 16 years) of children in England and Wales, have at least one parent who uses drugs (Advisory Council on the Misuse of Drugs, 2011). A questionnaire was sent to 423 maternity units in Sheffield and Glasgow for health professionals to complete. Ninety percent (92%, 238/259) of

the responding units said that they frequently asked pregnant women about drug and alcohol use and a mean of 1% (24/2407, range 0-172) of women who gave birth in the maternity units disclosed their drug use during pregnancy (Advisory Council on the Misuse of Drugs, 2011).

It was evident that evidence of the burden of drug use during pregnancy in the England and Wales is inconsistent. Since the Crime Survey for England and Wales does not currently include questions on drug use during pregnancy, a primary care database may be a potential tool for examining this problem. Alternatively, another method of estimating the burden of drug use during pregnancy is to examine adverse outcomes and symptoms due to drug use in infants' electronic health records. I will discuss the potential adverse outcomes and symptoms in the next section.

1.3.13.1 Potential adverse outcomes of drug use during pregnancy

Madgula *et al.* conducted a review on adverse outcomes due to drug use during pregnancy (Madgula et al., 2011a). The review reported that previous studies examining the adverse effects of drug use during pregnancy have had relatively small sample sizes and utilised different methodologies (Madgula et al., 2011a). The review concluded that there is no conclusive evidence for adverse birth outcomes due to drug use during pregnancy except for neonatal abstinence syndrome (NAS). Infants have a higher risk of developing NAS if a mother uses either opioids, barbiturate or benzodiazepine during pregnancy (Madgula et al., 2011a; O'Donnell et al., 2009; Winklbaur et al., 2008). Following this, NAS could potentially be used as indirect measure of specific drug use during pregnancy.

1.4 Rationale for Thesis

As previously mentioned in *section 1.3.7*, the scope and timing of the three different crime-surveys (England and Wales, Scotland and Northern Ireland) is not consistent and therefore it may be difficult to directly compare them. Additionally, the burden of drug use during pregnancy has been examined more

in Scotland hospital births (National Statistics Scotland, 2012). Therefore this thesis will focus on drug use and opioid substitution treatment in England and Wales, rather than for the whole of the UK.

It is evident to date, that there is little evidence of the burden of drug use and opioid substitution treatment during pregnancy in England and Wales. Pregnancy usually triggers women to visit their general practitioner (GP) which may provide an opportunity for drug-use to be raised and recorded. All women residing in the UK have the opportunity to be registered with a GP and receive free antenatal care (National Institute for Clinical Excellence, 2010b). Women are recommended to visit either their GP or midwife once they know they are pregnant (National Institute for Clinical Excellence, 2010b). A 2010 survey found that for 77% of women, a GP was the first healthcare practitioner they saw and that 45% of antenatal appointments occurred in general practice (Redshaw and Heikkila, 2010). Antenatal care is usually transferred to the midwifery service, and transferred back to the GP when a woman visits her GP six weeks after the birth of her baby (National Institute for Clinical Excellence, 2010b). If a woman chooses to consult her GP after giving birth, this timely appointment may lend itself as an opportunity for a GP to enquire about drug use together with other health related behaviours. If a woman discloses that she uses drugs, the GP is in a better position to offer long term support for both mother and child. GPs may also record information regarding drug use during and after pregnancy as a Read code in a woman's electronic health record. Data from the electronic health record could be viewed as an approach to monitoring women who use drugs.

Various methods were used in studies examining drug use during pregnancy and the results are conflicting (Advisory Council on the Misuse of Drugs, 2011; Farkas *et al.*, 1995; Fergusson *et al*., 2002; Sherwood *et al*., 1999). Pregnancy could be an opportune time for a GP to ask about drug use and therefore a primary care database may have the potential to assess the level of burden of drug use in and around pregnancy. In order to increase my understanding of pregnant women who use drugs, I will initially examine recording of drug use and opioid

substitution treatment in electronic health records of the general population. Following this, I will compare the results to national surveys conducted in England and Wales to ascertain that it is a suitable surveillance tool. Subsequently, I will focus on women in and around pregnancy and also examine infants' electronic health records for an indirect measure of drug use and/ or opioid substitution treatment during pregnancy.

1.5 How Does This Chapter Support My Thesis?

In the first chapter, I have set the scene and context and explained the rationale for the thesis, I will describe and discuss the research questions, aims and objectives in the next chapter (Chapter 2), followed by a short summary of each chapter.

CHAPTER 2 SUMMARY OF CHAPTERS

2.1 Content and Structure of Chapter 2

In this chapter, I describe the overall aim, objectives and research questions of the thesis, followed by short summaries of chapters 3-8.

2.2 Overall Aim

The overall aim of the thesis was to explore the level of burden of drug use and opioid substitution treatment in and around pregnancy in England and Wales by examining GP recording in individuals' electronic health records.

2.3 Research Questions

The two main research questions are:

1. Can a large primary care database (The Health Improvement Network (THIN)) be used as a surveillance tool for understanding drug use and opioid substitution treatment in the general population and specifically during pregnancy (in England and Wales)?
2. Can a large primary care database (THIN) be used as a tool to research drug use and opioid substitution treatment in general practice in the general population and specifically during pregnancy (in England and Wales)?

2.4 Overall Objectives

The main objectives of the PhD are to:

1. Further investigate GP recording of drug use (including recreational drug use) and opioid substitution treatment and compare results to national surveys and reports
2. Examine GP recording of drug use and opioid substitution treatment in and around pregnancy
3. Examine GP recording of neonatal abstinence syndrome, an indirect measure of drug use and opioid substitution treatment during pregnancy
4. Explore why, how and in which circumstances GPs record drug use in primary care.

2.5 Chapter Summaries

Chapter 3: METHODS

In Chapter 3, I justify why I decided to use mixed methods to answer the research questions. I describe the two large databases (The Health Improvement Network (THIN) and Hospital Episode Statistics (HES)) used in the quantitative studies and the qualitative interview methods

Chapter 4: Study 1: GP recording in the general population

In Chapter 4, I describe and examine GP recording of drug use and opioid substitution treatment in the general population using electronic health records from THIN. In order to achieve the main aim of the thesis (*section 2.2*), I first had to ascertain if THIN was a suitable tool to examine GP recording of drug use and/or opioid substitution treatment in the general population.

Aims of Study 1:

To describe and examine GP recording of drug use and opioid substitution treatment in the general population, using electronic health records

Objectives of Study 1:

Using data from the period between 1994-2012 in England and Wales, I sought to:

1. Explore the level of entry of different codes available for GPs to record drug use and opioid substitution treatment
2. Identify new records (first recording) of drug use and opioid substitution treatment in primary care
3. Examine recording rate ratios for new records of drug use and opioid substitution treatment
4. Estimate the period prevalence (2010/11 to 2012/13) of recorded drug use and opioid substitution treatment
5. Compare GP recording of drug use and opioid substitution treatment with national surveys

Chapter 5: Study two: GP recording in and around pregnancy

In the fifth chapter, I describe and discuss the second study, which focuses on recording of drug use and opioid substitution treatment in women in and around during pregnancy, using THIN. I use the females obtained in study 1 and women from a pre-existing pregnancy cohort to examine the number of women who have a GP recording before (36 months), during and after (36 months) pregnancy.

Aims of Study 2:

To describe GP recording of drug use and/or opioid substitution treatment in and around pregnancy.

Objectives of Study 2:

Using data for women residing in England and Wales in the time-periods in and around pregnancy, I sought to:

1. Examine the parity and demographics for women with and without recordings for drug use and/or prescriptions for opioid substitution treatment
2. Examine the timing of recordings for drug use and/or prescriptions for opioid substitution treatment
3. Explore the frequency of Read and/or prescription codes entered for each woman during specific time periods

Chapter 6: Study three: GP recording of Neonatal Abstinence Syndrome

In Chapter 6, I describe and discuss the third study, which focuses on GP recording of an outcome of drug use during pregnancy, neonatal drug withdrawal syndrome (NAS), in primary care. I discuss how I obtained a cohort of all infants registered between birth and 6 months and examined both infant and mother's records for a recording of NAS, using THIN. I calculate the recording rate per calendar year and I describe how I calculated the birth prevalence of NAS in secondary care, using HES. Finally, I assess how much of the discharge information (regarding NAS) from HES is entered onto the GP records in THIN.

Aims of Study 3:
To explore recording of NAS, a symptom of drug use during pregnancy in primary and secondary care.

Objectives of Study 3:

1. Develop a list of Read codes for NAS in primary care
2. Identify infants who have a Read code indicated for NAS and examine the demographics and other factors of infants with and without a recording for NAS in primary care
3. Calculate the recording rate of NAS per 1,000 live births in primary care
4. Calculate the recording rate of NAS per 1,000 live births in secondary care and compare how much of this information is entered in primary care electronic health records

Chapter 7: Study four: Factors influencing recording of drug use – a qualitative study

In this chapter, I describe and discuss the qualitative study which was essential for helping to understand the results from the previous three chapters. I explain how I conducted and analysed 12 semi-structured interviews with GPs. Finally, I discuss how I interpreted the qualitative data.

Aims of Study 4:
To understand GP recording of drug use and opioid substitution treatment and to use existing literature to contextualise my findings.

Objectives of Study 4:

1. To explore and generate an understanding of the factors determining GP recording of people who use drugs and/or receive opioid substitution treatment in primary care.

2. To examine if GPs use any specific protocols or codes for recording drug use and/or opioid substitution treatment

3. To examine and generate an understanding of the similarities and differences of recording drug use and/or opioid substitution treatment between the general population and pregnant women

4. To examine if GPs use any specific protocols or codes for referring individuals for treatment of drug use and/or opioid substitution treatment

Chapter 8: Summary and synthesis of results of quantitative and qualitative studies

In the penultimate chapter, I summarize and synthesize the results of the four studies. I consider how the studies support each other and support my findings.

Chapter 9: Discussion

In this final chapter, I will firstly present an overview of the thesis and summary of the findings. I will then present the following:

1. Illustrate how the thesis brings new knowledge and/or improves method.
2. Discuss the value of the Offending Crime and Justice Survey as a measure of drug use in the population.
3. Describe the overarching strengths and limitations of the thesis
4. Discuss what I have learnt during the thesis and what I might have done differently
5. Discuss if THIN is sufficient to address the hypothesis concerning drug use during pregnancy or the consequences of NAS?
6. Consider both the clinical and research implications of the thesis
7. Present the conclusions of the thesis

CHAPTER 3 METHODS

3.1 Content and Structure of Chapter 3

In this chapter, I begin by describing the differences between quantitative and qualitative methodologies. Secondly, I discuss and justify why I chose to use mixed methods for the thesis. Finally, I provide a description of and discussion about; The Health Improvement Network (THIN) primary care database (used in studies 1-3, Chapter 4-6), Hospital Episode Statistics (HES) secondary care database (used in study 3, Chapter 6) and qualitative interview methods (used in study 4,Chapter 7).

3.2 Quantitative and Qualitative Methodologies

Methodology is the strategic approach to gaining knowledge and conducting research (Green and Thorogood, 2004). Two principal methodologies are the deductive and inductive approaches (Pope and Mays, 2000). Furthermore, the two most common procedures in acquiring knowledge are quantitative and qualitative methods (Pope and Mays, 2000). Figure 3:1 illustrates the fundamental differences between quantitative and qualitative research. I will now discuss the two methodologies in more detail and how I applied these in my research design.

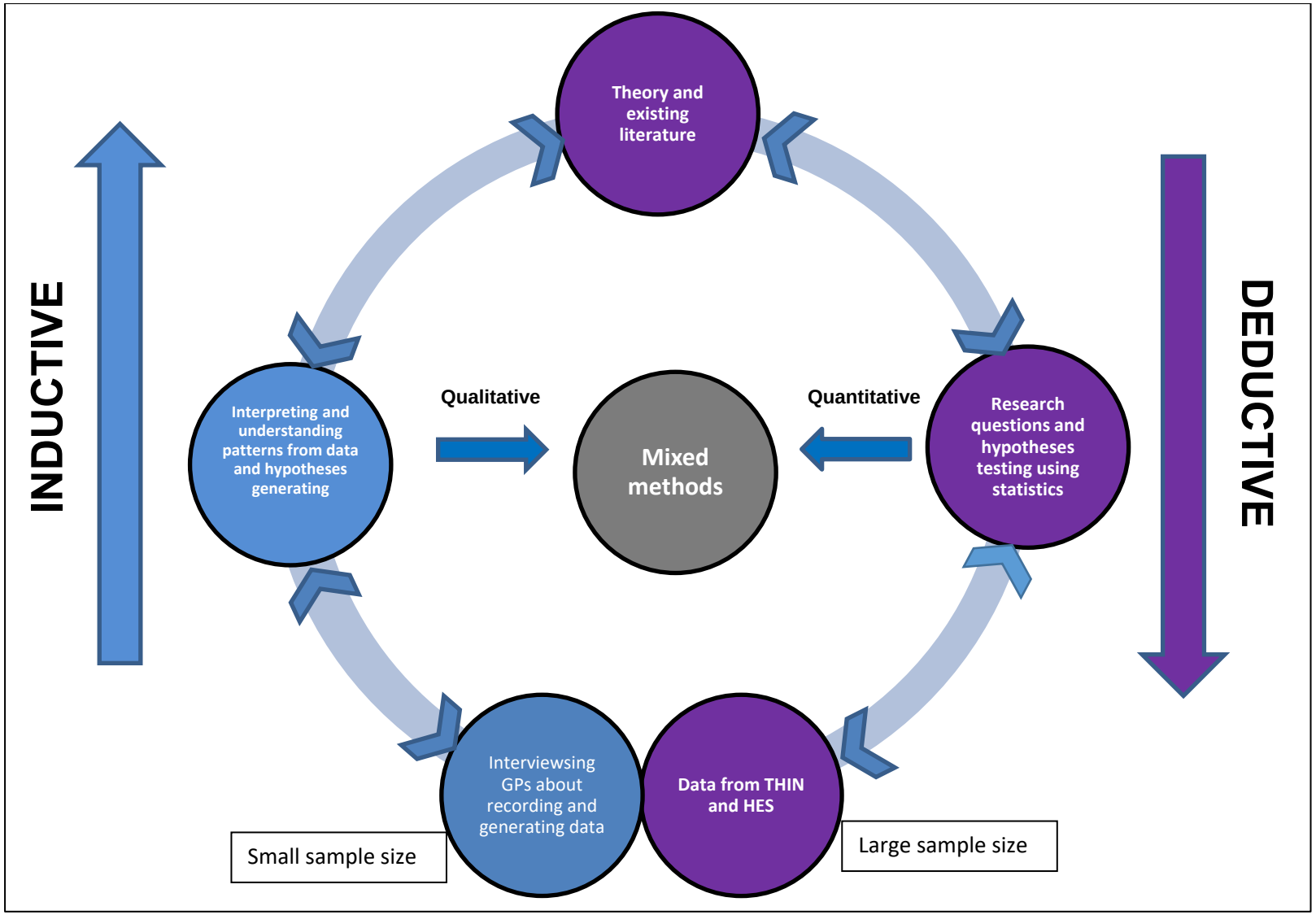


Figure 3:1: An illustration of the main differences between quantitative and qualitative research methodologies:

3.2.1 Quantitative methodologies

Quantitative methodologies attempt to answer the following questions; what and how much? There are different study designs used to conduct quantitative epidemiological research which include; randomised controlled trials, meta-analyses and observational studies (cohort, case-control and cross-sectional studies) (Green and Thorogood, 2004). Quantitative research is generally a deductive approach and hypotheses are tested to answer research questions (Pope and Mays, 2000). Research questions and hypotheses are generated from existing literature and theory (Green and Thorogood, 2004). The researcher needs to use statistical methods to analyse the data (collected or observed) in order to test hypotheses and answer specific research questions.

In the thesis, I initially developed my two main research questions from existing literature and theory:

1. *Can a large primary care database (The Health Improvement Network (THIN)) be used as a surveillance tool for understanding drug use and opioid substitution treatment in the general population and specifically during pregnancy (in England and Wales)?*
2. *Can a large primary care database (THIN) be used as a tool to research drug use and opioid substitution treatment in general practice in the general population and specifically during pregnancy (in England and Wales)?*

I then conducted three epidemiological studies and applied statistical methods in order to test the hypotheses and answer the research questions. The results from this work could then contribute to the existing landscape of literature (Figure 3:1).

3.2.2 Qualitative methodologies

Qualitative methodologies endeavour to answer questions such as why and how something occurs (Pope and Mays, 1995). There are various qualitative

methodologies applied to answer different qualitative research questions (*this will be discussed in more detail in section 3.6*). Qualitative research is characterised by researchers' interpretation of the results (Pope and Mays, 1995). It is also imperative that the researcher understands and reflects on his/her own views and incorporates this when interpreting the data (Green and Thorogood, 2004). Qualitative research is more likely to be associated with an inductive approach (Green and Thorogood, 2004). Although the sample size is generally smaller, the qualitative exploration usually generates richer and more in-depth data (Figure 3:1) (Green and Thorogood, 2004).

Once I had conducted my quantitative studies, I conducted a qualitative study in which I conducted semi-structured interviews with GPs regarding their behaviour of recording patients that use drugs and/or are prescribed opioid substitution treatment. I then analysed and interpreted the qualitative data in order to understand the patterns generated. The new hypotheses generated could then contribute to the existing landscape of literature (Figure 3:1).

I will now discuss and justify why I used mixed methods to answer my research questions.

3.3 Why I Used Mixed Methods

Mixed methods research comprises the use of using both quantitative and qualitative research methods (Brannen, 2005). Mixed methods research is defined as adopting more than one strategy to answer the research question and it is used more in medical and health research (Brannen, 2005). The mixed methods approach has been used in clinical trials with surveys of attitudes and beliefs, and epidemiological measures to improve understanding of health problems (Plano Clark, 2010).

My initial research experience involved generating data through experiments or observation and testing a hypothesis. Consequently, I was initially guided by quantitative methodologies to answer my two main research questions. However, it soon became evident that there were more questions that needed to be answered in terms of how and why the data was recorded. I therefore decided to take a different approach to acquiring knowledge in order to answer these new questions. It was essential to answer questions regarding the social context of how and why the data was recorded and it was therefore necessary that I also use qualitative methodologies to help interpret and understand my quantitative results and optimally answer my research questions (Pope *et al*., 2014). I chose to take a pragmatic approach and used both quantitative and qualitative methods, as one methodological approach could not answer all my research questions.

The increased use of mixed methods has led to the development of its own terminology, and techniques (Tashakkori and Teddlie, 2003). Denscome argued that whilst pragmatism is used for the philosophical understanding of mixed methods, mixed methods itself could be a distinct paradigm for social research (Denscombe, 2008). Triangulation of two methods helps achieve comprehensive understanding (Hammersley, 2005). However, the data collected cannot simply be added together to produce one answer and the methods should not be used to check or verify each other, but rather to complement each other and use each other as a critical lens (Hammersley, 2005). The deductive approach can help the qualitative analysis be more systematic and rigorous, whilst the inductive approach can aid in increased knowledge and understanding of empirical data.

Hammersley describes four ways of combining data analysis from two different research methods: expansion or elaboration, initiation, complementarity, and contradictions (Hammersley, 2005). I decided to use a combination of two of these methods of combining data; expansion and complementarity. Expansion describes how one type of data analysis can add to the understanding of the

other type of data analysis (Hammersley, 2005). Complementarity treats quantitative and qualitative differently, but uses the results in conjunction with each other to contrast and compare in order to enhance and build a greater understanding of the data (Hammersley, 2005). I will use both of these methods of combining data as my three quantitative studies (Studies 1-3, Chapters 4-6) focus on GP recording of drug use in electronic health records and the qualitative study (Study 4, Chapter 7) involves interviewing GPs who routinely enter data into patient's electronic health records. The qualitative findings should therefore add to the understanding and complement the three quantitative studies. Methodological triangulation could therefore strengthen the evidence of my quantitative work.

3.3.1 The design of the mixed method study and integrating the studies

The thesis developed into a mixed methods study and I therefore chose to use the explanatory sequential method, as I conducted the quantitative studies first, followed by the qualitative study and then analysed and interpreted all four studies (Figure 3:2) (Cresswell and Plano Clark, 2007).

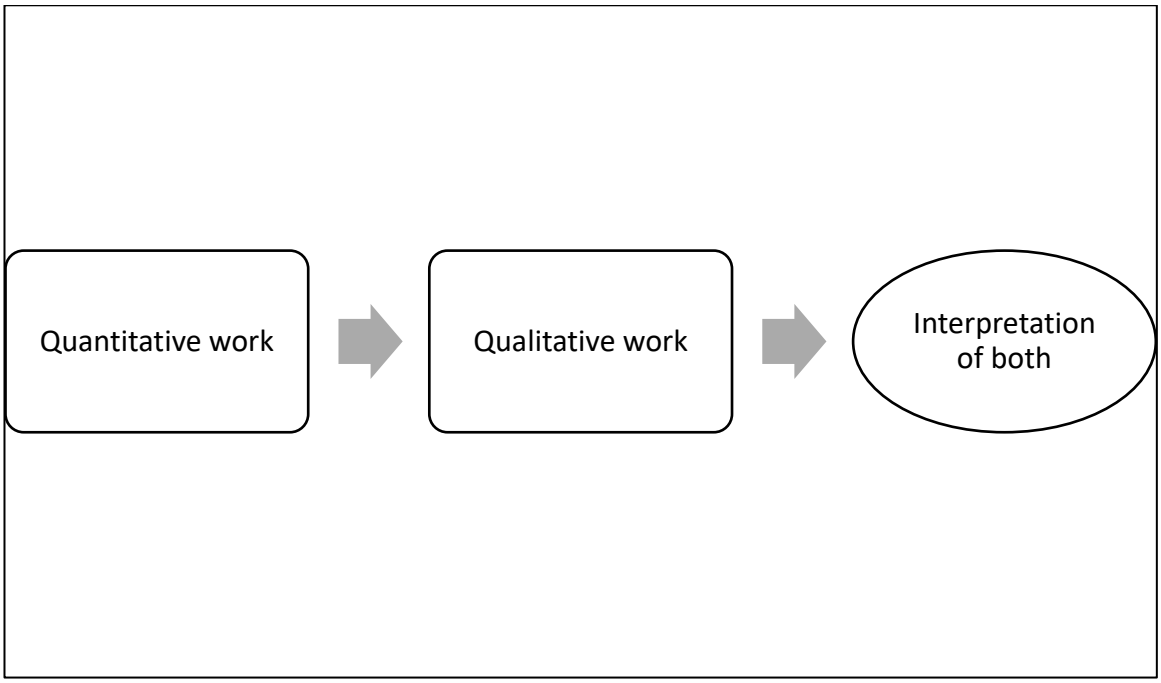


Figure 3:2: Explanatory sequential mixed methods design (Cresswell and Plano Clark, 2007)

I kept the analysis of the two different methodologies distinct until the interpretation phase of my thesis. I used a cohort design for studies 1-3 (*described in sections 4.7.3, 5.6.5 and 6.6.3*) and thematic analysis to analyse study 4. (*described in section in 7.5.7*). I then synthesised and integrated the results from all four studies at the interpretation stage.

I have justified why I used mixed methods in the thesis. I will now describe the two large databases that I used for my epidemiological studies 1-3, THIN and HES.

3.4 The Health Improvement Network

The Health Improvement Network (THIN) is a primary care database of anonymised patient electronic records. The database is based on practice staff (GP, nurses and administrative staff) recording information from consultations and other information about the patient using Vision software in the form of Read codes, prescriptions and/or free-text (*see section 1.3.5 for details*). The primary purpose of electronic health records is not for research, but rather to record consultations which provides a clinical window of primary care (CSD health research, 2015).

3.4.1 History of THIN

Dr John Preece was the first GP to use a computer to record patient consultations in 1960 (Benson, 2011). His work resulted in the computer-printed prescription form still currently used by GPs (Benson, 2011). Subsequently Dr John Perry worked on the Oxford GP record linkage project and developed OXMIS codes (*see section 1.3.5 for details)* (Benson, 2011). These codes were used by many GPs in the 1980's, however, the death of Dr Perry meant these codes were not developed and their usage was subsequently discontinued (Benson, 2011).

Abie Informatics Limited was founded in 1980 (Benson, 2011). The Abie medical dictionary was developed by Dr James Read, together with Abie Informatics (Benson, 2011). It was later renamed the Read code classification system (Benson, 2011; Chisholm, 1990). The system was constructed to be comprehensive, hierarchical, coded, computerised, cross-referenced and dynamic (Chisholm, 1990). The Read codes are a hierarchical classification system and each code has four digits (letters/numbers/baseline dot) (Chisholm, 1990). The codes were divided into sections and either based on pre-existing classification systems, or were newly developed (Chisholm, 1990). The Royal College of General Practitioners and British Medical Association recommended using Read codes as a national clinical coding system in 1988 (Benson, 2011).

Read codes are structured into hierarchical groups and divided into specific sections (*Appendix 4*). A Read code is made up of a code (medcode) and a description. The medcode is 7 characters which is case sensitive, whilst the description can have up to 60 characters (Table 3.1). There are common abbreviations used in Read codes, examples of these include H/O (history of), NOS (not otherwise specified) and F/H (family history) (CSD health research, 2015).

Table 3.1: Example of Read code (medcode) and description (CSD health research, 2015)

Medcode (7 characters, case sensitive)	Description (up to 60 characters)
1V22.00	Age at starting drug misuse
E242100	Cocaine dependence, continuous
1V0C.00	Drug addict

VAMP (Value Added Medical Products) health specialised in developing software for GPs to use for electronic health recording (García Rodríguez and Pérez Gutthann, 1998; Walley and Mantgani, 1997). VAMP health installed computer systems and software in GP practices in the UK. If a GP practice

joined VAMP, they received free computers, VAMP software and 12 months training (García Rodríguez and Pérez Gutthann, 1998; Hall, 1992; Walley and Mantgani, 1997). The practices' data was only included in the VAMP Research Database after the quality of their data reached a specific standard (García Rodríguez and Pérez Gutthann, 1998; Lis Y and Mann RD, 1995). In 1993, due to financial problems, the VAMP Research Database was taken over by Reuters Health Information, who donated the database a year later to the Department of Health. It was then renamed the General Practice Research Database (GPRD) and managed until 1999 by the Office for National Statistics. Subsequently, the Medicines and Healthcare Products Regulatory Agency (MHRA) (previously called the Medical Control Agency (MCA)) took it over. The GPRD is now a sub-division of the MHRA. GPRD changed name to Clinical Practice Research Datalink (CPRD) in 2012 (Clinical Practice Research Datalink, 2013).

After the closure of VAMP Research Database, some employees of VAMP formed EPIC, a non-profit organisation in 1995 (García Rodríguez and Pérez Gutthann, 1998; Lis Y and Mann RD, 1995). EPIC held an exclusive license to provide information on patient records (in GPRD) for medical research between 1995-2002 (García Rodríguez and Pérez Gutthann, 1998; Lis Y and Mann RD, 1995). Once the license expired, THIN (*see section 1.3.6 for details*) was formed by EPIC and Cegedim Strategic Data Medical Research (CSD; a European software company) (CSD health research, 2015). Subsequently CSD acquired EPIC and collaborated with In Practice Systems (INPS) who supplied a particular software, Vision, to 1800 general practices across the UK (CSD health research, 2015). Some general practices contribute data to both THIN and CPRD (Lewis *et al*., 2007). There is approximately a 60% overlap of practices between the two databases (Cai *et al*., 2012). As of April 2015, CSD became part of IMS Health Real World Evidence Solutions (IMS Health, 2015)

3.4.2 Description of THIN

The data is collected weekly by THIN and consolidated by CSD (CSD health research, 2015). The data is anonymised and contains information about patients registered in the particular general practices (Table 3.2) (CSD health research, 2015). Each patient's electronic records are linked by a unique patient id (patid) to the specific general practice (CSD health research, 2015).

Table 3.2: Content of THIN data (CSD health research, 2015)

Anonymised patient level information	Files in which the information is catalogued	Codes used
Demographic	Patient records	Field and description
Medical	Medical records	Field, description and medcodes
Prescribing	Therapy records	Field, description and Multilex/drug codes
Referral to specialists	Additional Health Data	Field, description, ahdcode and/or medcode
Diagnostic laboratory results	Additional Health Data	Field, description, ahdcode and/or medcode
Lifestyle characteristics	Additional Health Data	Field, description, ahdcode and/or medcode
Other measurements	Additional Health Data	Field, description, ahdcode and/or medcode
Postcode variable indicators (to classify deprivation)	PVI record	PVI
Data on the practices	*Practice file records	
Information on consultation date, time and length	*Consult file records	
Staff roles	*Staff file records	
Anonymised free-text comments	*Practice file records	Textid

*Additional data files the information is catalogued in

In the UK the majority of individuals are registered with a GP (Lis Y and Mann RD, 1995). By 2012, there were 570 general practices in the UK (England, Scotland, Northern Ireland and Wales) which contributed data to THIN covering approximately 6% of the population (CSD health research, 2015). During consultations, clinical information is entered in the form of standardised Read codes together with drugs prescribed onto a computer using Vision software (Chisholm, 1990). More information about the consultation can be entered as free-text during the consultation. Over 313, 000 comments have been anonymised and are available for a researcher with a THIN license (CSD health research, 2015). This amounts to approximately 35% of all the free-text-comments (CSD health research, 2015). If a comment is anonymised, a 7 character numeric identifier (textid) will be linked to a unique comment (CSD health research, 2015). Letters and discharge notes from secondary care and

other primary care services (e.g. midwives) are often scanned and not coded as Read codes or free-text comments. Sometimes GPs may highlight the scanned letters and enter Read codes for important symptoms and diagnoses. I will discuss in detail how I examined free-text comments in the electronic health records in *section 4.7.5.2.*

3.4.3 Validity of THIN

THIN is comparable to the general UK population in terms of demographics, mortality and prevalence of chronic and acute diseases, although under 25s, males and less affluent individuals are slightly underrepresented compared to national statistics (Blak *et al*., 2011). Individuals in the armed forces and prisoners are not included in THIN (*this is discussed in more detail in section 3.4.4*). Social deprivation is recorded in THIN as quintiles of Townsend scores, which is a measure of deprivation in the UK (Townsend, 1987). The score is created by measuring four variables; the number of individuals per household, employment, ownership of car and home to create a single measure of deprivation (Townsend *et al*., 1986). A higher scores indicate more deprived areas (Townsend *et al*., 1986). The region of the general practice is divided into regions equivalent to the former Strategic Health Authorities (SHA) for England and countries for Scotland, Wales and Northern Ireland (Health and Social Care Information Centre, 2013a).

There are certain recording issues in primary care databases, and in order to reduce this, two quality markers have been developed: the acceptable mortality rate date (AMR) and the acceptable computer usage date (ACU).

3.4.3.1 Acceptable mortality rate date (AMR)

Mortality is an important outcome measure when using a database for epidemiological research. However, as some practices have changed from one software to another, they would only have transferred individuals who were alive at the time they changed software and hence the overall mortality rate would have been too low in these practices (Hollowell, 1997; Maguire *et al*., 2009). Therefore, a data quality marker, Acceptable Mortality Ratio (AMR), was developed to ensure recording of death are comparable to expected national mortality figures (Hollowell, 1997; Maguire *et al*., 2009). The expected mortality rate is derived from the Office of National Statistics (ONS) for a particular practice based on the demographics. The AMR year for a practice is then determined, when the observed mortality rate of the practice is reporting a mortality rate which is comparable with the ONS mortality rate (Maguire *et al*., 2009).

3.4.3.2 Acceptable computer usage date (ACU)

In the 1990's some practices did not use their computer system completely and therefore another data quality marker for computer usage, Acceptable Computer Usage (ACU) date was developed by the electronic health records research team at UCL (Horsfall *et al*., 2013). This is a marker for when practices appear to be using their computer system rather than paper records. An ACU date would be assigned to each practice, on average, they have at least two therapy records, one medical records and an additional health data record per patient per year (Horsfall *et al*., 2013). The ACU year is on average approximately 3.3 years after the AMR year of a practice (Horsfall *et al*., 2013).The reliability of using THIN is improved if a combination ACU and AMR years are used instead of practice registration or computerisation (Horsfall *et al*., 2013).

3.4.4 Strengths and limitations of THIN

The main strength of using THIN, is that it provides a large amount of data from real life UK primary care. It also provides access to information on vulnerable and difficult groups to study or access such as pregnant women and individuals with mental health diagnoses. Furthermore, the database lends itself to research regarding rare exposures and outcomes.

There are various limitations to using THIN. Firstly only information about individuals who are registered with a general practice is included in THIN. GPs also needs to record specific aspects of the consultation using Read and/or drug codes and/or free-text. Read codes are not always specific to the symptom or diagnosis. Prescriptions may be more specific, but assumptions are made as to whether individual actually take the prescribed medication or not. As mentioned previously, free-text is available for some consultations, but not all free-text are anonymised and it may be costly to apply for access to the free-text. Referral letters that have been scanned into the clinical records and discharge letters may not be coded.

Another identified limitation is that the number of patients registered with an NHS number is higher than the registered population (Audit commission, 2012). In 2012, 53,493,729 individuals were living in the UK, however 55,724,785 people were registered with a GP (Audit commission, 2012). There have been several audit commission reports to evaluate this issue (Audit commission, 2006, 2012). These individuals fall into two categories:

1) Individuals who may have two NHS numbers
    a. Students who are registered both at their home and university resident address (Audit commission, 2006)
    b. Individuals who register with a new practice and do not inform their old general practice (Audit commission, 2006).
2) Individuals who have a single NHS number, but have left the general practice

a. Individuals who immigrate but choose not to de-register. They therefore remain on the practice register, but not on the resident population register (Audit commission, 2006).
b. Individuals who work and/or study in the UK short term, may also register with a general practice, but not be included in the resident population (Audit commission, 2006).
c. Asylum seekers who are no longer living in the UK may still be registered with a general practice (Audit commission, 2006).

Some GPs may intentionally not remove patients and are still receiving money for each of these patients (Audit commission, 2006).

There may also be individuals who register twice with intention, using their own and false identity in order to gain access to more prescriptions for either personal use or to sell (NHS Counter fraud services, 2011). This group includes individuals who use drugs and/or are receiving treatment for opioid substitution treatment (NHS Counter fraud services, 2011). However, the audit commission report in 2009 shows that there is an overall improvement in duplicate registrations from 185, 000 (2006) to 93, 000 (2009). The deceased and duplicate categories remain relatively high, and the removed asylum seekers category has increased by 10% (Table 3.3) (Audit commission, 2006, 2012).

Table 3.3: Comparison of results from duplicate audit commission reports in 2006 and 2009 (Audit commission, 2006, 2012)

Categories	Figures from 2006 audit commission report (%)	Figures from 2009 audit commission report (%)
Age reports (patients > 90 years old)	8	4
Temporary NHS number	7	N/A
Deceased	22	34
Duplicates	34	31
Gone away	28	N/A
Multiple occupancy	24	21

Categories	Figures from 2006 audit commission report (%)	Figures from 2009 audit commission report (%)
Removed asylum seekers	1	10

There are some groups of individuals who may be registered as residents, but not be registered with a practice. These groups include, the armed forces (0.3%), prisoners (0.2%) and non-registered immigrants (1%) (NHS England, 2013; UK Government, 2014). All armed forces service personnel, mobilised reservists and service family are registered with a defence medical services general practice, whilst prisoners are deregistered from their GP and registered with a prison GP (NHS England, 2013). Prisoners may have difficulty registering with a GP once they leave prison (UK Government, 2014). Homeless people may also not know how or have difficulty registering with a general practice, however the RCGP advise general practices to register homeless individuals (Royal College of General Practitioners, 2002).

Finally, it should be mentioned that data from primary care databases may not represent community incidence of conditions/diseases as some individuals may not present to the GP. If the individual does present, they may not be diagnosed or they may not disclose an issue and therefore symptoms and diagnoses may not be recorded in their electronic primary care health record. As illustrated in Figure 3:3, the proportion of individuals in the community who present to their general practice when they get ill is a sub-sample of those registered with a GP. An even smaller proportion of individual consultations will be recorded and/or coded electronically (Figure 3:3) (Huxley and Goldberg, 1993; Public Health England, 2015).

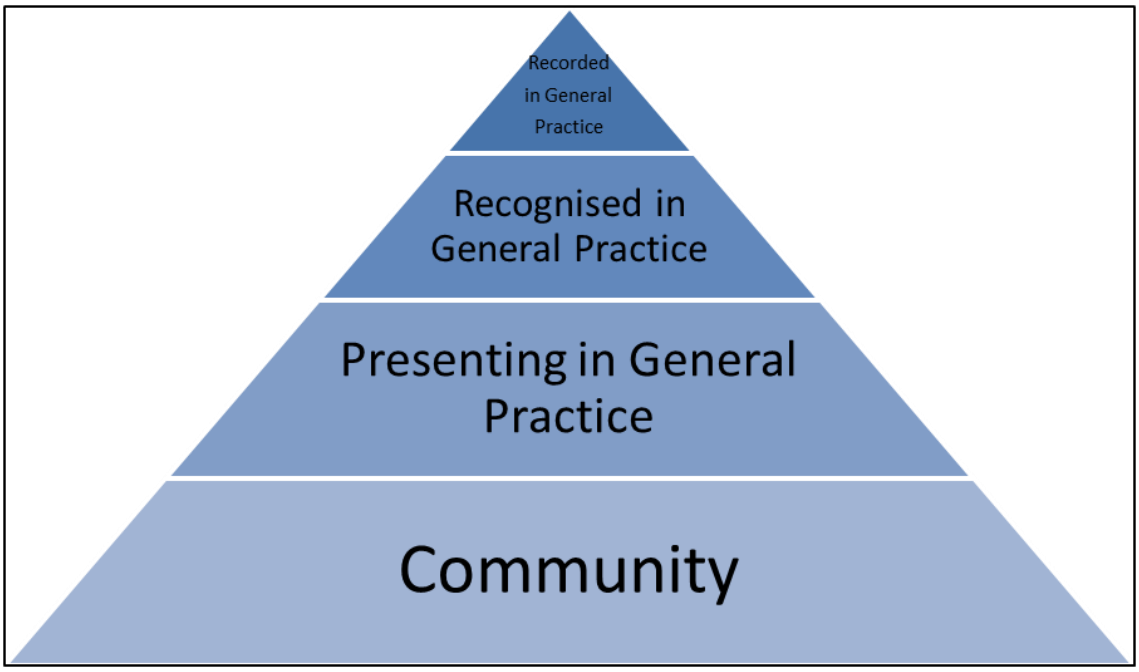


Figure 3:3: The pyramid illustrates that it is only a subset of individuals with a specific condition who present in general practice and of these it is only a smaller proportion who are recognised by general practice and an even smaller proportion have an entry made into their electronic health records. Adaption of Access to Health Care Pyramid (Huxley and Goldberg, 1993)

3.4.5 Reasons for using THIN in thesis

I decided to a primary care databases for my epidemiological studies as to date there are no large studies examining drug use and opioid substitution treatment in and around pregnancy in England and Wales. The Research Department of Primary Care and Population Health, UCL currently holds a license to use THIN and I therefore chose to use this database over GPRD. It is challenging to obtain information about such a sensitive and stigmatised issue, especially during pregnancy. As drug use had not been previously examined in THIN, it was necessary that I firstly identified a cohort of people who were recorded as using drugs and/or opioid substitution treatment. Following this, I would use a pre-existing cohort of women who had at least one pregnancy to identify pregnant women who were also recorded with drug use and/or opioid substitution treatment. Other methods of obtaining information about drug use and or opioid substitution treatment, such as a questionnaire, may be more costly and time intensive to obtain a large sample size and self-reporting may introduce response bias. THIN will allow me access to real life data from

primary care, information on a relatively rare exposure (drug use and/or opioid substitution treatment) and provide a large sample size.

My third epidemiological study was examining recording of Neonatal Abstinence Syndrome using THIN. There are however currently no studies looking at the birth prevalence of neonatal abstinence syndrome in England. Therefore, I examined the birth prevalence using data from Hospital Episode Statistics to compare with the results from THIN. I will now describe the hospital database that I will use for part of the third study.

3.5 Hospital Episode Statistics

3.5.1 Description of HES

Hospital Episode Statistics (HES) is a data repository for all admissions to the NHS hospitals in England (Health and Social Care Information Centre, 2012). Initially, only 10 percent of hospital data was collected and used nationally (Health and Social Care Information Centre, 2012). The concept of HES originated after 1987, following a report on collecting and using routine hospital data (Health and Social Care Information Centre, 2012). The aim of HES was to collect detailed information of all patient episodes occurring in NHS hospitals and sectors commissioned by the NHS (Health and Social Care Information Centre, 2012). All patients recorded in HES have their identifiers pseudonymised and replaced by a unique patient identifier; HESID (Health and Social Care Information Centre, 2012). The HESID is based on the patient's NHS number, date of birth, sex and postcode, it is unique and cannot be traced back to the patient (Health and Social Care Information Centre, 2012).

The length of stay from admission to discharge is called a 'spell' (Figure 3:4) (Health and Social Care Information Centre, 2013b). During a spell a patient can have one or more 'episodes' (Health and Social Care Information Centre, 2013b). Admission diagnoses are coded according to the International Coding

for Disease-10 (ICD-10) (Health and Social Care Information Centre, 2012). ICD-10 is a diagnostic tool which is used for epidemiology, health management and clinical reasons (World Health Organisation, 2010). The ICD-10 codes assist in monitoring incidence and prevalence rates of specific symptoms and diseases (World Health Organisation, 2010). ICD-10 replaced ICD-9 in 1994 and a revised version, ICD-11, will be implemented in 2017 (World Health Organisation, 2010). In HES, a four digit code is used to identify diagnoses for each episode (Murray *et al*., 2013). A patient can have up to 20 diagnoses per episode (Figure 3:4) (Health and Social Care Information Centre, 2013b).

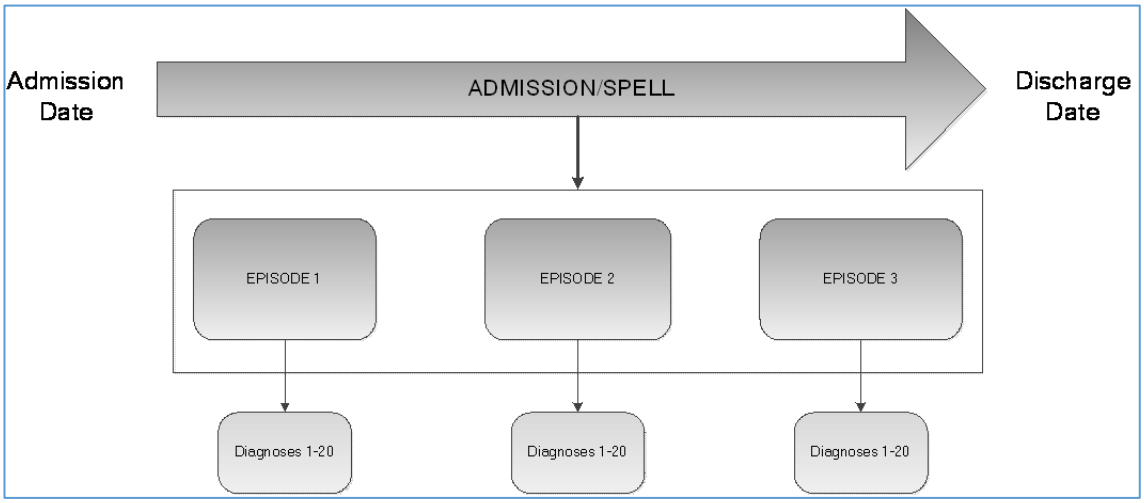


Figure 3:4: Admission and episodes in Hospital Episode Statistics (Health and Social Care Information Centre, 2013b)

In order for a diagnosis to be entered as an ICD-10 code, the doctor needs to highlight the diagnoses of interest in the patient's paper records or discharge notes (Department of Health, 2013). Both the records and notes are sent to hospital coders once the patients are discharged (Department of Health, 2013). The coders will then work systematically to determine the appropriate ICD-10 code to use and should contact the doctors if there are any queries (Department of Health, 2013). The correct coding is important, as diagnoses are mapped to payment to the NHS trust (Department of Health, 2013). An example of this is that if an individual has angina they will get one code, but if they have angina plus hypertension, they will receive a different code and they will receive a

higher payment (Department of Health, 2013). HES data is collected on a monthly basis and annual reports are produced for each financial year (1 April-31 March). HES data are derived from routinely collected administrative data which were pseudonymised before I received them, and therefore I did not require Research Ethics Committee approval (Health Research Authority, NHS, 2010).

3.5.2 Mother and baby records in HES

When a pregnant woman is admitted into hospital, she will have an inpatient record and once she gives birth she will have a maternity record. A maternity record consists of two parts; the delivery and birth records. The delivery record contains general information about the mother and a baby, which includes information about the delivery. Whilst the birth record is for the baby and contains some of the same information as the mother's record, as well as general information regarding the baby. The diagnostic information for the baby will not necessarily be in the mother's records as mother and baby records are not linked. If there are multiple births, each baby will have a unique baby record but the same delivery record (Figure 3:5) (Murray *et al*., 2013).

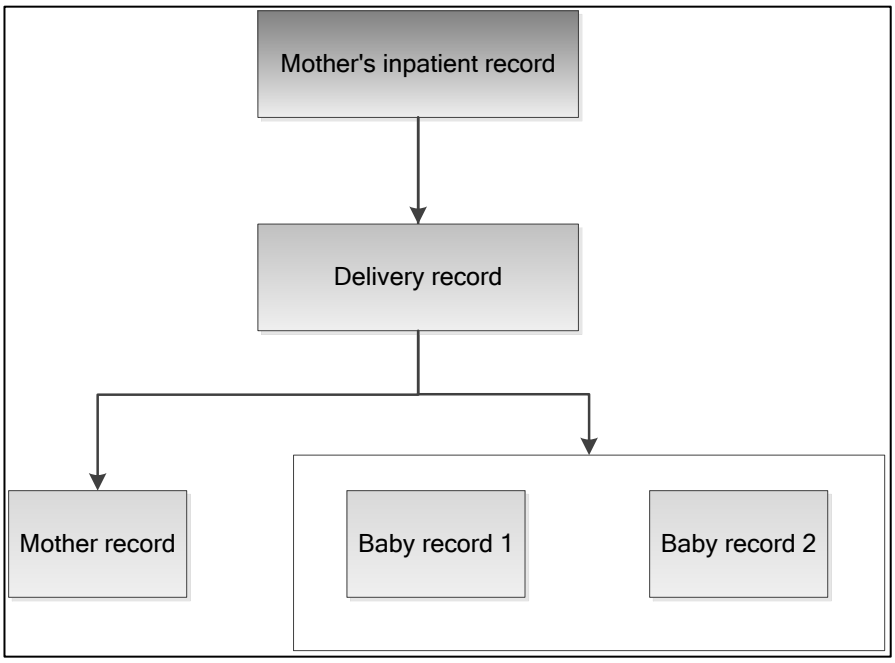


Figure 3:5: Structure of mother and child records in hospital episode statistics. This example illustrates a situation where the pregnancy resulted in twin births (Health and Social Care Information Centre, 2013b)

3.5.3 Validity, quality, strength and limitations of HES

The quality of data coded and sent to HES is of varying quality, but a report by Knight *et al.* showed how the number of hospitals providing good quality maternity data has improved over the years (Knight *et al*., 2013a). The quality of baby data is still relatively poor, especially with regards to missing data and social deprivation. In HES, social deprivation is measured by the index of multiple deprivation (IMD) which is based on postcode of residence (Department for Communities and Local Government, 2015). Due to a data extraction error by the data provider, IMD is only available for babies in HES who were readmitted in the first 6 months of life and not from the delivery record (Health and Social Care Information Centre, 2012). Therefore, currently IMD cannot be included when analysing neonatal HES data.

HES is a key resource for monitoring health outcomes and assisting in epidemiological research (Morleo *et al*., 2011; Murray *et al*., 2013; Royal College of Obstetricians and Gynaecologists, 2014). The database is an extensive electronic resource which is cost-effective, and can compare outcomes between hospitals and trusts (Health and Social Care Information Centre, 2012; Morleo *et al*., 2011). The unique HESID, allows longitudinal analysis of each individual patient. HES includes approximately 96% of births in England (Birthplace in England Collaborative Group *et al*., 2011). HES was therefore an appropriate database to examine the birth prevalence of infants recorded with NAS in England.

Limitations of HES relate to the quality of hospital administrative data. Firstly, using HES can lead to systematic error, either because of incorrect recognition of symptoms and/or disease, recording by the doctor and/or coding by the hospital coder. The quality of data varies across NHS hospital trusts. Secondly, the mother and baby identities are not linked in HES. Information regarding the mother may not be in the baby record. An example of this is if the type of opioid drug used by the mother is recorded, it may not be in the baby record. However there is not at present, a gold standard method to examine

NAS and therefore HES is the most appropriate database to obtain the birth prevalence of NAS.

3.5.4 Reasons for using HES in thesis

To date there have been no large epidemiological studies looking at an indirect measure of drug use during pregnancy, specifically NAS. My aim is to therefore compare recording of NAS in both primary and secondary care by using electronic health records from both. I can then assess how much of the maternity discharge information is entered onto the baby's electronic primary care records. HES has previously been used to calculate prevalence rates of foetal alcohol spectrum disorders in England (Morleo *et al*., 2011) and I therefore wanted to explore its use for obtaining estimates of the prevalence of NAS in England.

I will now describe and discuss different qualitative methods available for my fourth study.

3.6 Qualitative Data Collection, Sampling and Analysis Techniques

Qualitative research is generally interested in depth and/or understanding (Green and Thorogood, 2004). I will describe and justify why I decided to use particular methods for data collection, sampling and analysis for my qualitative study. Additionally, I will discuss rigor, data quality and the ethics of qualitative research methods.

3.6.1 Qualitative interviews for generating data

There are three common methods used to collect qualitative data; interviews, focus groups and participant observation (ethnography). The methods aid in generating and shaping the data.

Interviews are well established as the most common qualitative method used for health research (Green and Thorogood, 2004). An interview is a guided conversation between interviewer and interviewee (Ritchie and Lewis, 2003). The interview relies on the interview skills of the interviewer (Clough and Nutbrown, 2002). A good interviewer tries to develop a rapport with the interviewee by asking questions clearly, listening actively, pausing correctly and exploring the answers aptly (Ritchie and Lewis, 2003). The interviews can be conducted face-to-face, by telephone or using internet video-conferencing to gain insight and understanding (Ritchie and Lewis, 2003). Opdenakker argues that telephone and video-conference interviews will have a different interaction between researcher and interviewee compared with face-to-face interviews (Opdenakker, 2006). I therefore decided to conduct face-to-face interviews with all the participants, to help reduce the difference in interviewer-interviewee-interaction between interviews.

Semi-structured interviews, are based on a less formal structure and incorporate open-ended questions (Ritchie and Lewis, 2003). The reseracher develops an interview schedule in order to set the agenda and aims to cover specific topics (Cohen and Manion, 2011). The conversation may deviate due to the participant's response and both researcher and participant can pursue the response or idea in more detail (Ritchie and Lewis, 2003). The order of questions may vary in interviews and some questions may not be asked (Newton, 2010).

The main advantages of semi-structured interviews is that the researcher can prepare the questions ahead of time, yet the process and social cues still allow room for the participant to express their opinions and discuss a particular topic in more detail. They can also provide reliable data that can be contrasted and compared to other interviews (Opdenakker, 2006). Sensitive questions can also be asked in a relaxed environment, interviews can be recorded and there is less interactional difficulties which can be caused by an interview that is not face-to-face (Opdenakker, 2006). The limitations of using semi-strucutred

interviews are that they can be time-intensive (but not as long as in-depth interviews), the interviewer may be less inclined to take notes if the interview is being recorded and the interviewer needs to be actively listening and concentrating for the duration of the interview (Green and Thorogood, 2004). Transcription of the interview is time-consuming and/or expensive and travelling to and from interviews can be costly (Green and Thorogood, 2004; Opdenakker, 2006).

After careful consideration and discussion amongst my supervisors and collegues, I decided to use face-to-face semi-structured interviews for my qualitative study with GPs. I aimed to gain a deeper understanding of their perceptions, context and process of their recording practice of drug use. I specifically chose semi-structured interviews as there were some specific questions I needed to ask at the beginning of the interview, followed by more open-ended questions. I was aware of the importance of GP time and I intended to interview GPs from a range of locations, I therefore decided to conduct semi-structured rather than in-depth interviews or focus groups. I will discuss how I iteratively developed my topic guide for my face-to-face interviews in *section 7.5.3*.

3.6.2 Sampling techniques

Sampling techniques depend on the purpose of the qualitative study (Al-Busaidi, 2008). The aim of sampling is to identify people who have particular characteristics or live in specific circumstances that are important to answering the research question (Al-Busaidi, 2008). Unlike quantitative research, generalisability is not the main aim of the qualitative study sample (Green and Thorogood, 2004). It is also not necessary to have a large sample, as the focus is on the quality of the insights not if they are made by a representative sample of people (Green and Thorogood, 2004). There are no strict rules for deciding the sample size in qualitative research, it depends on the aim of the study and the feasibility in terms of costs and resources (Patton, 2002). It is difficult to pre-determine the sample size for qualitative research, and this is often needed

for research grants and ethics applications (Green and Thorogood, 2004). It is suggested that the researcher keeps sampling and analysing until there are no new themes arising, this is called 'sampling to saturation' (Patton, 2002). However, Patton argued that a researcher may run out of time and/or money before true saturation occurs (Patton, 2002).

There are many sampling techniques used in qualitative research. The main techniques are; convenience, snowballing, purposive and theoretical sampling. There are no superior sampling techniques and it depends on the research question, population, researcher and feasibility. I initially decided to use purposive sampling as it is a technique that involves selecting participants from a particular group who are likely to generate useful and appropriate data (Coyne, 1997). A researcher can select participants according to age, gender, status, profession, experience or location (Coyne, 1997). I chose to interview GPs who had a special interest in patients who use drugs. The clinical director of Substance Misuse Management in General Practice agreed to contact GPs who had completed the RCGP Certificate in the Management of Drug Misus*e (see section 7.5.2 for details)* (Royal College of General Practitioners, 2015a). However, after initial interviews and analysis, I decided to also use theoretical sampling which originated with the grounded theory approach (Coyne, 1997). The researcher simultaneously collects and analyses data in order to establish emerging ideas and theories and to guide their upcoming sampling (Coyne, 1997). I will discuss my sampling process in more detail in *section 7.5.2*.

3.6.3 Transcription and qualitative analysis methods

The data was transcribed to prove a record of the words without linguistic features such as pauses and stresses which I judged to be sufficient to answer the research questions. I will describe my transcription process in more detail in *section 7.5.4*.

I decided to use thematic analysis as it can be both an inductive and deductive approach (Joffe and Yardley, 2004). It is a method used to describe and interpret generated themes from the data (Joffe and Yardley, 2004). It can be very complex or simple, depending on the researcher's aims. The researcher can establish relationships between concepts and compare and contrast these with the rest of the data (Joffe and Yardley, 2004). The main advantage of thematic analysis is that it can be flexible, however the analysis can either be very robust or lack depth or in between (Green and Thorogood, 2004).

Thematic network analysis is a tool used to organise data and themes arising from thematic analysis (Attride-Stirling, 2001). This organising technique is practical, systematic, rigorous and sensitive (Attride-Stirling, 2001). As discussed earlier, thematic analysis aims to explore and gain insight into a phenomenon or idea from the text. A conceptual diagram can then be produced and this allows the researcher to conceptualise the themes (Figure 3:6) (Attride-Stirling, 2001). I reasoned that this step-by-step methodical approach would be the most appropriate technique for organising my themes. I will discuss in more detail how I thematically analysed my interviews in *section 7.5.7.*

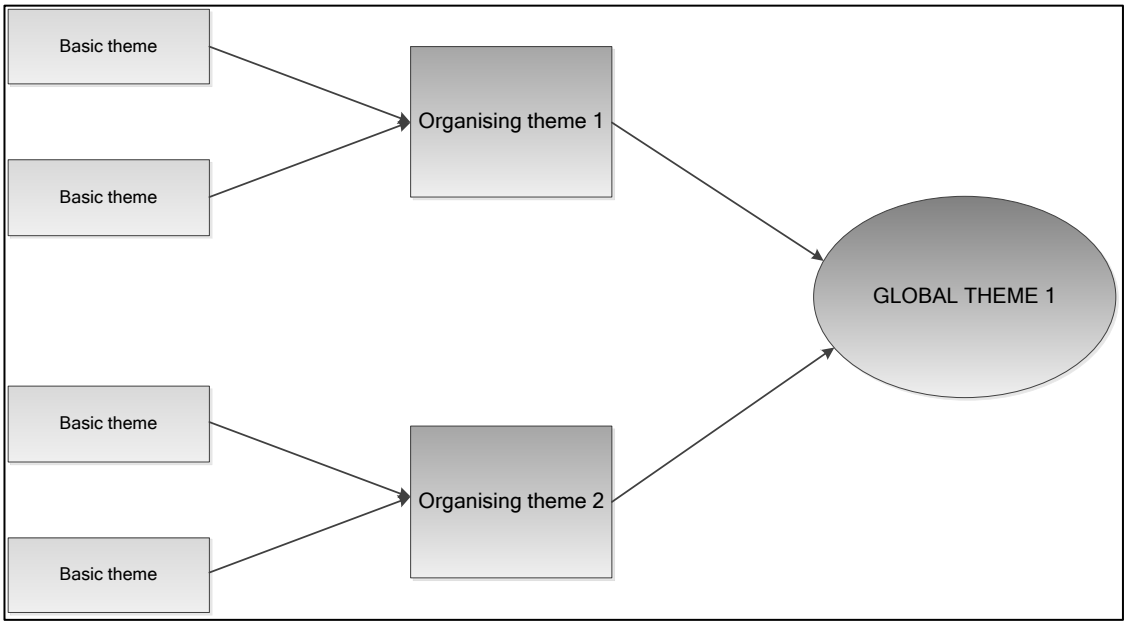


Figure 3:6: Thematic network analysis for organising themes arising from thematic analysis (Figure adapted from Attride-Stirling, 2001)

3.6.4 Improving rigour of qualitative analysis

3.6.4.1 Transparency of analysis

In order for the collection and analysis of interviews to be transparent, a clear record needs to be kept and reported (Green and Thorogood, 2004). It should also be reported in a way that non-qualitative researchers can understand (Clough and Nutbrown, 2002). I will endeavour to show transparency of how I analysed my data in chapter 7 (*see section 7.5.7*).

3.6.4.2 Improving validity

In order to improve validity, the researcher needs to provide enough evidence and context from the data in order for the reader to judge the interpretation of the text (Clough and Nutbrown, 2002). The researcher also needs to analyse any deviant cases that may occur (Green and Thorogood, 2004). I will provide appropriate evidence in order for the reader to interpret the findings in (*see section 7.5.7*).

3.6.4.3 Improving reliability

In order to improve reliability of my analysis, qualitative researchers can set up a data clinic. This clinic consists of other researchers analysing a sample of transcripts and then meeting to discuss similarity and differences in interpretation. A data clinic is a good method to improve the rigour of qualitative analysis (Bergman and Coxon, 2005). I will describe the data clinic that I conducted for study 4 later (Chapter 7 in *section 7.5.5).*

3.6.4.4 Comparative

The researcher needs to compare different interviews within the study (Green and Thorogood, 2004). They also need to compare these results with previous

studies (Green and Thorogood, 2004). I will compare my data within and with other studies in (*see section 7.5.7*).

3.6.4.5 Reflexivity

The researcher acts as the research instrument in qualitative research and therefore needs to monitor and critique their opinions, attitudes and interview techniques (Green and Thorogood, 2004). The researcher should be aware that they are integral to developing and shaping the data (Pope and Mays, 2000). It is therefore good reflexive practice to be aware of their own opinions, attitudes and social context, keep detailed field notes, listen to the interview shortly after it has taken place and reflect on good and poor aspects of their interviewing technique (Green and Thorogood, 2004; Pope and Mays, 2000). I will discuss how I addressed reflexivity throughout my qualitative study in *section 7.5.6*.

3.6.5 Ethical considerations for qualitative research

Most qualitative research does not involve direct impact/intervention, however there can be an emotional consequence when a participant is telling their story, such as having to live with ill health, reliving a traumatic event or discussing private and sensitive issues. The researcher needs to respect the participant's time and conversation and not focus soley on their research agenda. The researcher also needs to gain a sense of rapport before asking potentially sensitive questions and be empathetic and actively listen to the participant. Green described how she felt misunderstood and rushed when she was a participant during an interview and found that there was little opportunity for her to ask questions (Green and Thorogood, 2004). The participant needs to give informed consent before the interview process, and they should also be given the opportunity to refuse to give information or to withdraw from the study at any point. If a one-to-one interview may be too intimidating, a focus group may be a more appropriate method to use. I will discuss how I addressed ethical issues in my qualitative study in *sections 7.5.1 and 7.5.3*.

I have now described and justified the methods that I will be using for studies 1-4. I will now discuss how this chapter supports the thesis.

3.7 How Does This Chapter Support My Thesis?

I have described and discussed THIN database, which I will be using for all three epidemiological studies (Chapters 4-6). I have also described and discussed HES, which I will be using in Chapter 6. Finally, I have described and discussed qualitative methods that I will be using for the qualitative study (chapter 7). I will now introduce the first study: GP recording in the general population.

CHAPTER 4 STUDY 1: GP RECORDING IN THE GENERAL POPULATION

4.1 Content and Structure of Chapter 4

The main aim of the thesis was to understand drug use and opioid substitution treatment in and around pregnancy. However, in order to do this, I first had to ascertain if The Health Improvement Network (THIN) was a suitable surveillance tool for the general population. This chapter therefore covers a description and discussion of my first study which examines GP recording of drug use and opioid substitution treatment of both males and females in THIN. I also explored different codes available for GPs to use to record drug use and explain how annual recording rates (between 1994 and 2012), prevalence rates (between 2009 and 2012) and rate ratios were calculated. As previously mentioned in *section 1.3.7*, there are different crime surveys and treatment monitoring databases for England and Wales, Scotland and Northern Ireland. It is difficult to directly compare the three surveys as the scope and timing is not consistent. For this reason, I will be focusing on drug use and treatment in England and Wales rather than for the whole of the UK. This chapter contains the introduction, aim, specific objectives, methods, results and discussion for the first study.

This study addresses the first objective of my PhD (*see section 2.4 for details*) and will also contribute to answering part of my main research questions (*section 2.3*):

1. *Can a large primary care database (The Health Improvement Network (THIN)) be used as a surveillance tool for understanding drug use and opioid substitution treatment in the general population and specifically during pregnancy (in England and Wales)?*
2. *Can a large primary care database (THIN) be used as a tool to research drug use and opioid substitution treatment in general practice in the general population and specifically during pregnancy (in England and Wales)?*

Part of this chapter has been published in the Plos One Journal, 2015 (*Journal article is included in Appendix 11*)

4.2 Introduction

As mentioned previously in the Chapter 1, illicit drug use and misuse of controlled drugs is a public health problem with serious impacts on both mental and physical health (Madgula et al., 2011a). In 2012, between 162 and 324 million people had used an illegal drug globally (United Nations Office on Drugs and Crime, 2014). The prevalence of drug use in the United Kingdom (UK) is one of the highest in Europe, furthermore, the UK had the second highest number of illegal drug seizures in Europe in 2012 (European Monitoring Centre for Drugs and Drug Addiction, 2014a). According to the Crime survey for England and Wales, there has been a reduction in reported drug use from 11% in 2001/02 to 8.2% in 2012/13 (Office for National Statistics, 2013a). Approximately one-third (35.9%) of individuals aged between 16-59 years have taken an illicit drug and/or 15% have used a class A drug at least once in their life (Office for National Statistics, 2013a). The proportion of individuals who were classified as frequent drug users has decreased from 3.3% in 2011/12 to 2.8% in 2012/13 (Office for National Statistics, 2013a). These values may be underestimates as they are based on self-reports and hence may be subject to response bias (Office for National Statistics, 2013a, Frischer *et al.,* 2001). Moreover, the surveys exclude groups of individuals who may be more likely to use drugs; prisoners, homeless people and students living in halls of residence (Degenhardt *et al*., 2013; Health Protection Agency, 2012; Office for National Statistics, 2013a).

The majority of people who use drugs do so for recreational use and a small proportion become problem drug users and require treatment (see *section 1.3.2*) (Public Health England, 2015). As with recreational drug use, there has also been a reduction in problem drug users in treatment and the use of heroin and crack cocaine between 2005 and 2011 (Public Health England, 2015). In England and Wales, opioid substitution prescribing is controlled and therefore

more effectively monitored than drug use (Public Health England, 2015). Consequently, the National Treatment Agency monitors problem drug use in England, whilst the Welsh drug misuse database monitors in Wales (Public Health England, 2015, Welsh Government, 2015). The National Treatment Agency was established as a special health authority in 2001 and became part of Public Health England (PHE) in April 2013, which has incorporated prevention and recovery of drug dependency as one of the top five health priorities for 2013/2014 (Public Health England, 2015). The National Drug Treatment Monitoring System monitors over 1,500 community treatment centres which includes inpatient, outpatient and GP practices in England (Public Health England, 2015). Most of the National Treatment Agency services are accessed via self-referral and other referral sources including the NHS, the criminal justice system and GPs (Public Health England, 2015). As with recreational drug use, more males from deprived areas are in treatment for problematic drug use (Public Health England, 2015).

As previously mentioned in *section 1.3.11*, up to April, 2013 there were five studies that had used a primary care database to identify individuals with a recording of drug misuse and one study identifying individuals with prescriptions for opioid substitution treatment. All five of the cohort studies by Frischer *et al.,* used the General Practice Research Database (GPRD) to identify individuals recorded with drug misuse (Frischer et al., 2000; 2001, 2004, 2005, 2009). The first study's aim was to ascertain if the GPRD could be used as a surveillance tool for monitoring problematic drug use, whilst the second (pilot), third and fourth studies examined the prevalence of comorbid psychiatric illness and substance misuse and the fourth focused on the time-trends of recorded drug misuse

The first study, published in 2000, aimed to see if the GPRD (in West Midlands, between January 1993 until December 1997) could be used as a surveillance tool and supplement an existing reporting system for problematic drug use, the Regional Drug Misuse Database (RDMD) *(see section 1.3.8 for details)*

(Frischer *et al*., 2000). As there were no specific OXMIS codes *(see section 1.3.5 for details)* for problematic drug use or validation studies at this time, the authors identified and included all possible codes for drug misuse or dependence and drug overdose. In total, forty OXMIS codes were identified as codes that GPs could use to record problematic drug use, however codes for referral to drug treatment were not included and the authors did not acknowledge that GPs may not record the drug use using OXMIS codes and may either record it in the free-text or not record it at all (Frischer *et al*., 2000). Individuals who had one of these codes in their electronic health records were identified and examined to see if they also had a diagnosis for a psychiatric morbidity and/or a hospital referral (Frischer *et al*., 2000). The main findings were that recording trends were higher in the GPRD (n=6,574) compared with the RDMD (n=3,643). The authors suggested that the discrepancy in number could be attributed to the decrease in mandatory reported cases to the RDMD and more individuals receiving treatment for problem drug use in primary care (Frischer *et al*., 2000). Additionally, over half of the recorded cases in GPRD had a psychiatric co-morbidity and ten percent had a hospital referral. The authors concluded that although GPs did not record the specific drug used, the GPRD may be a good contributor to overall drug misuse trends (Frischer *et al*., 2000).

Frischer *et al*. published preliminary findings from a pilot study examining the prevalence of comorbid mental illness and drug use recorded in GPRD (Frischer and Akram, 2001). A patient was defined as having a comorbidity if they had both a mental illness and drug use diagnosis in their medical records (between January 1993 until December 1997) in the West Midlands. The authors identified 40 and 369 OXMIS codes that GPs could use to record drug use and mental illness respectively. They divided the drug use codes into three categories (based on ICD-9 codes), “non-dependent abuse of illicit drugs”, “dependence on/or addiction to illicit drugs” and “abuse of prescribed drugs”. The main findings showed that 0.25% of the cohort had a recorded for drug use, 11.26% a recording for mental illness and 0.12% had a recording for both. The authors concluded that the GPRD may be suitable for identifying and analysing

individuals with a comorbidity of mental illness and drug misuse (Frischer and Akram, 2001).

The same authors published another study in 2004 to examine the prevalence of comorbid psychiatric illness and substance misuse between January 1993 until December 1998 in England and Wales (Frischer *et al*., 2004). They initially conducted a small validation study with a random sample (they did not present the actual number) and found that 92% of patients being treated for substance misuse in secondary care also had a diagnosis of substance misuse in their electronic health record. They identified 258 possible Read and OXMIS codes for substance misuse disorder, however, they recognised that the codes were broad and most were not specific for the drug used. Similarly to the study they conducted in 2000, they also did not include referral for drug treatment (Frischer *et al*., 2000). They used results from their pilot study published in 2001, and substance misuse recordings into three groups; “drug misuse”, “drug dependence” and “licit drug dependence” (Frischer and Akram, 2001). Additionally, they included previously validated codes for psychiatric illness (divided into 6 groups). Annual prevalence, incidence rates, continued prevalent and chronic cases for individuals with a comorbidity aged between 16-84 years were calculated. The annual prevalence increased in all age-groups except for individuals aged between 65-74 years; the ratio of males to females increased from 1.1:1 to 1.37:1. The proportion of individuals from two of the substance misuse categories; (“drug misuse” and “drug dependence”) increased, whilst those in the category, “licit drug dependence” decreased. Additionally, the mean age in all three substance misuse categories differed (“drug misuse”; 30.2 years, “drug dependence”; 33.4 years and “licit drug dependence”; 45.3 years). The authors emphasized that GPs are seeing more comorbid patients in primary care and that GPs are often the first point of contact for drug misusers (Frischer *et al*., 2004).

A study published in 2005 by the same authors, aimed to examine the relationship between substance misuse and psychiatric illness in England and

Wales (Frischer *et al*., 2005). They used the same OXMIS and Read codes (n=258) for substance misuse as the study published in 2004. Between 1993 and 1998, 15.1% (936,128) of individuals had a code for psychiatric illness, 0.37% (22,904) had a code for substance misuse and 3969 individuals had codes for both. They estimated that individuals who were coded with substance misuse first were 1.54 times more likely to develop a psychiatric illness, whilst those with a psychiatric illness were 2.09 times more likely to have a code for substance misuse. The authors concluded that the study did not support the hypothesis that an increase in comorbidity was mostly due to an increase in substance misuse (Frischer *et al*., 2005).

A later study by Frischer *et al.* (2009) examined recorded prevalence and new cases of drug misuse in primary care in individuals aged 16-59 years, between January 1998 and December 2005 in the UK (Frischer *et al*., 2009). In contrast to their previous studies, the authors defined drug misuse differently, they still included codes for misuse and dependence and further added codes for referral and/or prescriptions for treatment, but did not include codes for licit drug dependence (Frischer *et al*., 2000, 2001, 2004, 2005, 2009). They identified 241 possible diagnostic codes and 12 prescription codes and suggested that individuals who had a diagnostic and/or prescription code had a serious enough problem to warrant a recording. Both the prevalence and incidence rates decreased for the 16-24 age-group, whilst in the older age-groups, both prevalence and incidence increased or remained relatively stable. The authors suggested a decline in recording which could be due to a decrease in overall drug use especially in the 16-24 year age-group as a result of the 1998 drug policy *(see section 1.3.8 for details)* (Frischer *et al*., 2009).

The authors acknowledged that there were several advantages to using GPRD. Firstly, the database contained recorded information on drug misusers (regardless of the drug that was being used), time trends of drug misuse, associated co-morbidities and prescribing patterns (Frischer *et al*., 2000, 2001, 2004, 2005, 2009). Secondly, from 1997, GPs no longer had to legally notify

problem drug users to the home office addicts' index and Regional Drug Misuse Database unless they were receiving opioid substitution treatment *(see section 1.3.8 for details).* Therefore the GPRD was more likely to capture drug users than the RDMD (Frischer *et al*., 2000). However, they also acknowledged that it was difficult to identify the specific drug used (Frischer *et al.,* 2005). Furthermore the authors argued that the information from primary care is not as prone to bias as population surveys as surveys require self-reporting and do not include certain groups (e.g. homeless individuals) (Frischer *et al*., 2004). The GPRD population had a similarly age and gender distribution to the UK and patient level socio-economic status has become available since studies conducted in 2001 and the percentage of the population that GPRD represents has also increased over time (Frischer *et al*., 2000, 2001, 2004, 2009). The authors emphasized that GPs were often the first point of contact for drug misusers (Frischer *et al*., 2004). However, the first three studies (Frischer *et al.* 2000, 2001, 2004) were conducted before the 1998 drug policy was implemented *(see section 1.3.8 for details).* This policy encouraged a transition of problematic drug treatment from primary care into community drug clinics and therefore cohort studies conducted before this may have identified more problem drug users than future studies.

The authors also identified several limitations to using GPRD. Firstly, they acknowledged that the GPRD would only capture individuals who were permanently registered with a general practice, who also accessed primary care and disclosed their drug misuse to the GP. Additionally, GPs needed to record the drug misuse in the electronic health records using either OXMIS or Read codes (Frischer *et al*., 2004). The authors however did not acknowledge the fact that GPs may record drug misuse using free-text or not record it at all. Lastly, Frischer *et al.* 2009 did question the appropriate use of primary care data for examining epidemiology trends in drug misuse as the authors recognized that defining a true incident case using primary care databases is challenging as the individual may have been recorded previously when registered with a different general practice. The decline of drug misusers identified in GPRD in the last study (Frischer *et al.*, 2009) may have been due to

more individuals receiving drug misuse treatment from community drug clinics rather than general practice and some general practices opted out of treating individuals with problematic drug use (Frischer *et al.*, 2009)

Cornish *et al.* utilised the GPRD to examine individuals who had been diagnosed with substance misuse and prescribed opiate substitution treatment between 1990 and 2005 in the UK (Cornish *et al*., 2010). The main outcome of the study was mortality rates related to the timing of prescriptions. Individuals were included if they had at least one prescription of methadone or buprenorphine plus a diagnosis for substance misuse (Cornish *et al*., 2010). They were also included if they were prescribed dihydrocodeine together with either methadone or buprenorphine, but excluded if they were prescribed injectable methadone or buprenorphine (Cornish *et al*., 2010). However, the authors did not specify which Read or OXMIS codes were used to confirm the diagnosis of substance misuse. After exclusion, 5577 patients were identified and the study highlighted that the risk of mortality was increased at the start of opioid substitution treatment (14-28 days) and the month after treatment has discontinued (Cornish *et al*., 2010).

The authors acknowledged that the main strengths of using GPRD was that it represented approximately 5% of the UK population and provided a representative sample of individuals who were prescribed opioid substitution treatment in general practice (Cornish *et al*., 2010). They also argued that mortality rates could be detected more effectively in large observational studies using GPRD, compared with examining one general practice, drug clinic or a randomised controlled trial.

Cornish *et al*. also identified several limitations to using GPRD; information regarding prescription doses, duration and quantity was sometimes missing for some patients, individuals who changed general practice during the study were lost to follow-up, covariates were limited due to the nature of recording in

electronic health records and the outcome measured was all-cause mortality as the records did not always specify the cause of death (Cornish *et al*., 2010). Finally, individuals who were prescribed only dihydrocodeine or other opioid substitution treatments were not included in the study.

Based on the studies described above, my first study sought to assess more recent changes that may have occurred in GP recording of drug use, include individuals recorded with both problematic and recreational drug use and include all individuals who were prescribed an opioid substitution treatment. I will then externally compare the results from THIN to annual reports produced by The Crime Survey for England and Wales, The National Treatment Drug Monitoring System and The Welsh National Database for Substance Misuse.to ascertain if electronic primary health records are a suitable tool for surveillance of drug use and opioid substitution treatment for the general population.

4.3 Aim of Study 1

To describe and examine GP recording of drug use and opioid substitution treatment in the general population using electronic health records

4.4 Specific Objectives of Study 1

Using data from England and Wales and the period between 1994 and 2012, I sought to:

1. Explore the level of entry of different codes available for GPs to record drug use and opioid substitution treatment
2. Identify new records (first recording) of drug use and opioid substitution treatment in primary care
3. Examine recording rate ratios for new records of drug use and opioid substitution treatment
4. Estimate the period prevalence (2010/11 to 2012/13) of recorded drug use and opioid substitution treatment

5. Compare GP recording of drug use and opioid substitution treatment with national surveys

4.5 Hypotheses for Study 1

Hypothesis 1: Recording Read codes for drug use occurs more in:

a) males than females,
b) youngest age-groups (16-24 years) compared to the oldest age-groups (45-59 years)
c) those living in the most deprived areas (fifth quintile of Townsend scores) compared to those from the least deprived areas (first quintile of Townsend scores).

Hypothesis 2: Prescriptions for opioid substitution treatment were more likely to be given to:

a) males, than females
b) youngest age-groups (16-24 years) compared to the oldest age-groups (45-59 years)
c) those living in the most deprived areas (fifth quintile of Townsend scores) compared to those from the least deprived areas (first quintile of Townsend scores).

Hypothesis 3: Recording of Read codes for opioid substitution treatment occurred more in:

a) males, than females
b) youngest age-groups (16-24 years) compared to the oldest age-groups (45-59 years)
d) those living in the most deprived areas (fifth quintile of Townsend scores) compared to those from the least deprived areas (first quintile of Townsend scores).

4.6 Ethics

The National Health Service South-East Multicentre Research Ethics Committee granted approval for the THIN scheme to obtain and provide anonymous patient data for research in 2003. The Scientific Review Committee (set up in 2009 in the UK) approved this study in 2013 (Approval number: 13–026). Cegedim Strategic Data Medical Research UK administers SRC application process.

4.7 Methods

4.7.1 Read code and prescription lists

For each patient a GP can enter a Read code for a symptom or diagnosis and a code for a prescription in their computer system (*see 1.3.5 and 3.4.2 for details*). I developed a list of Read codes and codes for prescriptions according to the methods described by Davé and Petersen to identify individuals who use drugs or are prescribed opioid substitution treatment (Davé and Petersen, 2009). I used specific illegal and controlled drugs and derivatives of these drugs as search terms for drug use Read codes and specific opioid substitution treatments as search terms for relevant prescriptions (Drugscope, 2015d; Ford, 2013, Frischer *et al*., 2009; Joint Formulary Committee, 2013, NICE, 2010a, NICE, 2007a, Office for National Statistics, 2013a; United Nations Office on Drugs and Crime, 2014) (Table 4.1). Many drug users receive opioid substitution treatment in the community rather than from their GP (Public Health England, 2015). However, the GP may be aware that they receive treatment and thus use these latter Read codes on their computer system. I therefore used specific search terms to develop Read code lists for opioid substitution treatment (Table 4.1) (National Treatment Agency for Substance Misuse, 2012a; Royal College of General Practitioners, 2011a).

Table 4.1: Search terms for developing Read and prescription code lists for drug use and opioid substitution treatment (OST)

Read codes for drug use	Prescriptions for OST	Read codes for OST
Amphetamine	Methadone	Methadone
Benzodiazepines	Buprenorphine	Buprenorphine
Cannabis	Naltrexone	Opioid substitution treatment
Cocaine	Lofexidine	Opioid replacement therapy
Crack Cocaine	Dihydrocodeine	Drug addiction therapy
Crystal Meth	Diamorphine	Drug addiction treatment
Dependence		Drug dependence therapy
Heroin		Drug misuse treatment
Inhalant		
Ketamine		
Khat		
Lysergic acid diethylamide (LSD)		
Magic Mushrooms		
Mandrax		
Mephedrone		
Methadrone		
Methamphetamine		
Methylone		
Naphyrone		
Nitrites		
Phencyclidine		
Polydrug		
Sedative		
Solvent		

Once I had developed the code lists, a GP, (Professor Irwin Nazareth) and I manually examined the lists and took out any duplicates or any codes that had an ambiguous meaning (e.g. “drug tolerance”). I categorised codes into generic and specific codes and examined those codes GPs most frequently used. For each prescription, I examined the dose for each drug and included those which

followed the recommended doses by the National Institute for Health and Care Excellence (NICE), Royal College of General Practitioners (RCGP) and British National Formularies (BNF) for detoxification programmes (Ford *et al*., 2013; Joint Formulary Committee, 2013, National Institute for Clinical Excellence, 2010a).

For some individuals, it was not entirely obvious if dihydrocodeine was prescribed for an indication other than to treat substance misuse. In those situations, I examined time between prescriptions and individuals were only considered to receive dihydrocodeine for drug misuse if it were prescribed at intervals less than 14 days and a dose greater than 450mg (Ford, 2013). I initially included diamorphine in my opioid substitution treatment prescription list, as diamorphine is still prescribed for a small number of opioid dependent individuals in the UK, due to 5-10% of these individuals not responding to recommended treatments (Strang *et al*., 2010). GPs require a home office license to prescribe diamorphine (Metrebian *et al*., 2006). However, after explorative investigations of the data, I decided to exclude diamorphine prescriptions as I was uncertain if they were being prescribed for substance misuse treatment or for other purposes.

4.7.2 Study population

I obtained information from all individuals who were aged between 16-59 years and permanently registered with a general practice in England and Wales which provided data to THIN between January 1994 and December 2012. Patients are registered with a general practice for different lengths of time and I therefore used patient years as the denominator. I stratified analysis by age and year and accounted for change over time. An example to illustrate this was if an individual was 18 years in 2000 and contributed 10 years of data, the individual would then contribute to the 16-24 age-band until 2006 and subsequently contribute to the 35-34 year age band.

4.7.2.1 Individuals recorded as either using drugs and/or receiving opioid substitution treatment

I identified a group of people based on the first recording (between 1994 and 2012) of either a:

1) Read code for individuals who use drugs and/or
2) Prescription for opioid substitution treatment and/or
3) Read code for opioid substitution treatment

I selected the first record for all individuals and examined the association between individuals who use drugs and opioid substitution treatment and the following covariates: gender, age, deprivation and time-period.

4.7.3 Statistical analysis

I summarised the socio-demographic profiles of individuals who had a recording of drug use or opioid substitution treatment. I estimated recording rates and 95% confidence intervals of a new recording entry for calendar years between 1994 and 2012, taking into account the length of time that each individual was registered with the general practice.

I conducted Poisson regressions to calculate the unadjusted and adjusted recording rate ratios (RR) with 95% confidence intervals of GP recording of people who use drugs and/or opioid substitution treatment. I decided *a priori* on the basis of the existing literature to include age, gender, deprivation and region in the analysis as they may be potential confounders (European Monitoring Centre for Drugs and Drug Addiction, 2014a; Frischer *et al*., 2009; Office for National Statistics, 2013b). I examined if there was effect modification and stratified the covariate if effect modification existed (Kirkwood and Sterne, 2003). I divided age into four age-bands and calendar years into 1994-2000, 2001-2006 and 2007-2012 time-periods. In order to select the model that best fits the data, I carried out hypothesis testing using likelihood tests (Table 4.2) (Kirkwood and Sterne, 2003).

Table 4.2: Selection of appropriate model

Model	Covariates in model	No of parameters
2	Gender	2
3	Age	4
4	Deprivation	5
5	Time-period	3
6	Region	11
7	Gender & age	6
8	Gender, age & deprivation	11
9	Gender, age, deprivation & time-period	14
10	Gender, age, deprivation, time-period & region	25

The prevalence of recording is sensitive to how long a patient has been registered in a general practice, I therefore only calculated the prevalence between the financial years, 2010/11 to 2012/13. I then aimed to compare the results from THIN with national survey reports, which use financial years for reporting.

4.7.4 External comparison

As previously mentioned in *section 1.3.8*, the Crime Survey for England and Wales is a nationally represented sample of adults between the ages of 16-59 which measures general population prevalence. I compared the findings in THIN with those of the Crime Survey for England and Wales, National Treatment Agency and Welsh substance misuse database, and estimated the proportion captured in THIN.

All data was analysed using STATA (version 13) statistical software (Stata Corp LP, College Station, Texas).

4.7.5 Sensitivity analysis

4.7.5.1 Recording of drug use and/or opioid substitution treatment in relation to registration

Primary care databases are used to determine incidence rates of certain acute and chronic conditions. Only new cases should be included when calculating incidence rates. Prevalent cases can, however be misclassified as incident cases due to the following two reasons:

1) When a new patient registers at a general practice, they may be asked to fill out a health questionnaire. Information from the questionnaire is then entered into their electronic medical records (Lewis *et al*., 2005). Their records from their previous general practice should be transferred to the new practice and important aspects of their patient history should be entered electronically (Lewis *et al*., 2005). The information is usually highlighted by a GP and should be entered as a retrospective diagnosis by the GP or administrative staff. If the information is not entered as a retrospective entry, the information may seem as though it is a new symptom or condition as the date of the diagnosis will be the same as the date of entry (Lewis *et al*., 2005).
2) The patient may have registered with a new general practice as a result of the condition. The condition is therefore not a true new case.

Therefore incidence rates could be overestimated during the first year of patient registration. Lewis *et al* conducted a study using GPRD (*section 1.3.6*) to examine how many months a researcher should exclude after patient registration to obtain accurate incidence rates (Lewis *et al*., 2005). The study also examined if different diseases had a different time lag from patient registration. Lewis *et al*. found that the incidence rates were consistently overestimated for many conditions during the time shortly after patient registration (Lewis *et al*., 2005). The period of overestimation was different for different diseases; overestimation occurred for the first 3, 6 and 12 months for acute diseases, neoplastic disease and chronic or relapsing diseases respectively. They therefore recommended that researchers using GPRD

exclude a specific time period (dependent on the disease) after patient registration, in order to include actual incidence cases.

Lewis *et al.* developed the 'Lewis' plot which is a graph where time since registration (x axis) is plotted against the annual incidence rate per 1000 person years at risk (y axis). A researcher can replicate this plot with the particular disease or condition that they are examining and determine how long after patient registration they should include in order to avoid bias and overestimation of incidence rates (Lewis *et al*., 2005).

For this study I was investigating the recording rate of drug use and opioid substitution treatment rather than the incident cases. The reasons I could not determine the incidence of drug use were the following:

1) The GP may not enter the patient information retrospectively
2) The patient may have been using drugs previously, but only disclosed their drug use for the first time in the first consultation with the new GP or in the health questionnaire
3) The patient may have been using drugs previously, but registered with a general practice due to signs and symptoms resulting from drug use.

I still wanted to investigate when most of the recording of drug use and opioid substitution treatment was occurring in primary care in relation to patient registration. I therefore produced a graph for recording of Read codes for drug use and prescriptions and Read codes for opioid substitution treatment in relation to registration (Lewis *et al*., 2005).

4.7.5.2 Free-text comments

As previously mentioned, a GP can enter information about the consultation as Read codes or free-text. In addition to examining Read codes, I developed a free-text list by using the following search terms in the THIN comments data

file:“addiction”, “amphetamine”, “buprenorphine”, “cannabis”, “cocaine”, “dependence”, “drug”, “heroin”, “inhalant”, “ketamine”, “LSD”, “marijuana”, “methadone”, “mephedrone”, “sedative”, “solvent”, “overdose”, “withdrawal". Of the possible unique and frequently used comments, I excluded duplicates and then went through each of these comments manually to ascertain if they were relevant or not. After excluding duplicates, I merged the remaining comments with the medical records and any additional health data records to see how many of the individuals who had the comments, also had a Read code for drug use and/or a prescription for opioid substitution treatment.

4.8 Results

4.8.1 Analysis of Read and prescription codes identified and used by GPs

Overall, there were 517 different Read codes for drug use, 154 prescription codes for opioid substitution treatment and 54 Read codes for opioid substitution treatment available for GPs to use (Table 4.3) (*See Appendix 5 for comprehensive codes lists*).

Table 4.3: Number of Read codes and prescriptions after exclusion of duplicates, ambiguous or unrelated codes

Possible codes	Possible codes	Number of codes included in analysis
Read codes for drug use	765	517
Prescription codes for opioid substitution treatment	268	154
Read codes for opioid substitution treatment	488	43

There was a wide range of codes that GPs could use to record drug use, however, GPs only used half (51%, 267/517) of the available Read codes for drug use in THIN. The twenty most frequently used codes accounts for only

3.7% of the total available codes and only 2.5% (n=6) of these are specific to a particular drug Table 4.4 and Table 4.5.

Table 4.4: Read codes available for GPs to use for recording drug use

Categories of Read codes used	All drug use Read codes		Specific to drug use (e.g. cannabis use)		Generic drug use (e.g. drug user)	
	N/denom	%	N/denom	%	N/denom	%
Drug use Read codes available	517		246/517	46.4	284/517	53.6
Drug use Read codes used by GPs	267/517	50.3	118/246	47.6	149/284	52.4
20 most frequent drug use Read codes used	20/517	3.7	6/246	2.5	14/284	4.9

denom=denominator

Table 4.5: The ten most frequently used Read codes for drug use in THIN

Description	Specific or generic	Frequency	% (denom=33,508)
Benzodiazepine dependence	Specific	4,408	10.9
Cannabis type drug dependence	Specific	3,169	7.9
Drug addiction	Generic	2,396	5.9
Drug addiction therapy	Generic	2,148	5.4
Drug dependence	Generic	1,760	4.4
Drug user	Generic	1,686	4.2
Drug withdrawal syndrome	Generic	1,597	3.9
H/O cannabis misuse	Specific	1,557	3.9
H/O: drug abuse	Generic	1,190	2.9
H/O: drug dependency	Generic	1,189	2.9

denom=denominator

GPs prescribed only 18% (n=27) of the available prescriptions for opioid substitution treatment in primary care, furthermore, the twenty most frequently prescribed drugs account for only 12.9% of the total available prescription codes (Table 4.6 and Table 4.7). Buprenorphine HCL, sublingual tablets 200µg and methadone oral solution (1mg/ml) were the most frequently prescribed

drugs for opioid substitution treatment (*See Appendix 6 for comprehensive codes lists*).

Table 4.6: Prescription codes available for GPs to record opioid substitution treatment

	N/denom	% (denom=154)
Total prescription codes available	154	
Prescription codes used by GPs	27/154	17.5
20 most frequent prescription codes used	20/154	12.9

denom=denominator

Table 4.7: The ten most common prescriptions for opioid substitution treatment in THIN

Drug prescribed	Frequency	% (denom= 10,869)
Buprenorphine HCL sublingual tab 200µg	4,270	39.3
Methadone oral soln 1mg/ml	2,731	25.1
Methadone sf oral soln 1mg/ml	948	8.7
Buprenorphine HCL sublingual tab 2mg	682	6.3
Buprenorphine HCL sublingual tab 400 µg	608	5.6
Buprenorphine HCL sublingual tab 8mg	429	3.9
Naltrexone HCL tabs 50mg	398	3.7
Lofexidine tabs 0.2mg	277	2.6
Methadone linc 2mg/5ml	165	1.5
Methadone tabs 5mg	155	1.4

denom=denominator

A larger percentage (72%, n=31/43) of possible Read codes for opioid substitution treatment were used by GPs in contrast to Read codes for drug use and prescription codes, almost half (46.5%) of these Read codes were included in the ten most frequently used (Table 4.8 and Table 4.9) (*See Appendix 7 for comprehensive codes lists*).

Table 4.8: Read codes available for GPs to record opioid substitution treatment (OST)

	All OST Read codes		Specific (e.g. methadone therapy)		Generic (e.g. drug addiction therapy)	
	N/denom	%	N/denom	%	N/denom	%
Total OST Read codes available	43		27/43	62.7	16/43	37.3
OST Read codes used in THIN	31/43	72	16/27	59.2	15/16	93.8
10 most frequent codes used in THIN	20/43	46.5	9/27	33.3	11/16	68.7

denom=denominator, OST=Opioid Substitution treatment

Table 4.9: The 10 most common Read codes for opioid substitution treatment in THIN

Description	Specific or generic	Frequency	% (denom= 7,655)
Drug addiction therapy	Generic	4,203	54.9
Drug addiction therapy-methadone	Specific	1,993	26.0
Methadone dependence	Specific	432	5.6
Drug addiction maintenance therapy - methadone	Specific	345	4.5
Drug addiction detoxification therapy - methadone	Specific	236	3.1
Drug dependence therapy	Generic	129	1.7
H/O methadone misuse	Specific	47	0.6
Drug addiction maintenance therapy - buprenorphine	Specific	36	0.5
Buprenorphine maintenance therapy	Specific	32	0.4
Methadone maintenance	Specific	30	0.4

denom=denominator

In summary, there are many codes available for GPs to use in contrast to other disease areas, however GPs only use a small percentage of these available codes.

4.8.2 Rates for first recording of Read codes and/or prescriptions

In total, there were 33,508 individuals with a record of drug use, 10,869 individuals with prescriptions for opioid substitution treatment, and 7,655 individuals with Read codes for opioid substitution treatment. Patients had different combinations of Read and prescription codes in their electronic health records (Figure 4:1), but relatively few individuals had entries of all three. Hence, there were 28,179 (63.7%) individuals recorded as using drugs, but not receiving any opioid substitution treatment in primary care.

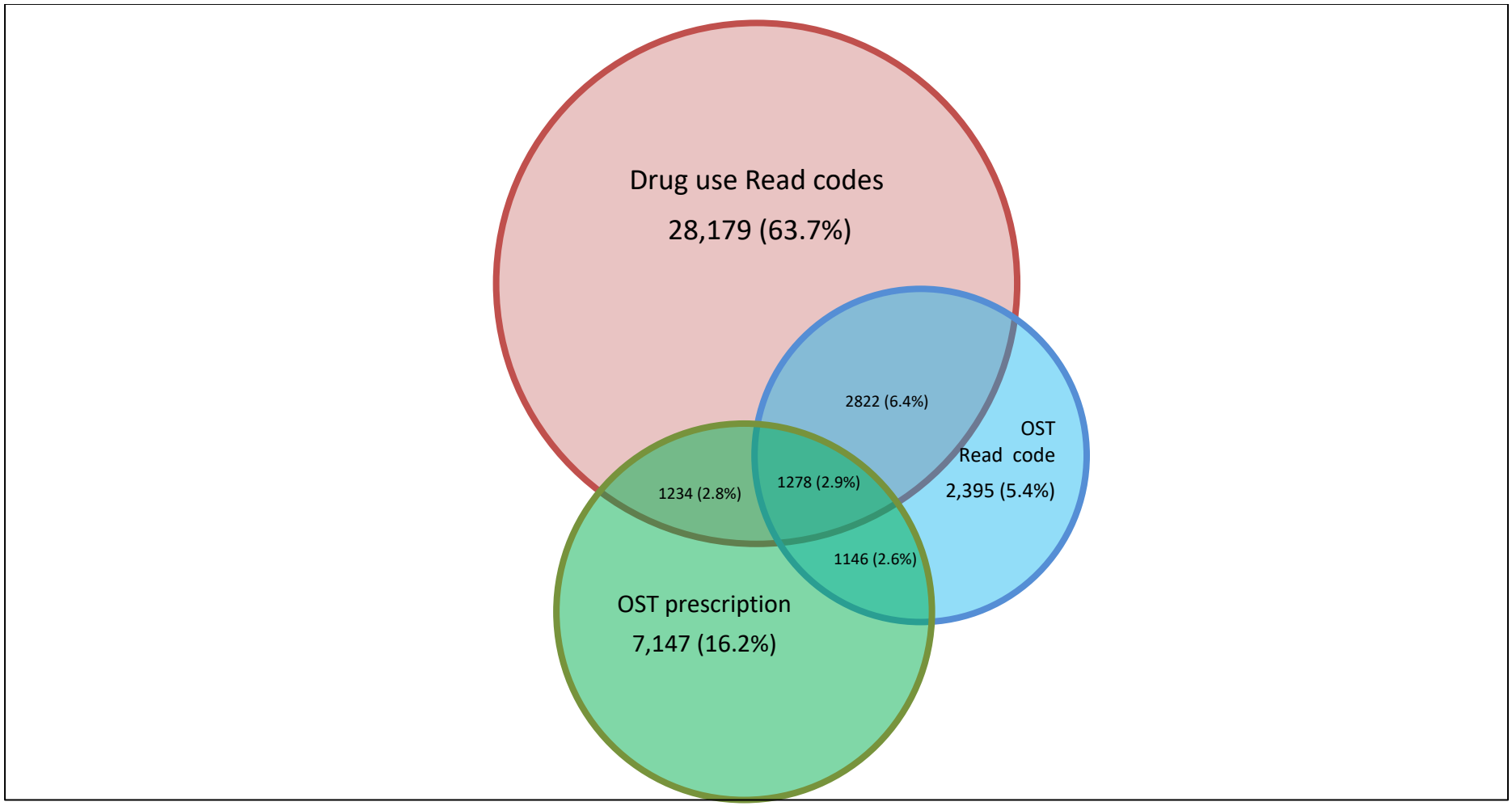


Figure 4:1: Venn diagram illustrating the number of individuals who had a recording for drug use and/or opioid substitution treatment (OST)

(Reproduced with permission of the rights holder, *Plos One*)

Overall there were more males than females with a recording of drug use and/or opioid substitution treatment. Of those with a recording for drug use, most were between the ages of 16-24 years, from the North East of England and the most deprived quintile (

Table 4.10). Fewer individuals had Read or prescription codes for opioid substitution treatment, but the regional and socio-demographic patterns were similar, although they were slightly older and most of the individuals with a Read code for treatment were from the North West of England.

Table 4.10: Demographics, first recording rate (95% CI) for drug use Read codes and opioid substitution treatment (OST) prescription and Read codes by gender, age-band, region and Townsend deprivation score. (Rate=first recording rate/1000 person years at risk)

	Drug use Read codes		OST prescriptions		OST Read codes	
Demographics	**N (%) N=33,508**	**Rate (95% CI) per 1000/PYAR**	**N (%) N=10,869**	**Rate (95% CI) per 1000/PYAR**	**N (%) N=7,655**	**Rate (95% CI) per 1000/PYAR**
Gender						
Males	22,622 (67.5)	1.49 (1.40-1.60)	6721 (61.8)	0.45 (0.39-0.51)	5241 (68.4)	0.33 (0.28-0.370
Females	10,886 (32.5)	0.74 (0.67-0.82)	4748 (38.2)	0.35 (0.29-0.38)	2414 (31.6)	0.50 (0.42-0.56)
Age-band						
16-24	10,650 (31.8)	2.47 (2.23-2.72)	1,542 (14.2)	0.43 (0.33-0.55)	1,482 (19.4)	0.34 (0.27-0.44)
25-34	10,994 (32.8)	1.76 (1.60-1.93)	3,122 (28.7)	0.53 (0.44-0.63)	3,377 (44.1)	0.50 (0.43-0.59)
35-44	6,704 (20.0)	0.88 (0.77-0.99)	2,624 (24.1)	0.37 (0.30-0.46)	1,970 (25.7)	0.24 (0.20-0.30)
45-59	5,160 (15.4)	0.41 (0.33-0.50)	3,581 (32.9)	0.33 (0.27-0.39)	826 (10.8)	0.06 (0.04-0.08)
Region						
London	4,051 (12.1)	0.06 (0.05-0.07)	788 (7.25)	0.24 (0.16-0.34)	606 (7.92)	0.16 (0.11-0.24)
East Midlands	1,514 (4.52)	0.06 (0.04-0.07)	608 (5.59)	0.46 (0.30-0.69)	433 (5.66)	0.27 (0.17-0.43)
East of England	2,768 (8.26)	0.12 (0.11-0.13)	750 (6.90)	0.34 (0.22-0.49)	453 (5.92)	0.16 (0.10-0.26)
West Midlands	3,051 (9.11)	0.06 (0.05-0.06)	1,243 (11.4)	0.37 (0.28-0.50)	851 (11.1)	0.22 (0.16-0.31)
North East	1,258 (3.75)	0.15 (0.09-0.17)	559 (5.14)	0.64 (0.41-0.96)	314 (4.10)	0.29 (0.18-0.48)

	Drug use Read codes		OST prescriptions		OST Read codes	
Demographics	**N (%) N=33,508**	**Rate (95% CI) per 1000/PYAR**	**N (%) N=10,869**	**Rate (95% CI) per 1000/PYAR**	**N (%) N=7,655**	**Rate (95% CI) per 1000/PYAR**
North West	5,513 (16.5)	0.10 (0.09-0.11)	1,721 (15.8)	0.54 (0.42-0.68)	1,669 (21.8)	0.46 (0.37-0.57)
South Central	3,990 (11.9)	0.12 (0.10-0.15)	417 (3.84)	0.33 (0.25-0.44)	240 (3.14)	0.20 (0.15-0.27)
South East Coast	3,865 (11.5)	0.13 (0.12-0.15)	1,459 (13.4)	0.34 (0.24-0.48)	1,063 (13.9)	0.16 (0.11-0.26)
South West	3,112 (9.29)	0.05 (0.05-0.06)	1,127 (10.3)	0.46 (0.34-0.61)	539 (7.04)	0.24 (0.17-0.34)
Yorkshire & Humberside	1,211 (3.61)	0.05 (0.04-0.07)	1,362 (12.5)	0.35 (0.21-0.56)	782 (10.2)	0.18 (0.10-0.32)
Wales	3,175 (9.48)	0.09 (0.08-0.10)	835 (7.68)	0.38 (0.26-0.54)	705 (9.21)	0.27 (0.19-0.40)
Townsend deprivation						
1(least deprived)	3,825 (12.0)	0.45 (0.38-0.53)	1,475 (14.3)	0.19 (0.15-0.25)	526 (7.21)	0.06 (0.04-0.09)
2	4,200 (13.1)	0.65 (0.56-0.76)	1,552 (15.0)	0.26 (0.20-0.34)	696 (9.62)	0.17 (0.11-0.25)
3	6,321 (19.8)	1.06 (0.93-1.20)	2,092 (20.2)	0.37 (0.29-0.47)	1,275 (17.5)	0.38 (0.27-0.52)
4	8,571 (26.8)	1.68 (1.50-1.88)	2,691 (26.0)	0.58 (0.47-0.71)	2,166 (29.8)	0.77 (0.59-1.02)
5(most deprived)	9,076 (28.4)	2.89 (2.59-3.21)	2,526 (24.4)	0.89 (0.72-1.09)	2,604 (35.8)	1.55 (1.24-1.96)
Time-period						
1994-2000	5493 (16.4)	1.18 (1.07-1.25)	2011 (15.5)	0.47 (0.41-0.53)	1066 (13.9)	0.18 (0.15-0.21)
2001-2006	13,307 (39.7)	1.14 (1.11-1.19)	4197 (38.6)	0.36 (0.33-0.39)	3444 (45.0)	0.30 (0.27-0.33)
2007-2012	14,708 (43.9)	1.11 (1.07-1.16)	4661 (42.9)	0.34 (0.32-0.37)	3145 (41.1)	0.24 (0.22-0.26)

4.8.3 Statistical model

I observed an effect modification for gender and therefore stratified the results of age, deprivation and region by gender. Following my hypothesis testing to select the most appropriate model, I included age and deprivation. As there was no evidence that region improved the fit of the model (p=0.08 for males and p=0.07 for females), I excluded this variable from my final model.

4.8.4 Recording rate ratios for drug use Read codes

Men were almost twice as likely to have a Read code in their electronic health records for drug use when compared to women (RR 1.71, 95% CI: 1.68-1.75). For men, compared to the oldest age group, the youngest age group was five and a half times more likely to have a recording for drug use when adjusted for deprivation (RR 5.59, 95% CI:5.37-5.83) (Table 4.11).

Table 4.11: Unadjusted and adjusted Rate Ratios (95% CI) for drug use Read codes by age-band and deprivation (1994-2012)

	Males		Females	
Demographics	**Unadjusted RR (95% CI)**	***Adjusted RR (95% CI)**	**Unadjusted RR (95% CI)**	***Adjusted RR (95% CI)**
Age-group				
16-24	5.89 (5.66-6.14)	5.59 (5.37-5.83)	2.79 (2.66-2.93)	2.54 (2.42-2.68)
25-34	5.73 (5.51-5.96)	5.09 (4.89-5.31)	2.54 (2.42-2.66)	2.15 (2.05-2.26)
35-44	2.86 (2.74-2.99)	2.64 (2.52-2.77)	1.63 (1.55-1.72)	1.49 (1.41-1.57)
45-59	1	1	1	1
Deprivation				
1 (least deprived)	1	1	1	1
2	1.42 (1.35-1.49)	1.41 (1.34-1.49)	1.32 (1.24-1.41)	1.36 (1.27-1.46)

	Males		Females	
Demographics	**Unadjusted RR (95% CI)**	***Adjusted RR (95% CI)**	**Unadjusted RR (95% CI)**	***Adjusted RR (95% CI)**
3	2.18 (2.09-2.29)	2.04 (1.94-2.14)	1.92 (1.81-2.03)	1.89 (1.78-2.02)
4	3.41 (3.27-3.56)	2.97 (2.84-3.11)	2.75 (2.60-2.90)	2.73 (2.57-2.91)
5 (most deprived)	5.64 (5.40-5.89)	4.83 (4.62-5.06)	4.39 (4.16-4.64)	4.28 (4.03-4.56)

*Adjusted for age and deprivation

There were consistently more individuals between the ages 16-24 years who had a Read code for drug use than those in the 25-34 year age-group before 2012. However, the rates of these two age-groups converge in 2012 (Figure 4:2).

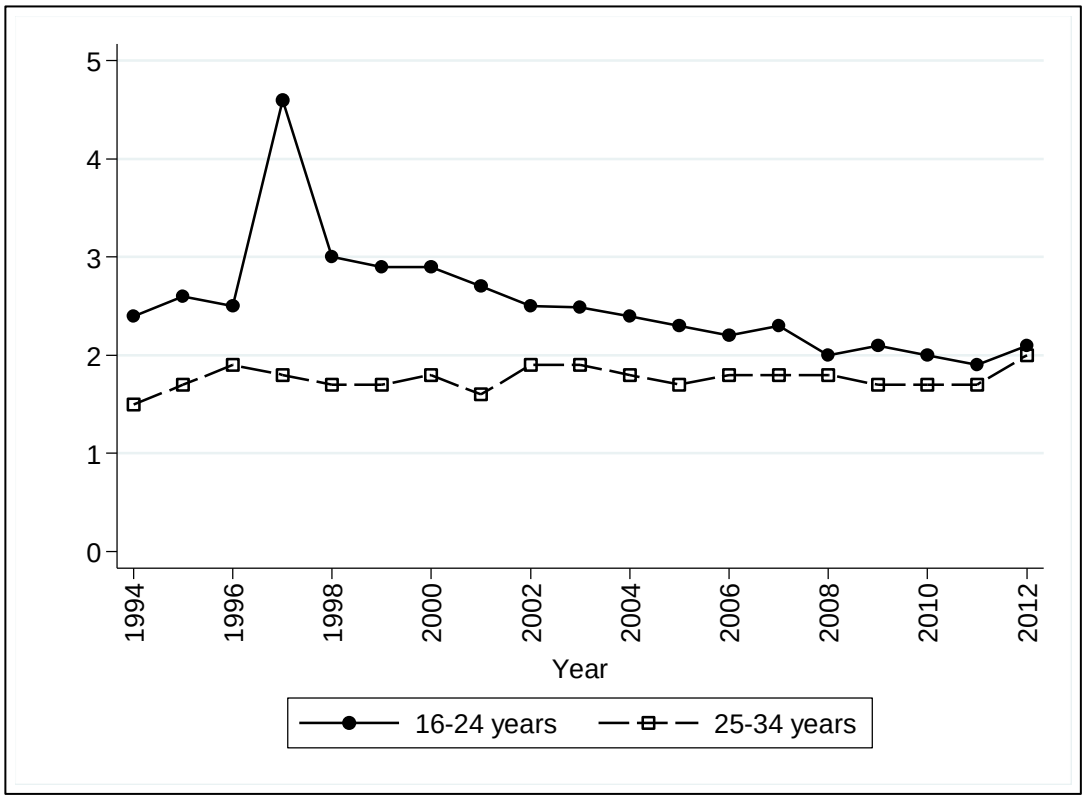


Figure 4:2: First recording rates of Read codes for drug use by age-bands (16-24 and 25-34 years) per 1000 person years at risk (1994-2012)

There was also a trend with regards to social deprivation; men from the highest quintile of deprivation were almost five times more likely to have Read code for drug use compared to those from the lowest quintile of deprivation when adjusted for age (RR 4.83 95% CI: 4.62-5.06) (Figure 4:3 and Table 4.11).

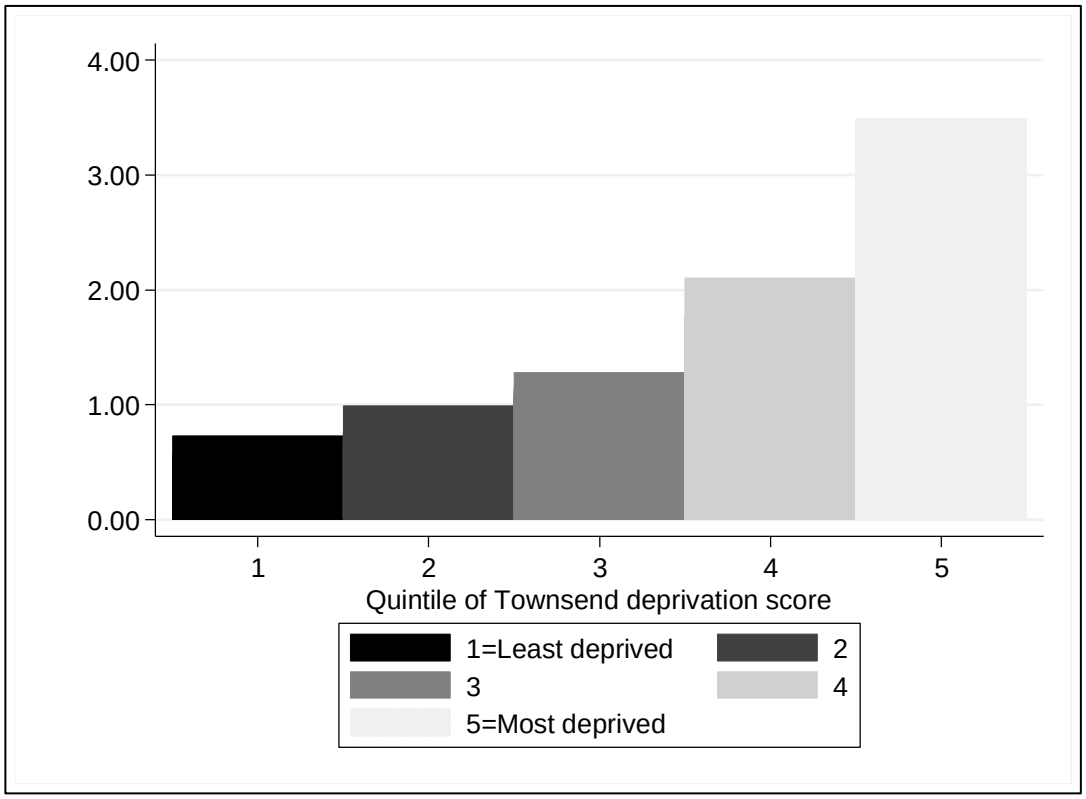


Figure 4:3: First recording rate of drug use (Read code) by deprivation for men

For women, the pattern was similar to men, although the contrasts were less stark (Table 4.11).

4.8.4.1 Accept or reject hypothesis 1:

1) I accepted the first hypothesis, as individuals who had a recording for drug use were more likely to be

a) males than female (Recording Risk Ratio (RRR): 1.71, 95% CI: 1.68-1.75)
b) aged between 16-24 years compared with adults aged 45-59 (RRR: 5.59, 95% CI: 5.37-5.83)
c) from the most deprived areas compared to the least deprived areas (RRR: 4.83, 95% CI: 4.62-5.06)

4.8.5 Recording rate ratios for opioid substitution treatment prescription codes

There were more individuals with a record for drug use than those receiving a prescription for opioid substitution treatment. More men than women received opioid substitution treatment (RR 1.22, 95% CI: 1.18–1.28), and also the most deprived group were more likely to have an opioid substitution treatment entry in their records (Table 4.12)

Table 4.12: Unadjusted and adjusted Rate Ratios (95% CI) for opioid substitution treatment prescriptions by age-band and deprivation (1994-2012)

	Males		Females	
Demographics	**Unadjusted RR (95% CI)**	***Adjusted RR (95% CI)**	**Unadjusted RR (95% CI)**	***Adjusted RR (95% CI)**
Age-groups				
16-24	1.38 (1.27-1.49)	1.25 (1.15-1.36)	0.89 (0.81-0.97)	0.81 (0.74-0.89)
25-34	2.72 (2.55-2.91)	2.33 (2.18-2.50)	1.39 (1.29-1.50)	1.19 (1.12-1.29)
35-44	1.82 (1.70-1.95)	1.64 (1.53-1.76)	1.16 (1.08-1.25)	1.08 (1.00-1.67)
45-59	1	1	1	1
Deprivation				
1 (least deprived)	1	1	1	1
2	1.40 (1.26-1.54)	1.37 (1.23-1.52)	1.34 (1.21-1.48)	1.33 (1.21-1.47)

	Males		Females	
Demographics	**Unadjusted RR (95% CI)**	***Adjusted RR (95% CI)**	**Unadjusted RR (95% CI)**	***Adjusted RR (95% CI)**
3	2.07 (1.89-2.27)	1.98 (1.80-2.17)	1.66 (1.51-1.83)	1.64 (1.49-1.81)
4	3.10 (2.84-3.38)	2.87 (2.62-3.12)	2.29 (2.08-2.51)	2.24 (2.05-2.47)
5(most deprived)	4.86 (4.45-5.30)	4.44 (4.06-4.84)	3.01 (2.74-3.32)	2.95 (2.68-3.25)

*Adjusted for age and deprivation

Men were slightly older (25-34 years) when they had their first entry for opioid substitution treatment compared to when they had their first record for drug use entered in their electronic health records (Table 4.11 and Table 4.12). Younger women compared to the 45-64 year age-band were less likely to have a prescription for opioid substitution treatment (Figure 4:4).

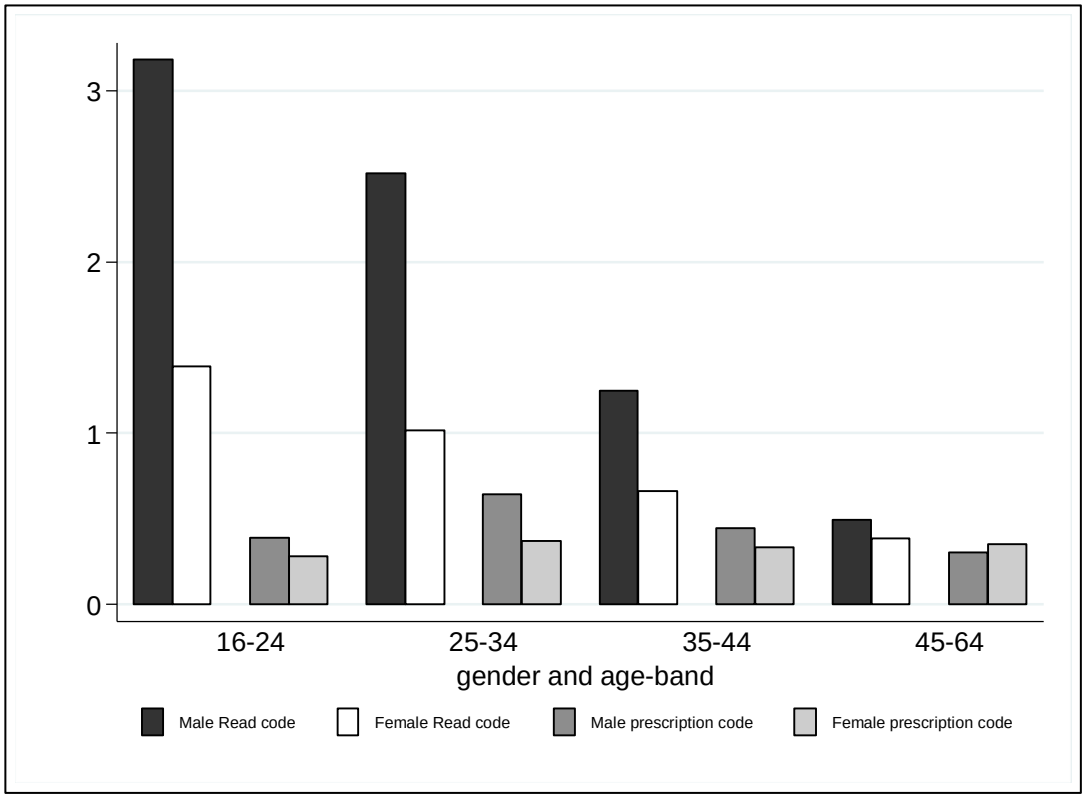


Figure 4:4: Read (drug use) and prescription codes (opioid substitution treatment) by age-band (in years) and gender per 1000 person years at risk (1994-2012)

There were more individuals with prescriptions for opioid substitution treatment between 1997 and 2002, however the age-groups cross each other around 2002, and then more individuals in the 25-34 age-band received treatment compared to the younger age group (Figure 4:5).

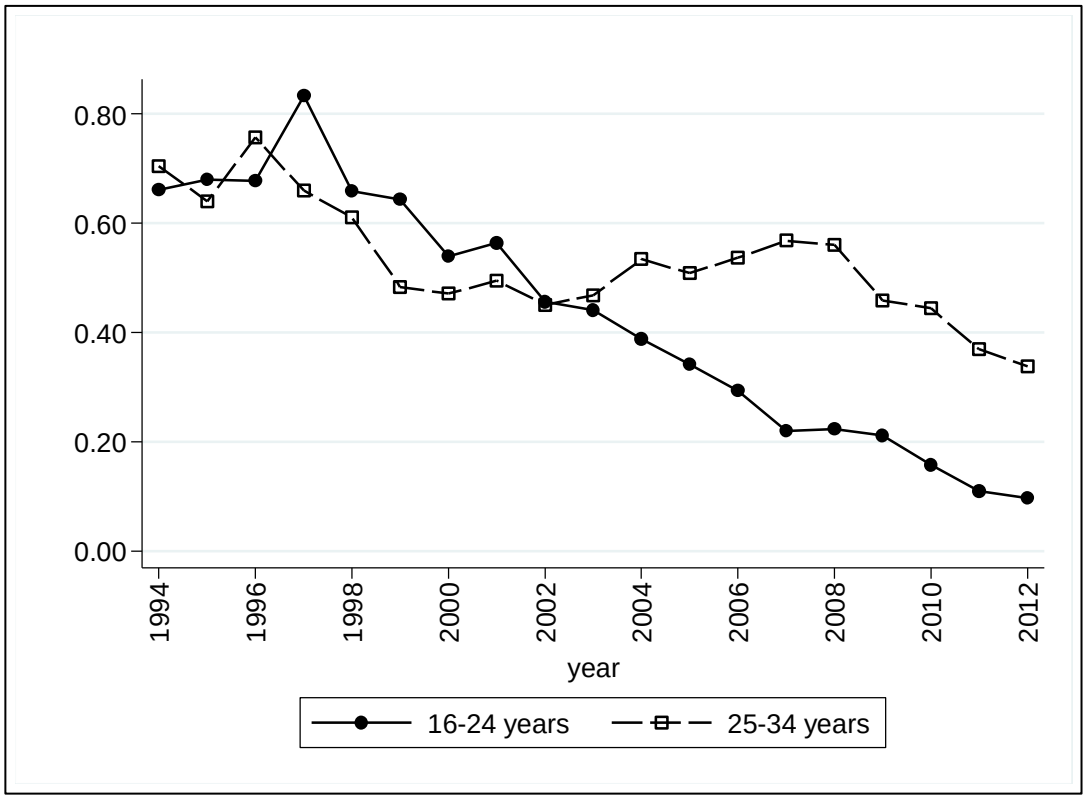


Figure 4:5: First recording rate of opioid substitution treatment by age-bands (16-24 and 25-34 years) per 1000 person years at risk (1994-2012)

Similar to the Read codes for drug use, there was also a trend with regards to social deprivation, men from the highest quintile of deprivation were over four times more likely to have a prescription for opioid substitution treatment compared to those from lowest quintile of deprivation (RR 4.44, 95% CI:4.06-4.84) (Figure 4:6 and Table 4.12).

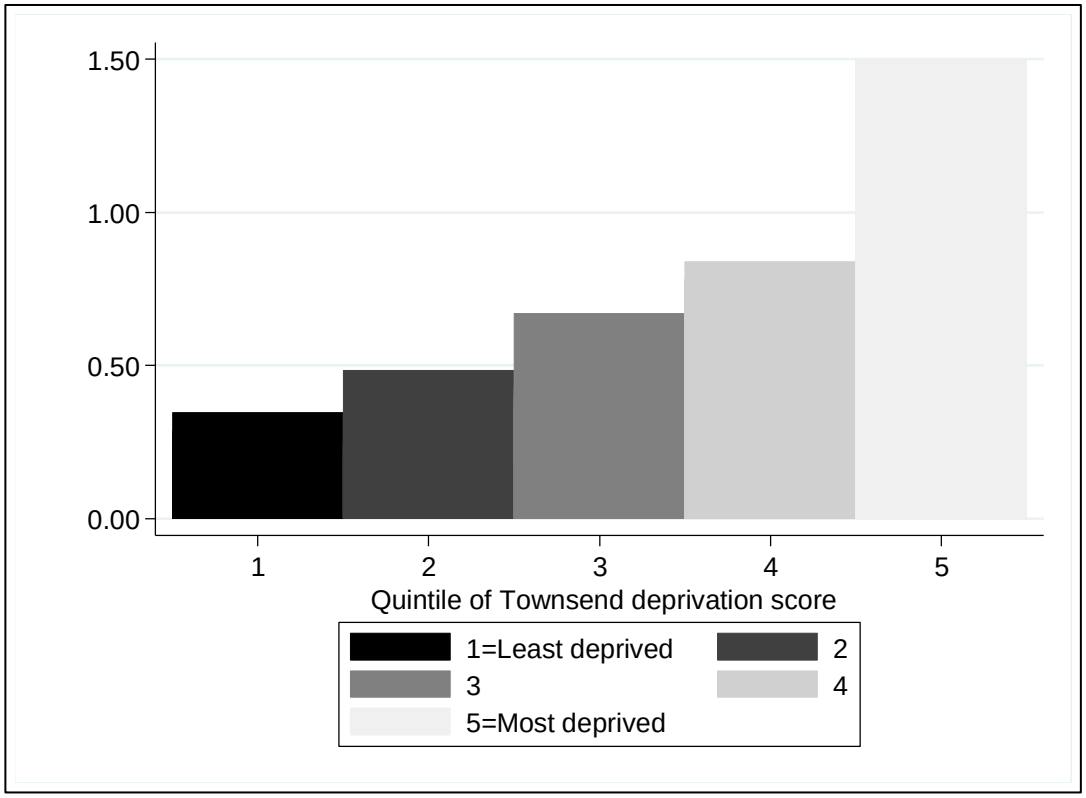


Figure 4:6: First recording rate of opioid substitution treatment prescription by deprivation for men

4.8.5.1 Accept or reject hypothesis 2

I accepted parts a and c of the second hypothesis, as individuals who had a prescription for opioid substitution treatment were more likely to be:

a) male than female (RRR: 1.22, 95% CI: 1.18–1.28)
b) from the most deprived areas compared to the least deprived areas (RRR: 4.86, 95% CI: 4.45-5.30)

I rejected part b of the second hypothesis, as individuals from the older age group (25-34 years) compared with the oldest age-group (45-59 years) were more likely to have a prescription of opioid substitution treatment. (RRR: 2.72, 95% CI: 2.55-2.91)

4.8.6 Rate ratios for Read codes for opioid substitution treatment

Similar patterns were found for Read codes for opioid substitution treatment to those of the prescription codes (higher RR for males, 25-34 age-band and from the most deprived quintile (Table 4.13).

Table 4.13: Unadjusted and adjusted Rate Ratios (95% CI) for opioid substitution treatment Read codes by age-band and deprivation (1994-2012)

	Males		Females	
Demographics	**Unadjusted RR (95% CI)**	**Adjusted RR (95% CI)**	**Unadjusted RR (95% CI)**	**Adjusted RR (95% CI)**
Age-group				
16-24	4.46 (4.01-4.96)	4.27 (3.83-4.76)	5.94 (5.14-6.86)	5.28 (4.55-6.12)
25-34	10.3 (9.40-11.31)	9.00 (8.18-9.19)	9.24(8.09-10.55)	7.37 (6.43-8.45)
35-44	5.39 (4.89-5.95)	4.94 (4.46-5.47)	4.05 (3.50-4.68)	3.56 (3.07-4.13)
45-59	1	1	1	1
Deprivation				
1 (least deprived)	1	1	1	1
2	1.74 (1.52-1.99)	1.69 (1.46-1.92)	1.64 (1.34-2.01)	1.57 (1.28-1.93)
3	3.03 (2.67-3.42)	2.72 (2.40-3.08)	3.42 (2.86-4.08)	3.00 (2.51-3.59)
4	5.89 (5.25-6.61)	4.96 (4.42-5.57)	6.11 (5.16-7.24)	4.98 (4.20-5.89)
5(most deprived)	11.2 (10.0-12.6)	9.21 (8.22-10.31)	10.9(9.19-12.8)	8.38 (7.09-9.91)

*Adjusted for age and deprivation

4.8.6.1 Accept or reject hypothesis 3

I accepted parts a and c of the third hypothesis, as individuals who had a recording for a Read code for opioid substitution treatment were more likely to be:

c) male than female (RRR: 1.62, 95% CI: 1.28–1.78)
d) from the most deprived areas compared to the least deprived areas (RRR: 9.21, 95% CI: 8.22-10.31)

I rejected part b of the second hypothesis, as individuals from the older age group (25-34 years) were more likely to have a prescription of opioid substitution

treatment compared with the oldest age-group (45-59 years). (RRR: 9.00, 95% CI: 8.18-9.19)

4.8.7 Prevalence of Read codes for drug use and prescriptions and Read codes for opioid substitution treatment

Between the financial years of 2010/11 and 2012/13, the prevalence rates remained relatively stable for Read codes for drug use (2.3 per 1000), prescriptions for opioid substitution treatment (0.8 per 1000) and Read codes for opioids substitution treatment (0.3 per 1000).

4.8.8 External comparison of findings with national surveys.

4.8.8.1 The Crime Survey for England and Wales

The prevalence rates from the Crime Survey for England and Wales and THIN are shown in Table 4.14. Assuming that the Crime Survey for England and Wales is representative of the population of England and Wales, 25% (2.2/8.7) of those estimated as using drugs in the population were captured in THIN.

Table 4.14: Comparison of prevalence rates between the Crime Survey for England and Wales and THIN

Year	Estimated number of people using drugs in England and Wales* (million)	Estimated number of people who use drugs in England and Wales (per 1000)	Prevalence of people with a recording of drug use in THIN (per 1000)	% recorded in THIN
2010/11	2.8	8.6	2.2	25
2011/12	2.9	8.8	2.1	23
2012/13	2.9	8.7	2.2	25
Mean	2.9	8.7	2.2	25

*(Office of National Statistics 2010-2013)

4.8.8.2 National Drug Treatment Monitoring System (NDTMS) and the Welsh Substance Misuse Database

Before November 2012, the NDTMS did not categorize where an individual received their treatment (Public Health England, 2013a). I could therefore only compare the estimated number of individuals who would have received treatment from general practice in 2012/13. According to the NDTMS, a fifth (22%) of individuals received a new prescription for treatment of drug use from their GP in 2012/13 (Public Health England, 2013a). About half of the total individuals recorded in the NDTMS are in treatment for opioid use alone and may therefore be treated with opioid substitution treatment (Public Health England, 2013a). From these figures, I estimated that 548 individuals (6% of population) should be receiving their treatment from general practice. The amount of individuals that I identified receiving a new prescription for opioid substitution treatment was very close to the number recorded by NDTMS (98.7% 541/548), (Table 4.15).

Table 4.15: Comparison of individuals recorded in National Drug Treatment Monitoring System and THIN

NTMDS report 2012/13	**England**
Number of people in drug treatment in England during 2012/13	194,110 0.37 per 1000
% receiving first-time psychosocial or pharmaceutical interventions	72.4% (140,629/194,110)
% receiving first-time pharmaceutical interventions	61.4% (86,392/140,629)
% receiving pharmaceutical treatment from general practice	22% (19,014/86,392)
% of opiate users in drug treatment (therefore requiring OST)	48% (93,434/194,110)
Estimated number receiving opioid substitution treatment from general practice	9127 (0.48x19,014)
Estimated number receiving opioid substitution treatment in THIN	547 (0.06 x 9127)
No of individuals with a new recording for opioid substitution treatment capture in THIN	528

(Public Health England, 2013a) OST=Opioid Substitution Treatment

I was unable to estimate the number from the Welsh substance misuse database, as they did not categorise where individuals received their opioid substitution treatment from (Welsh Government, 2013).

4.8.9 Sensitivity analysis

4.8.9.1 Recording of drug use and opioid substitution treatment in relation to registration

Recording for drug use drops steeply after in the first two months after registration (Figure 4:7). The pattern is similar for prescriptions and Read codes for opioid substitution treatment

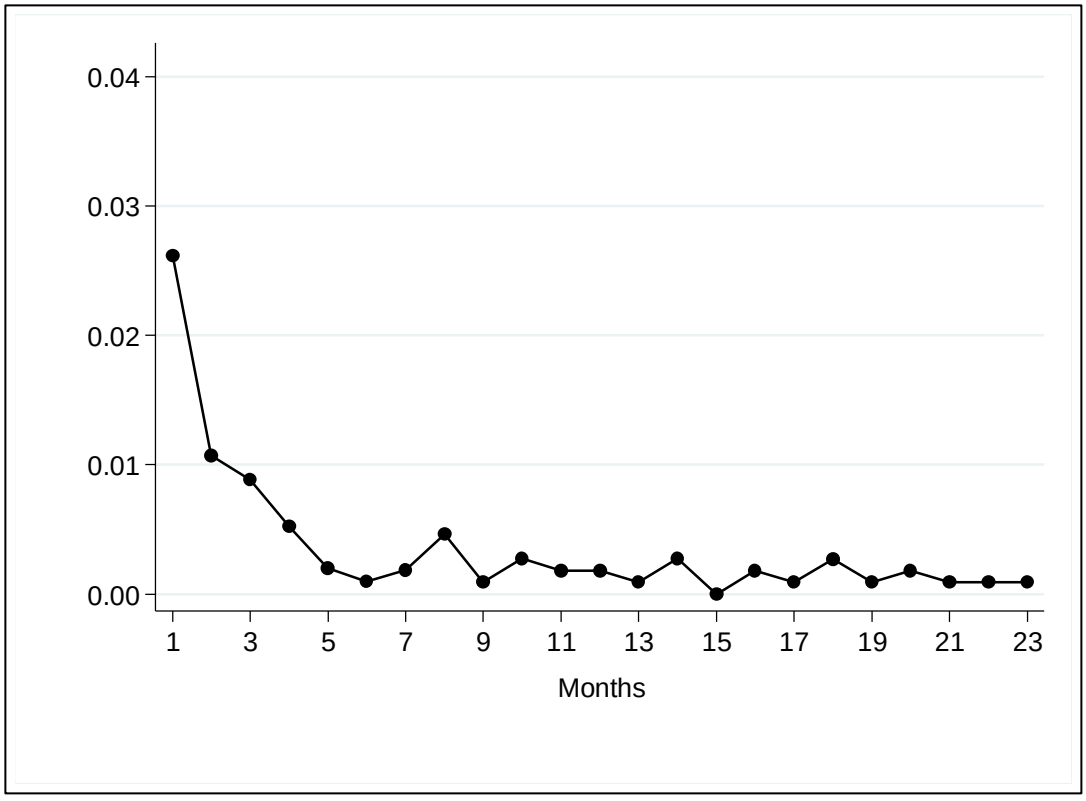


Figure 4:7: Recording rates of drug use Read codes in the first 2-3 months after patient registration

As previously mentioned, I decided not to exclude individuals with their first code recorded shortly after registration as I was not looking for incidence cases and did not want to underestimate the recording.

4.8.9.2 Free-text comments

From the 313,240 anonymised free-text comments, I identified 198 unique free-text comments from the THIN comments data file that related to drug use and opioid substitution treatment (Figure 4:8).

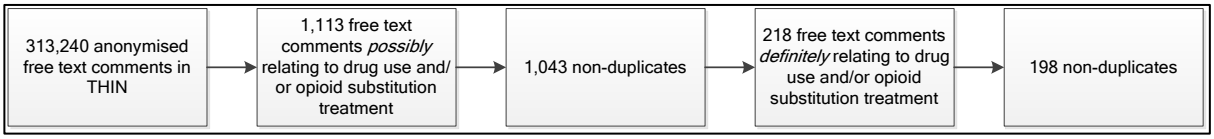


Figure 4:8: Development of relevant free-text comments

Of these, 185 were unique and 13 were used more than once (Table 4.16).

Table 4.16: Frequently used free-text comments relating to drug use and/or opioid substitution treatment

Free-text comment		
Advised to stop	Diazepam and derivatives	Heroin overdose
Amphetamine	Dihydrocodeine	Methadone
Cannabis	Drug induced	Overdose
Codeine and derivatives	Heroin	Valium dependence
Counselled		

There were 520 individuals who had a free-text comment relevant to drug use and/or opioid substitution treatment (Figure 4:9). Therefore, when I examine free-text comments, an extra 520 individuals were identified as using drugs. Almost three quarters (73.5%, n=32,356) of individuals who had a Read and/or drug code

for drug use or opioid substitution treatment also had an anonymised free-text comment. However, only 4.2% (n=1,356) of these free-text comments were relevant to drug use or treatment (Figure 4:9).

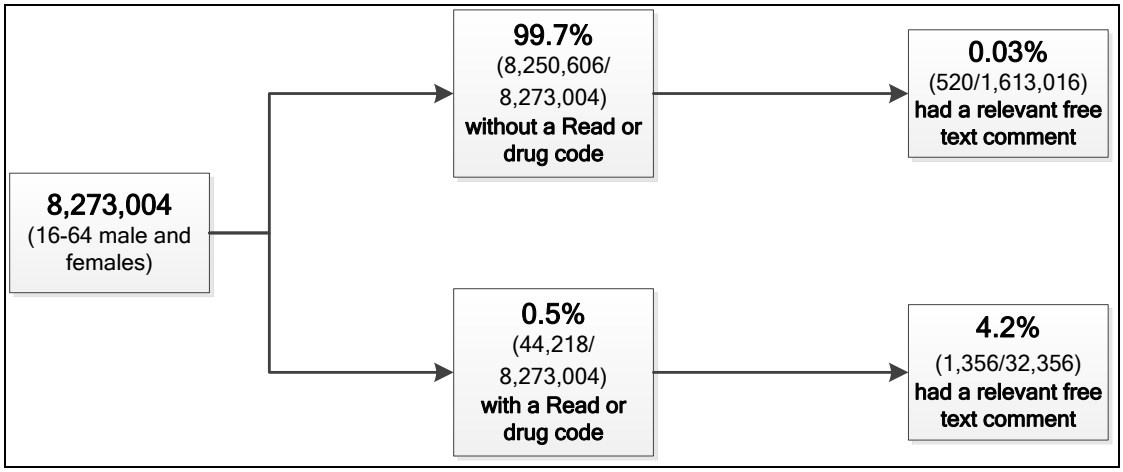


Figure 4:9: Relevant free-text comments for individuals with and without Read and/or prescription codes for drug use or opioid substitution treatment.

4.9 Discussion

4.9.1 Summary of main findings

The main findings of this study illustrate that there were individuals who were recognised and have a recording for drug use in their primary care records, however, only a quarter of those estimated as using drugs in the population were captured in THIN. Furthermore, a large proportion of these individuals did not receive treatment in primary care. However, 96% of individuals receiving prescriptions for opioid substitution treatment from general practice were identified in THIN.

Overall, there were more males than females with recordings for drug use and of those with a record, most were between the ages of 16-24 years, in the highest quintile of deprivation, residing in the North East of England and during the period 1994 and 2000. Most of the men in the older age-group (25-34 years), from same quintile of deprivation and region had a prescription for opioid substitution

treatment, whilst more men from the North West of England and Read code for opioid substitution treatment. Annual prevalence rates remained relatively stable between 2010/11 and 2012/13.

4.9.2 Comparison with existing literature

4.9.3 Gender

Findings from this first study show that women were two thirds less likely to have a recording for drug use and/or opioid substitution treatment compare with men in THIN. As previously mentioned, this is consistent with the Crime Survey for England and Wales, the National Drug Treatment Monitoring System and the Welsh drug misuse database (National Treatment Agency for Substance Misuse, 2012a; Office for National Statistics, 2013a; Welsh Government, 2012). Since 1996 there have been 50-60% more male drug users in England and Wales and 73% of people in treatment were male (National Treatment Agency for Substance Misuse, 2012a; Welsh Government, 2012). However, the gender difference in my study may be slightly underestimated for two reasons; firstly, women between the ages of 16-60 years consult their GP more than men and secondly, younger males from more deprived areas are slightly under-represented in THIN (Blak *et al*., 2011; Wang *et al*., 2013).

4.9.4 Age-group

The results regarding age-group from this study showed similar patterns to the Crime Survey for England and Wales, whereby individuals from the younger age-group (16-24 years) were more likely to have a recording for drug use compared with individuals from the older age-groups (Office for National Statistics, 2013b).

In my study, more individuals from the younger age-group (16-24 years old) were receiving a prescription for opioid substitution treatment group up until 2002.

However, after 1999, more individuals from the 25-34 year age-group received prescriptions (National Treatment Agency for Substance Misuse, 2012a). These findings echo annual reports from the National Drug Treatment Monitoring System whereby opiate use has decreased significantly in the 16-24 year age-group. Additionally the percentage of heroin and methadone users in the population has remained unchanged for the last few years and this could explain that individuals who require opioid substitution treatment are shifting into the older age-groups (National Treatment Agency for Substance Misuse, 2012a).

4.9.5 Social deprivation

Findings from my study illustrate that the larger recording rates of drug use are associated with higher social deprivation. Similarly, The Crime Survey for England and Wales also found an inverse association between frequent drug use and income and reported that frequent drug use is higher in more deprived urban areas (Office for National Statistics, 2013b). Likewise, more prescriptions for opioid substitution treatment were given to individuals from the highest quintile of deprivation in THIN. These findings echo the annual reports from The National Treatment Agency where individuals in treatment for drug use are more socially deprived (National Treatment Agency for Substance Misuse, 2012a).

4.10 Conclusion

It was evident from this study that primary care databases could be used to monitor trends but not rates of drug use in the general population. In contrast, even though little opioid substitution treatment occurs in general practice, it is well recorded in electronic health records and therefore it can be used to monitor both trends and rates in the general population.

4.11 How Does This Chapter Support My Thesis?

Results from the first study suggested that THIN is similar to national surveys with regards to trends in the general population and could potentially be used to understand and examine drug use and opioid substitution treatment in and around pregnancy. The next chapter will focus on females from the first study who were also pregnant.

CHAPTER 5 STUDY 2: GP RECORDING IN AND AROUND PREGNANCY

5.1 Content and Structure of Chapter 5

My first study (Chapter 4) focused on GP recording of individuals who use drugs and are treated with opioid substitution treatment in the general population. In this chapter, I focus on recording of women in and around pregnancy. I use the females obtained in my first study and narrow it down to women who were also pregnant in order to examine the number of women who have one or more recordings for drug use and/or opioid substitution treatment during the time-period 36 months either side of and during pregnancy. This chapter contains the introduction, aim, specific objectives, methods, results and discussion for the second study.

The study addresses objective two of the thesis (*section 2.4*) and will also contribute to answering the second part of my main research questions (*section 2.3*):

1. *Can a large primary care database (The Health Improvement Network (THIN)) be used as a surveillance tool for understanding drug use and opioid substitution treatment in the general population and specifically during pregnancy (in England and Wales)?*
2. *Can a large primary care database (THIN) be used as a tool to research drug use and opioid substitution treatment in general practice in the general population and specifically during pregnancy (in England and Wales)?*

5.2 Introduction

In England and Wales, there have been few large epidemiological studies that have examined the prevalence of drug use and opioid substitution treatment in and

around pregnancy. (Advisory Council on the Misuse of Drugs, 2011; Farkas *et al*., 1995; Fergusson *et al*., 2002; Sherwood *et al*., 1999). Drug use during pregnancy is complex due to the increased risk to the unborn child (Advisory Council on the Misuse of Drugs, 2011). Additionally, a woman's circumstances may be exacerbated by concurrent adverse social and lifestyle factors for example; poverty; physical and emotional abuse or neglect, separation, inadequate accommodation and exposure to criminal activity (Advisory Council on the Misuse of Drugs, 2011).

Estimates of drug use during pregnancy may be inaccurate due to a large amount of underreporting. The reasons for underreporting or non-disclosure include the following (Centre for Maternal and Child Enquiries, 2011):

- the stigma of drug use during pregnancy;
- unawareness of pregnancy due to amenorrhoea;
- no or late attendance to the GP and/or antenatal clinic; and
- the fear of the newborn being taking away

However, it may more likely that a GP would record a woman as a drug user if she is pregnant because a child would be involved (Advisory Council on the Misuse of Drugs, 2011). In contrast to drug use, if opioid substitution treatment is prescribed in general practice, it should be accurately documented in the electronic health records (Public Health England, 2015). However, if a woman receives prescriptions from either the community drug clinic or specialist midwife service, the information may not be captured in the woman's primary electronic health record.

As mentioned in *section 1.3.13,* there have been four significant studies conducted in the England, but none in Wales that have examined drug use in pregnancy up to

April, 2013. The studies by Farkas *et al.* and Sherwood *et al.* used biological measures (urine analysis) to determine drug use during pregnancy (Farkas *et al*., 1995; Sherwood *et al*., 1999). Whilst the studies by Ferguson *et al.* and the Advisory Council on the Misuse of Drugs utilised questionnaires (Advisory Council on the Misuse of Drugs, 2011; Fergusson *et al*., 2002).

The first study conducted by Farkas *et al*. found that 10% (106/1,000) of women attending a 12 week antenatal check in East London, tested positive (urine analysis) for drug use, with cannabis being the most common (8.5%, 85/1,000) drug used (Farkas *et al.*, 1995). Sherwood *et al.* also used anonymous urine samples sent by GPs for analysis during the first trimester in South London *(Sherwood et al*., 1999). Their sample size was slightly smaller (807 vs 1,000), however, almost 6% more women tested positive for drug use (15.6%, 126/807) (Sherwood *et al*., 1999). As with Farkas *et al*., cannabis was the most common (14.5%, 117 of 807) drug used by women in the first trimester (Sherwood *et al*., 1999).

The main strength of these two studies was that they relied on biological methods rather than self-reporting (Farkas *et al*., 1995; Sherwood, *et al*., 1999). Additionally, the studies did not require signed consent as the identity of the women was completely anonymised (Professor R Sherwood, 2015: personal communication (email) 11th August). The main limitations of both studies were that they used a relatively small sample size and included women from only one area of London which meant that results were not generalisable to the rest of the UK population.

The third study involved analysis of the Avon Longitudinal Study of Parents and Children Study (ALSPAC) (Fergusson *et al*., 2002). Pregnant women (n=12, 000)

enrolled on the study (expecting to give birth between 1 April 1991-31 December 1992) were given self-reported questionnaires on cannabis use between 18-20 weeks gestation. Only one other question about other drug use was included ("Use of hard drugs during pregnancy" yes/no). The following adverse foetal outcomes were also examined; late foetal and neonatal death, neonatal special care admissions, birth weight, length and head circumference. The authors reported that 5% of women in their study smoked cannabis during pregnancy, whilst 6.8% reported using other hard drugs. Women who used cannabis were more likely to be younger, more educated, have lower parity, smoke, drink more alcohol, coffee and tea and use other hard drugs. They also reported that cannabis did not lead to any of the measured adverse birth outcomes, however the babies born from mothers who used cannabis were smaller (90 grams lighter) (Fergusson *et al*., 2002).

The final study was conducted by The Advisory Council on the Misuse of Drugs prevention working group in June 2011, which subsequently produced the Hidden Harm report in response to the need of children of problem drug users (Advisory Council on the Misuse of Drugs, 2011). The findings estimated that between 200,000-300,000 children (2-3% of under 16 year olds) in England and Wales, have at least one parent who uses drugs (Advisory Council on the Misuse of Drugs, 2011). The study sent a questionnaire to 423 maternity units in Sheffield and Glasgow and ninety percent (92%, 238/259) of the responding units reported frequently asking pregnant women about drug and alcohol use. A mean of 1% (24/2,407, range 0-172) of women who gave birth in the maternity units disclosed their drug use during pregnancy (Advisory Council on the Misuse of Drugs, 2011).

The findings of both the later studies showed that less women used drugs during pregnancy compared with the studies that used biological measures (Advisory Council on the Misuse of Drugs, 2011; Ferguson *et al.*, 2002). Ferguson *et al*.

acknowledged that drug use may be under-reported in the ALSPAC study as the self-reported questionnaire is subject to response bias (Fergusson *et al*., 2002). Furthermore, the study conducted by the Advisory Council on the Misuse of Drugs had a response rate of 61% and therefore a risk of selection bias due to non-responders was introduced (Pannucci and Wilkins, 2010). Additionally, using a questionnaire could increase the risk of recall bias by the staff in the maternity units (Choi and Pak, 2004). Reporting of drug use to health professionals could lead to adverse consequences, and women may therefore chose not to disclose.

These four studies are the largest regarding recreational drug use during pregnancy in England and Wales to date. However, results are conflicting and there are no studies that identify women who use drugs during pregnancy in a general practice setting. For 77% of newly pregnant women, GPs are the first healthcare practitioners they see (Redshaw and Heikkila, 2010). My second study therefore aims to give an estimate of recording of women who use drugs in and around pregnancy in primary care. Additionally by using a primary care database, the risk of response and recall bias may be reduced. In my first study (Chapter 4), where I examined the recording of drug use and opioid substitution treatment in the general population, I found that a third of individuals who had a recording for drug use and/or opioid substitution treatment were female and the majority of these females were of child bearing age. A large primary care database study may therefore be beneficial to examine GP recording of drug use and opioid substitution treatment in and around pregnancy and to also assist in answering the two research questions (*section 2.3*)

5.3 Aim of Study 2

To describe GP recording of drug use and/or opioid substitution treatment in and around pregnancy.

5.4 Specific Objectives of Study 2

Using data for women residing in England and Wales in the time-periods 36 months either side of and during pregnancy, I sought to:

1. Examine the parity and demographics for women with and without recordings for drug use and/or prescriptions for opioid substitution treatment
2. Examine the timing of recordings for drug use and/or prescriptions for opioid substitution treatment
3. Explore the frequency of Read and/or prescription codes entered for each woman during specific time periods

5.5 Hypotheses for Study 2

Hypothesis 1: There was no difference in the recording of drug use (Read codes) in the time periods before and after pregnancy compared with during pregnancy

Hypothesis 2: There was no difference in prescribing opioid substitution treatment in the time periods before and after pregnancy compared with during pregnancy

Hypothesis 3: There was no difference in recording of opioid substitution treatment (Read codes) in the time periods before and after pregnancy compared with during pregnancy

5.6 Methods

5.6.1 Women who have Read codes for drug use and or prescriptions/Read codes for opioid substitution treatment in and around pregnancy

In order to examine the parity and demographics for women with and without a recording for drug use and/or prescriptions for opioid substitution treatment, I firstly describe how I developed the time definitive pregnancy cohort from the pregnancy cohort in THIN. Secondly I examined the number of women who had at least one

Read and/or drug code and finally, I examined the parity and demographics of women in the time definitive cohort.

5.6.1.1 Pregnancy cohort in THIN

The pregnancy cohort in THIN was created by my supervisor, Dr Irene Petersen in 2012. This cohort includes all women who have had a complete pregnancy (based on the delivery date of the baby) or women who have a recording for a pregnancy (based on the estimated due date of the baby). In order to be sure that true pregnancies were included in the cohort, some restrictions were applied when obtaining records of individual women in THIN. Each pregnancy needed to adhere to at least two situations in order to be included (Table 5.1). If a woman only had evidence from the last menstrual period and antenatal records, she also needed evidence from conditions 6 (*"Last antenatal record must be at least 105 days after estimated pregnancy start date"*) and 7 ("*A woman must not have another pregnancy record with a delivery date within 280 days either before or after the delivery date for the current pregnancy record"*) (Table 5.1). Condition 7 could indicate that a miscarriage record has been mixed up with another pregnancy record. If a woman had more than one record for a pregnancy with the same start date, the record with the latest delivery date was used, as records tended to be more complete and if a record was problematic and/or ambiguous, it was not included in the cohort.

Table 5.1: Evidence to determine a true pregnancy in THIN

Different indications of a true pregnancy
1. Last menstrual period date*
2. Antenatal record*
3. Delivery record
4. Postnatal care record
5. Child whose GP record could be matched to the current pregnancy

*If an individual only had evidence from 1 and 2, they also needed evidence from the following two conditions

6. Last antenatal record must be at least 105 days after estimated pregnancy start date
7. A woman must not have another pregnancy record with a delivery date within 280 days either before or after the delivery date for the current pregnancy record.

The start of the pregnancy was calculated from various methods including the date of last menstrual period, delivery date and postnatal check dates. A pregnancy could not be validated by the birth of a child and therefore some of the recorded pregnancies could be false. Some of the pregnancies with an estimated due date may not have gone to term due to a miscarriage which may not have been recorded. The final pregnancy cohort comprised of 420,234 women and 586,312 pregnancies.

5.6.1.2 Time definitive cohort (Preg_81_cohort)

In order to develop the cohort of pregnant women who were registered permanently for 36 months either side of and during pregnancy, I first defined and generated the different time-periods. I initially examined different time-points between the start of pregnancy and delivery. After exploration, I decided to examine time-period of pregnancy as one time-point as there was very little difference in recording during the first 6 weeks, first, second and third trimester.

Definition and generation of time-periods in pregnancy cohort (Figure 5:1)

a. Before pregnancy:

I divided the 36 months prior to the start of a woman's pregnancy into 9 month time-periods (-36 to -28, -27 to -19, -18 to -10, -9 to -1).

b. During pregnancy

This includes the time between the start of pregnancy and the delivery of the baby. The time period was approximately 9 months, but this depended on the length of gestation for each pregnancy.

c. After pregnancy

I divided the 36 months after the delivery of the baby into 9 month time-periods (Birth to +9, +10 to+18, +19 to +27, +28 to +36).

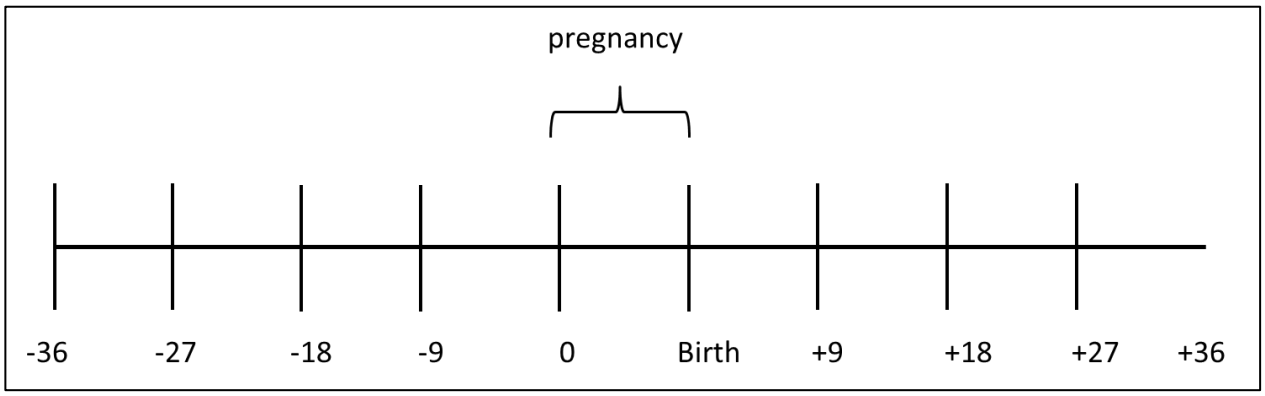


Figure 5:1: Time definitions in and around pregnancy

Women who fitted the following three criteria were defined as **preg_81_cohort** (Figure 5:2):

1. Included in the original pregnancy cohort in THIN, and
2. Resided in England or Wales, and
3. Were continuously registered with the same practice for 36 months before, during and 36 months after pregnancy

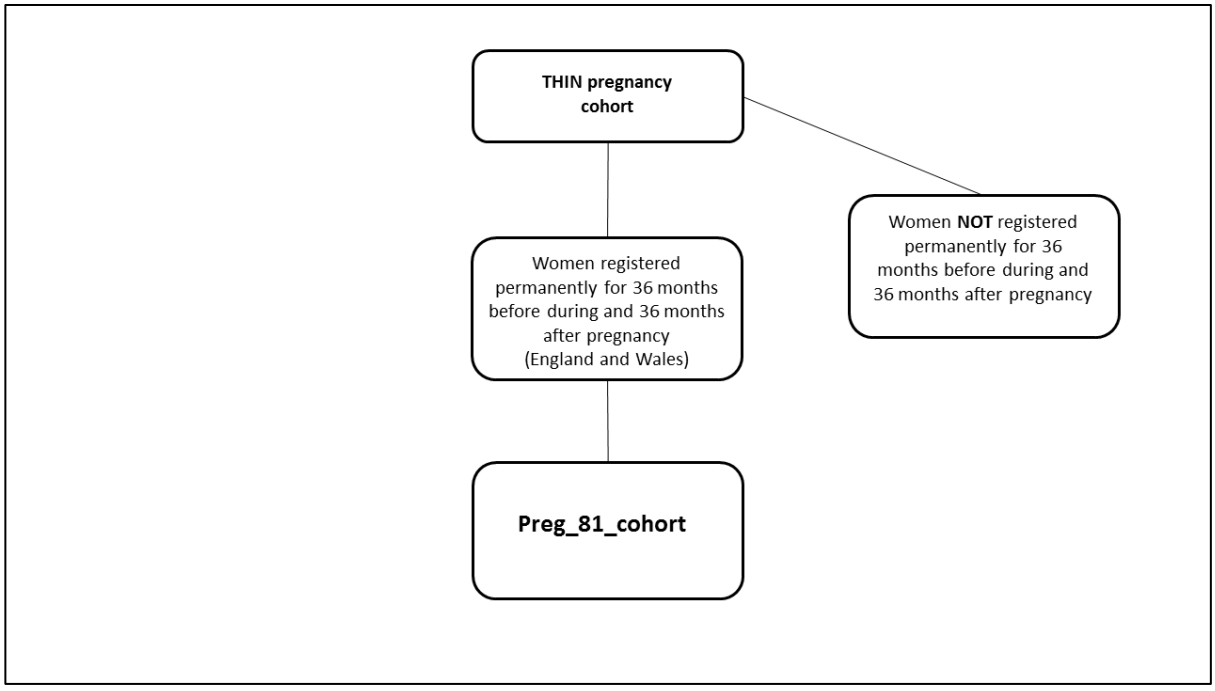


Figure 5:2: The development of preg_81_cohort

5.6.1.3 Women who had Read codes for drug use and/or prescriptions or Read codes for opioid substitution treatment in THIN

I included all women with a recording for drug use and/or opioid substitution treatment, aged between 16-55 years, from my first study (*see section 4.7.2*). I also decided to identify all recordings of drug use and/or opioid substitution treatment and not just the first recording. The reason being that a woman may have had her first recording outside the defined study time periods in and around pregnancy. I therefore created three new sub-groups of females with:

1) One or more Read codes for drug use
2) One or more prescriptions for opioid substitution treatment
3) One or more Read codes for opioid substitution treatment

The three sub-groups together included all women who had at least one recording for drug use and/or opioid substitution treatment.

I then merged the women who had at least one recording for drug use and/or opioid substitution treatment with the preg_81_cohort using the unique identities of the women. The total number of women in preg_81_cohort was the denominator when conducting analysis (Figure 5:3).

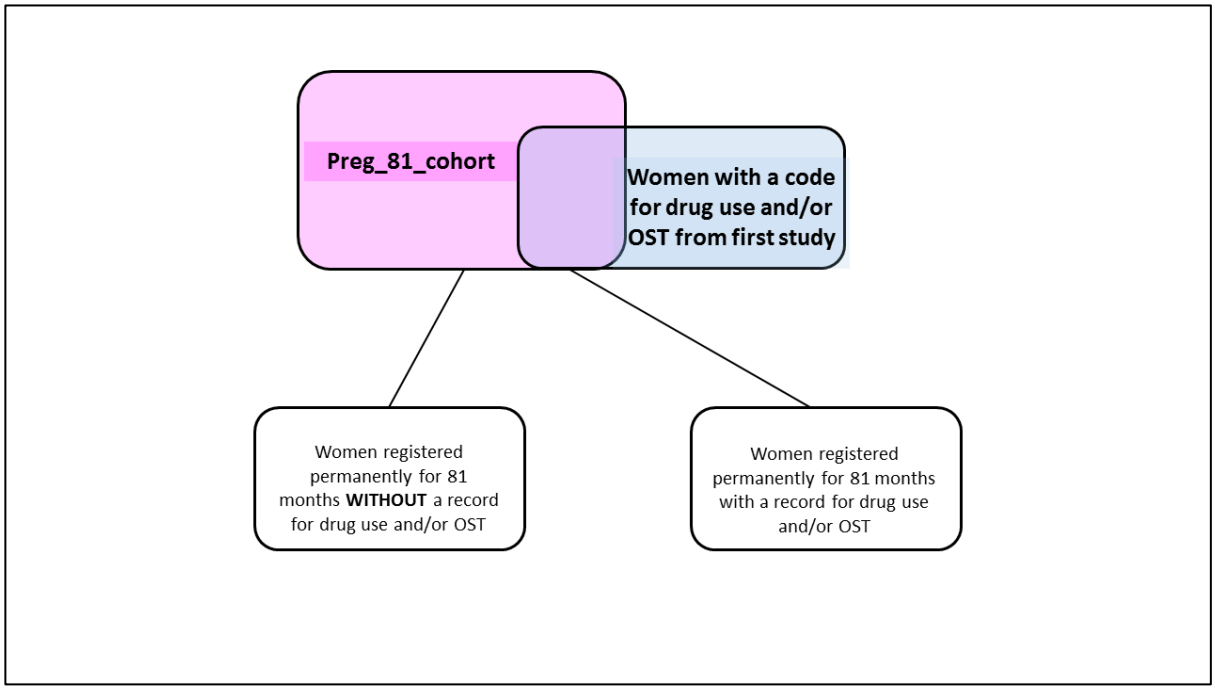


Figure 5:3: Preg_81_cohort merged with women with at least one recording for drug use and/or opioid substitution treatment (OST)

5.6.2 Parity and demographics for all women in preg_81_cohort

5.6.2.1 Selecting a random sample from preg_81_cohort

Some women have more than one pregnancy, so I decided to use similar methods to Petersen *et al.,* and Man *et al.,* and selected a random pregnancy for each woman (Man *et al*., 2012; Petersen *et al*., 2011). This was to avoid clustering of data and ensure that the pregnancies in the sample were independent of each other (Kirkwood and Sterne, 2003). All women from preg_81_cohort would then be included but only one of their pregnancies would be used in the analysis.

5.6.2.2 Parity of women

In order to examine the parity of women in the particular general practice, I summed their total number of pregnancies. I examined if the distribution of parity was similar for women with and without a recording for drug use and/or opioid substitution treatment

5.6.2.3 Age of woman at pregnancy

In order to examine the age of all women at the start of their randomly selected pregnancy, I subtracted the date at the start of pregnancy from the mother's date of birth. I then divided the ages into six categories: <19, 20-24, 25-29, 30-34, 35-39 and >=40 years old.

5.6.2.4 Deprivation and region

In order to examine the deprivation status and the region the women resided in, I examined the Townsend deprivation scores and region (strategic health authority (SHA)) for all women (*section 3.4.2*)

5.6.3 Timing of recording for drug use and/or opioid substitution treatment in preg_81_cohort

In order examine the timing of recordings for drug use and/or prescriptions for opioid substitution treatment, I examined if a woman had at least one recording for drug use and/or opioid substitution treatment for each nine month time-period, as defined in Figure 5:1.

5.6.4 Frequency of Read codes for drug use and prescription/Read codes for opioid substitution treatment at different time intervals during pregnancy

In order to explore the frequency of Read and/or prescription codes entered for each woman during specific time periods, I explored the most frequently used Read codes for drug use and prescriptions and Read codes for opioid substitution treatment that were used at different time-periods in and around pregnancy, and examined if their frequencies differed during these time intervals.

5.6.5 Statistical analysis

I conducted the following statistical analysis:

1. Summarised the following in terms of frequencies and percentages:
   i) Recording for Read codes for drug use and/or prescriptions and Read codes for opioid substitution treatment (first recording and all recordings) for all females from the first study
   ii) Number of women in preg_81_cohort who had one or more recordings for drug use and/or opioid substitution treatment
2. Conducted a t-test for age at the start of pregnancy to ascertain if there was a difference between women with and without a code for drug use and/or opioid substitution treatment
3. Conducted logistic regressions to explain the effects of age, deprivation and region on recording of drug use (binary outcome). I decided *a priori* on the basis of the existing literature to include age, deprivation and region in the analysis as they may be potential confounders (European Monitoring Centre for Drugs and Drug Addiction, 2014; Frischer *et al*., 2009; Office for National Statistics, 2013a). I examined if there was effect modification by age, deprivation and region (Kirkwood and Sterne, 2003). If effect modification existed, I stratified the covariate. In order to select which model fitted the data the best, I carried out hypothesis testing using likelihood ratio tests (Table 5.2) (Kirkwood and Sterne, 2003).

Table 5.2: Selection of appropriate model

Model	Covariates in model	No of parameters
2	Age	6
3	Deprivation	5
4	Region	11
5	Parity	2
6	Age & deprivation	10
7	Age, deprivation & region	20
8	Age, deprivation, region & parity	21

4. Calculated the timing of recording of drug use and/or opioid substitution treatment prescriptions for women in preg_81_cohort:
   i) using all women in preg_81_cohort as the denominator
   ii) I calculated prevalence ratios and 95% confidence intervals. The reference group was the time-period during pregnancy for preg_81_cohort.
5. Summarised the most frequently used codes for drug use and opioid substitution treatment for all records for each woman in preg_81_cohort

All data was analysed using STATA (version 13) statistical software (Stata Corp LP, College Station, Texas).

5.6.6 Sensitivity analysis

In order to ascertain if a more transient population with regards to registration gave different results, I obtained a different time-definitive cohort which included women who were registered permanently for nine months before, during and nine months after pregnancy. I conducted the same statistical analysis as in *section 5.6.5.*

5.7 Results

5.7.1 Parity and demographics for women with and without a recording for drug use and/or prescriptions for opioid substitution treatment

5.7.1.1 Number of women with a code for drug use and/or opioid substitution treatment

A third (32.5% 18,048/52,632) of individuals with a first recording for drug use and/or opioid substitution treatment from my first study (Chapter 4) were female. I identified a total of 872,798 recordings for drug use and/or opioid substitution treatment from the electronic health records (Table 5.3).

Table 5.3: Number of Read codes for drug use, prescriptions and Read codes for Opioid substitution treatment (OST)

	Read code for drug use	Prescription for OST	Read code for OST	Total
All females, first record	10,886	4,748	2,414	18,048
All females, all records	236,926	576,788	59,084	872,798

*OST=opioid substitution treatment

5.7.1.2 Number of women in preg_81_cohort

There were originally 420,234 women in the pregnancy cohort, of those women, a fifth (20.5%, n=86,002) were registered permanently for 36 months either side of and during pregnancy in a practice located in either England or Wales. Of the women in preg_81_cohort, 0.98% (835/86,002) had a recording for drug use and/or opioid substitution treatment (Figure 5:4).

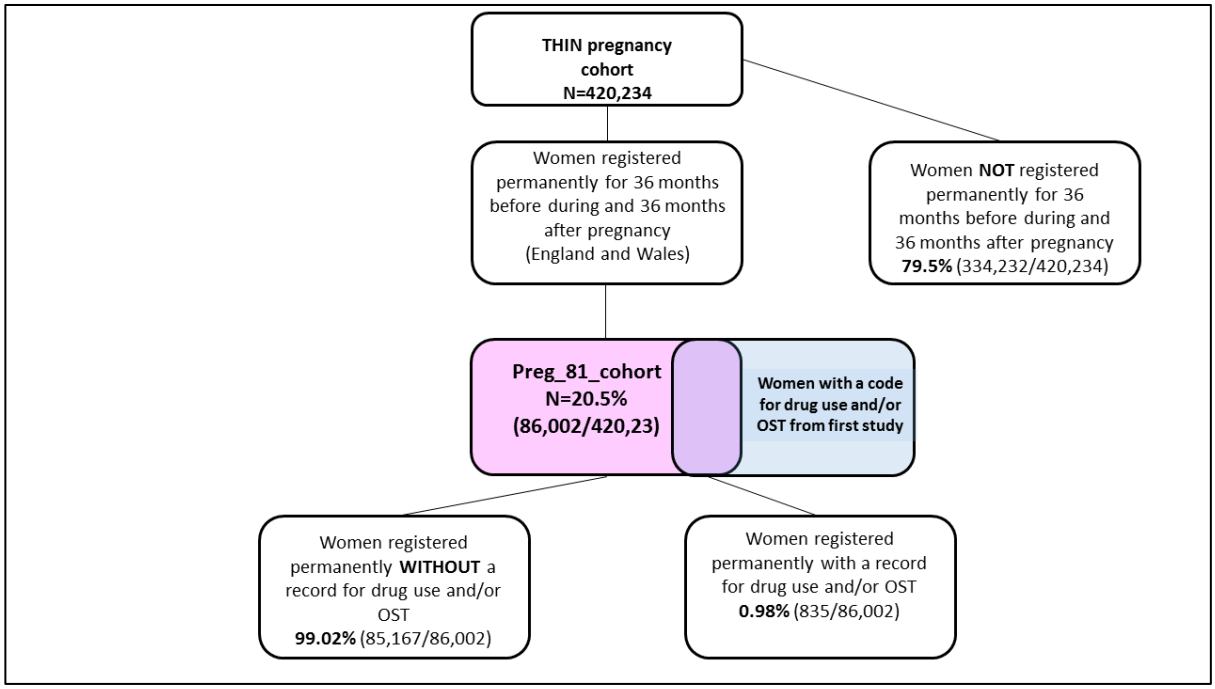


Figure 5:4: Results for the preg_81_cohort (OST=Opioid Substitution Treatment)

5.7.1 Statistical model

Following the hypothesis testing to select the most appropriate model, I included age, deprivation and region. There was no evidence that parity improved the fit of the model (p=0.08) and I therefore excluded this variable from my final model. I observed no effect modification by any of the covariates

5.7.1.1 Parity

The parity between the women who did and did not have a recording for drug use and/or opioid substitution treatment was similar. Almost 90% (86.8%, 74,661/85,167 and 87.5%, 731/835) of the women in preg_81_cohort had one pregnancy and 11% (9,552/85,167and 92/835) had two pregnancies (Table 5.4).

1.1.1.1 Maternal age at the start of the pregnancy

The mean age of women with a recording for drug use and/or opioid substitution treatment (27.3 years, sd ± 6.1) differed significantly by 2 years compared to women without a recording (29.3 years, sd ± 6.3) ($p<0.0001$). Women who were younger than 24 years were twice as likely to have a recording for drug use and/or opioid substitution treatment compared with women over 40 years (Table 5.4).

5.7.1.2 Maternal level of deprivation

The rate of recording was highest for women in the most deprived group (2.08 per 100 pregnancies). Additionally, women from the most deprived group were five times more likely to have a recording compared with women in the least deprived group (5.05 (3.96-6.44).

5.7.1.3 Maternal region

Women residing in the North East of England had the highest recording rate (1.79 per 100 pregnancies). Furthermore, women living in the North East (OR: 3.4, 95% CI: 2.2-5.2) and East Midlands (OR: 3.03, 95% CI: 1.9-4.6) regions of England were approximately three times more likely to have a recording for drug use and or opioid substitution treatment, compared with women living in London (Table 5.4).

Table 5.4: Summary of the preg_81_cohort (N=86,002): Parity, age, deprivation and region

	No recording N=85,167(99.02%)	Rate per 100 pregnancies	Recording N=835 (0.98%)	Rate per 100 pregnancies	Unadjusted OR (95% CI)	Adjusted* OR (95% CI)
Parity	**N (%)**		**N (%)**		**OR (95% CI)**	**OR (95% CI)**
1	74,661 (86.8)	99.03	731 (87.5)	0.97	1.07 (0.90-1.27)	
2	9,552 (11.2)	99.05	92 (11.0)	0.09		
Age (years)	**N (%)**		**N (%)**		**OR (95% CI)**	**OR (95% CI)**
<19	6,510 (7.60)	98.47	101 (12.1)	**1.53**	**2.51 (1.52-4.15)**	**2.26 (1.36-3.74)**
20-24	12,601 (14.7)	98.48	194 (23.2)	1.52	**2.49 (1.53-4.03)**	**2.25 (1.38-3.66)**
25-29	21,386 (24.9)	98.99	218 (26.1)	1.01	**1.65 (1.01-2.67)**	1.53 (0.95-2.49)
30-34	26,546 (30.9)	99.26	199 (23.8)	0.74	1.21 (0.74-1.96)	1.15 (0.71-1.87)
35-39	15,215 (17.7)	99.31	105 (12.6)	0.68	1.11 (0.67-1.84)	1.09 (0.66-1.80)
>=40	2,909 (3.40)	**99.39**	18 (2.20)	0.62	1	1
Deprivation	**N (%)**		**N (%)**		**OR (95% CI)**	**OR (95% CI)**
1 least deprived	21,624 (25.1)	**99.58**	91 (10.9)	0.42	1	1
2	16,685 (19.4)	99.37	105 (12.6)	0.63	**1.48 (1.12-1.96)**	**1.47 (1.11-1.95)**
3	17,474 (20.3)	99.17	147 (17.6)	0.83	**1.99 (1.54-2.59)**	**1.99 (1.53-2.60)**
4	16,086 (18.7)	98.57	233 (27.9)	1.43	**3.44 (2.69-4.38)**	**3.29 (2.57-4.22)**
5 most deprived	11,098 (12.9)	97.92	236 (28.3)	**2.08**	**5.05 (3.96-6.44)**	**4.62 (3.58-5.96)**
Region	**N (%)**		**N (%)**		**OR (95% CI)**	**OR (95% CI)**

	No recording N=85,167(99.02%)	Rate per 100 pregnancies	Recording N=835 (0.98%)	Rate per 100 pregnancies	Unadjusted OR (95% CI)	Adjusted* OR (95% CI)
London	7,195 (8.40)	**99.52**	35 (4.20)	0.48	1	1
East Midlands	4,647 (5.40)	98.75	59 (7.10)	1.25	**2.61 (1.72-3.97)****	**3.03 (1.98-4.63)**
East of England	6,538 (7.60)	99.02	65 (7.80)	0.98	**2.04 (1.35-3.09)**	**2.76 (1.82-4.19)**
West Midlands	10,567 (12.3)	98.94	113 (13.5)	1.06	**2.19 (1.50-3.21)**	**2.64 (1.80-3.88)**
North East	3,357 (3.90)	98.22	61 (7.30)	**1.79**	**3.73 (2.46-5.76)**	**3.40 (2.23-5.18)**
North West	13,495 (15.7)	98.73	173 (20.7)	1.27	**2.64 (1.83-3.79)**	**2.85 (1.97-4.12)**
Y&H*	3,797 (4.40)	99.32	26 (3.10)	0.68	1.41 (0.85-2.34)	1.62 (0.97-2.72)
South Central	11,794 (13.7)	99.08	109 (13.1)	0.92	1.90 (1.29-2.78)	2.73 (1.85-4.02)
South East Coast	7,383 (8.60)	99.46	40 (4.80)	0.54	1.11 (0.71-1.75)	1.55 (0.98-2.46)
South West	9,931 (11.6)	99.21	79 (9.50)	0.79	1.64 (1.09-2.43)	2.00 (1.34-3.00)
Wales	6,463 (7.60)	98.85	75 (9.00)	1.15	2.39 (1.59-3.57)	2.69 (1.78-4.03)

OR=Odds Ratio CI= Confidence Interval
*Adjusted for maternal age, deprivation and region
Y&H=Yorkshire and Humberside

5.7.2 Timing of recordings for drug use and/or prescriptions for opioid substitution treatment

5.7.2.1 Timing for all women in preg_81_cohort (denominator: all women in cohort, n=86,002)

Read codes for drug use

Compared to 36 months before pregnancy, recording of Read codes for drug use increased in the time-period 9 months before pregnancy, where 0.2% (175/86,002) of women in preg_81_cohort had a recording. Recording of Read codes for drug use reduced (0.14% (123/86,002) during pregnancy. After pregnancy, recording of drug use gradually increased until it remained relatively stable. Approximately 0.17% (143/86,002) of women in preg_81_cohort had a recording after the 27 month time-period (Figure 5:5).

Prescriptions for opioid substitution treatment

Conversely, a lower percentage (0.09%, 75/86,002) of women in preg_81_cohort had at least one prescription for opioid substitution treatment in the time-periods before pregnancy. Prescriptions reduced slightly during pregnancy, but increased in the time-periods after pregnancy, where approximately 0.12% (106/86,002) of women in preg_81_cohort received a prescription (Figure 5:5).

Read codes for opioid substitution treatment

The percentage of women with at least one Read code for opioid substitution treatment remained lower (± 0.003%, 26/86,002) but relatively stable compared to prescriptions and Read codes for drug use (Figure 5:5).

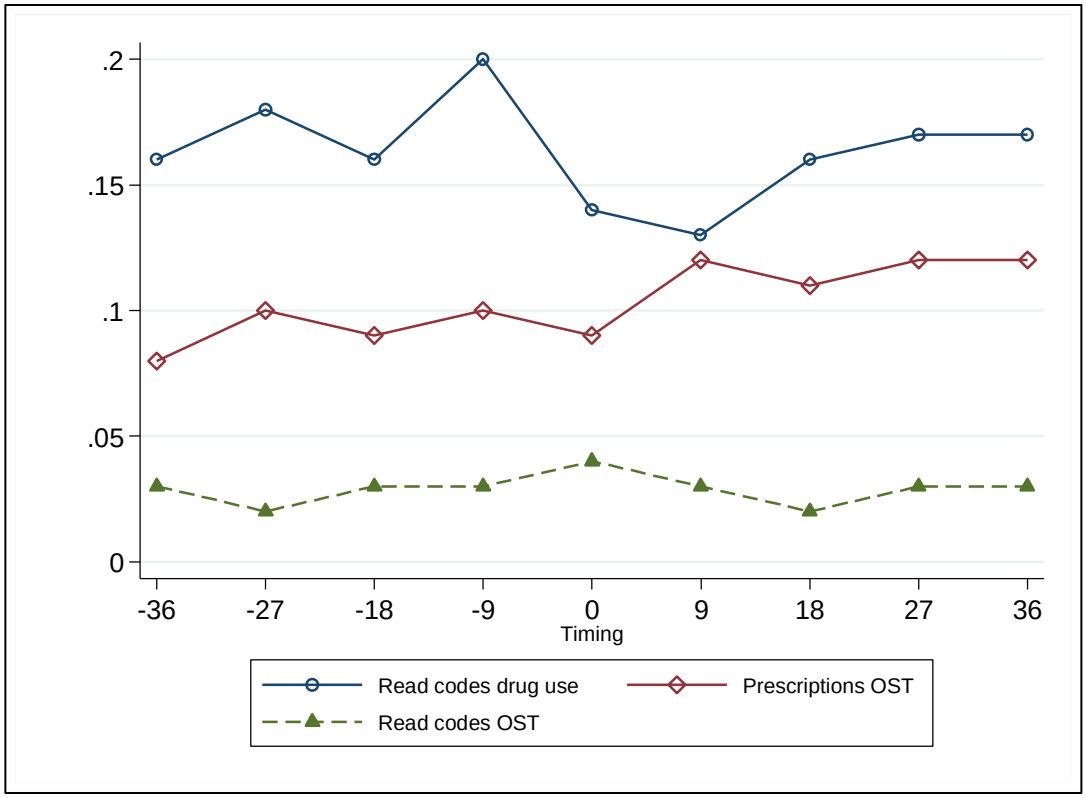


Figure 5:5: Timing of recording of at least one recording (Read code for drug use, prescription and Read code for Opioid Substitution Treatment (OST)) with the time-periods; 36 months either side of and during pregnancy. (Denominator: total number of women, N=86,002) Time-periods defined in methods section 5.6.1.2

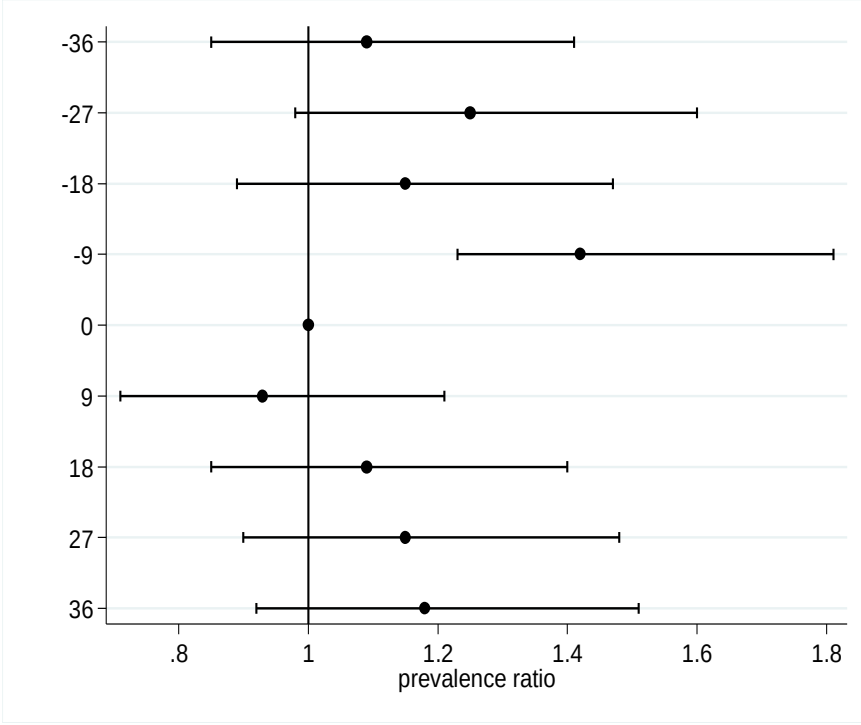
5.7.2.2 Prevalence rate ratios for recording codes and prescriptions in preg_81_drug_cohort and accept or reject hypotheses 1-3

Read codes for drug use

I rejected the first hypothesis as recording occurred 42% more 9 months before pregnancy compared with the time period during pregnancy (Prevalence Ratio (PR): 1.42: 95% CI: 1.23-1.81) (Table 5.5).

Table 5.5: Prevalence ratios (PR) of recordings of Read codes for drug use (Reference time=during pregnancy) Time period defined in methods section 5.6.1.2.

Time periods	Prevalence ratios (95% CI)
-36 to -28	1.09 (0.85-1.41)
-27 to -19	1.25 (0.98-1.60)
-18 to -10	1.15 (0.89-1.47)
-9 to -1	**1.42 (1.23-1.81)**
During Pregnancy	1
0 to 9	0.93 (0.71-1.21)
10 to 18	1.09 (0.85-1.40)
19 to 27	1.15 (0.90-1.48)
28 to 36	1.18 (0.92-1.51)

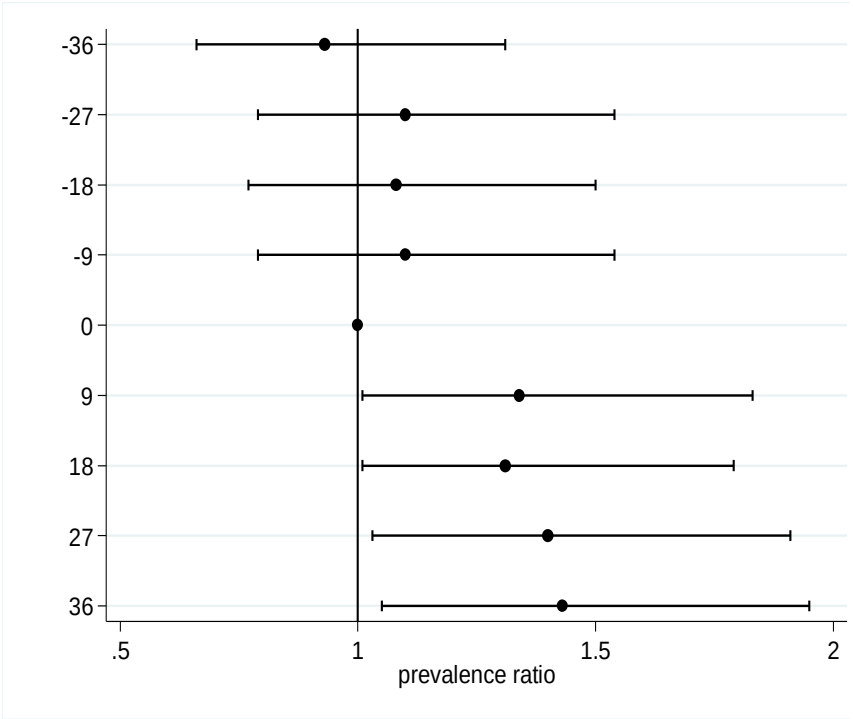


Prescriptions for opioid substitution treatment (Hypothesis 2)

I rejected the second hypothesis as prescriptions for opioid substitution treatment were given 30-40% more 9 months (PR: 1.34, 95% CI: 1.01-1.83), 18 months (PR: 1.31, 95% CI: 1.01-1.79), 27 months (PR: 1.40, 95% CI: 1.03-1.91), and 36 months (PR: 1.43, 95% CI: 1.05-1.95), after pregnancy compared with during pregnancy (Table 5.6).

Table 5.6: Prevalence ratios (PR) of recordings of prescriptions for opioid substitution treatment use (reference time=during pregnancy) Time period defined in methods section 5.6.1.2.

Time periods	Prevalence ratios (95% CI)
-36 to -28	0.93 (0.66-1.31)
-27 to -19	1.10 (0.79-1.54)
-18 to -10	1.08 (0.77-1.50)
-9 to -1	1.10 (0.79-1.54)
During Pregnancy	1
0 to 9	**1.34 (1.01-1.83)**
10 to 18	**1.31 (1.01-1.79)**
19 to 27	**1.40 (1.03-1.91)**
28 to 36	**1.43 (1.05-1.95)**

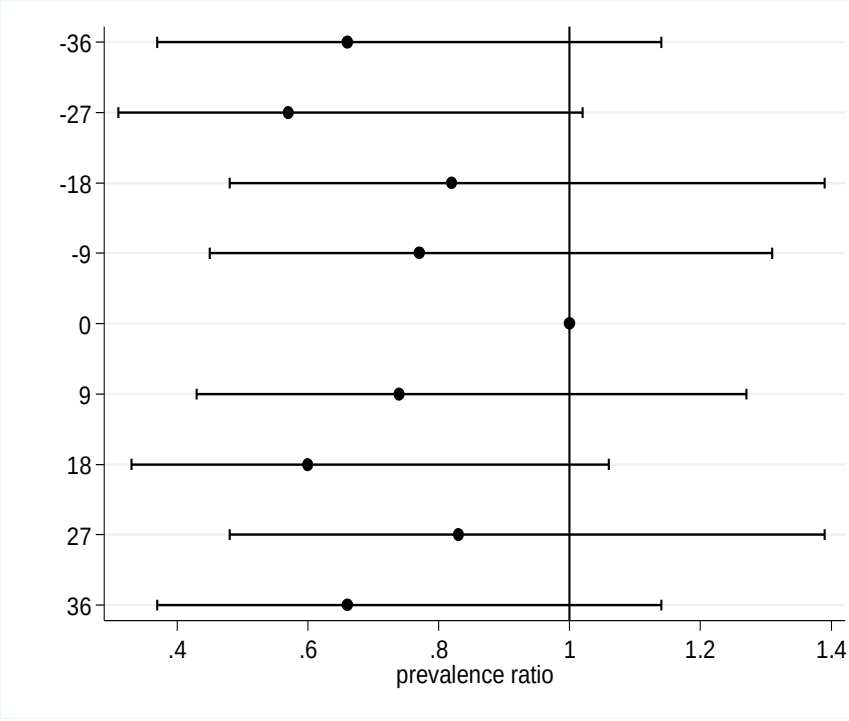


Read codes for opioid substitution treatment (Hypothesis 3)

I accepted the third hypothesis as there as was no significant difference in recording of Read codes for opioid substitution treatment in the time periods before and after pregnancy compared with during pregnancy. (Table 5.7).

Table 5.7: Prevalence ratios (PR) of recordings of Read codes for opioid substitution treatment use (reference time=during pregnancy) Time period defined in methods section 5.6.1.2.

Time periods	Prevalence ratios (95% CI)
-36 to -28	0.66 (0.37-1.14)
-27 to -19	0.57 (0.31-1.02)
-18 to -10	0.82 (0.48-1.39)
-9 to -1	0.77 (0.45-1.31)
During Pregnancy	1
0 to 9	0.74 (0.43-1.27)
10 to 18	0.60 (0.33-1.06)
19 to 27	0.83 (0.48-1.39)
28 to 36	0.66 (0.37-1.14)



5.7.3 Frequency of Read and/or prescription codes entered for each woman during specific time periods

Read codes for drug use

The most frequently used generic Read codes for drug use in and around pregnancy in preg_81_cohort were “drug dependence”, “drug withdrawal

syndrome", "misuse of drugs NOS" and "opioid type drug dependence" (Figure 5:6).

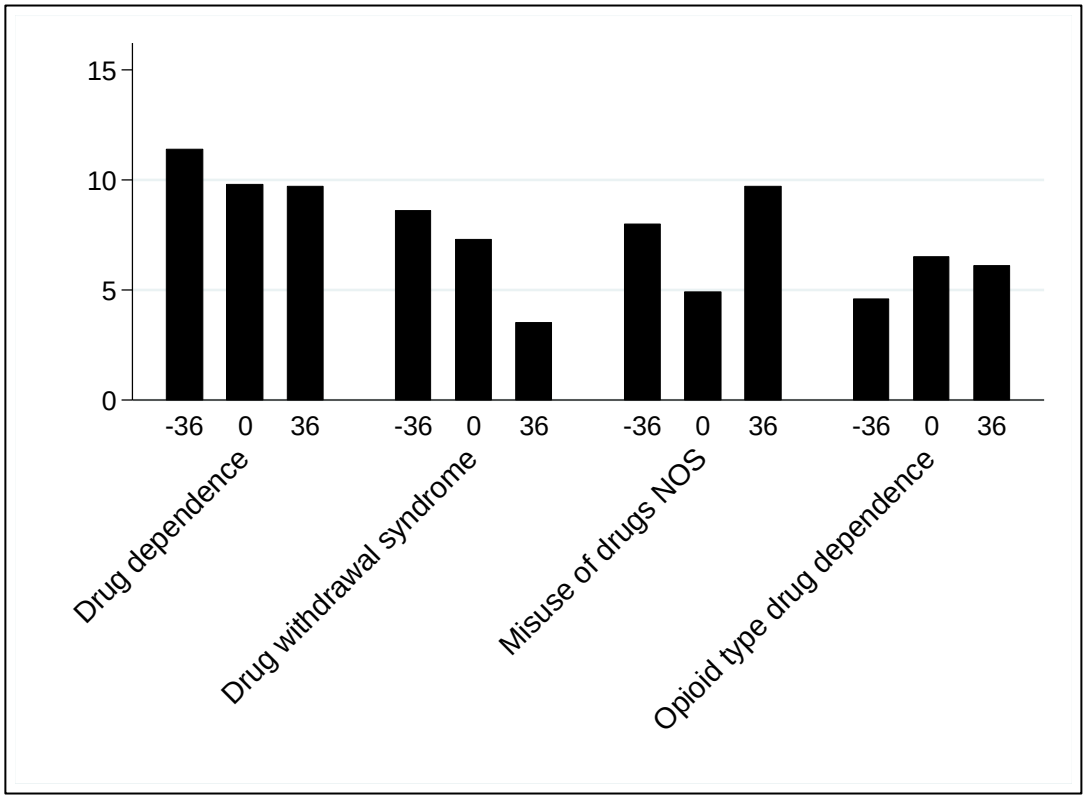


Figure 5:6: Four most frequently used generic Read codes for drug use 36 months in and around pregnancy (preg_81_cohort) (-36=36 months before pregnancy, 0=during pregnancy, 36=36 months after pregnancy) Time-periods defined in methods section 5.6.1.2

Whereas the most frequently used specific Read codes in and around pregnancy were "heroin dependence" and "benzodiazepine dependence" (Figure 5:7).

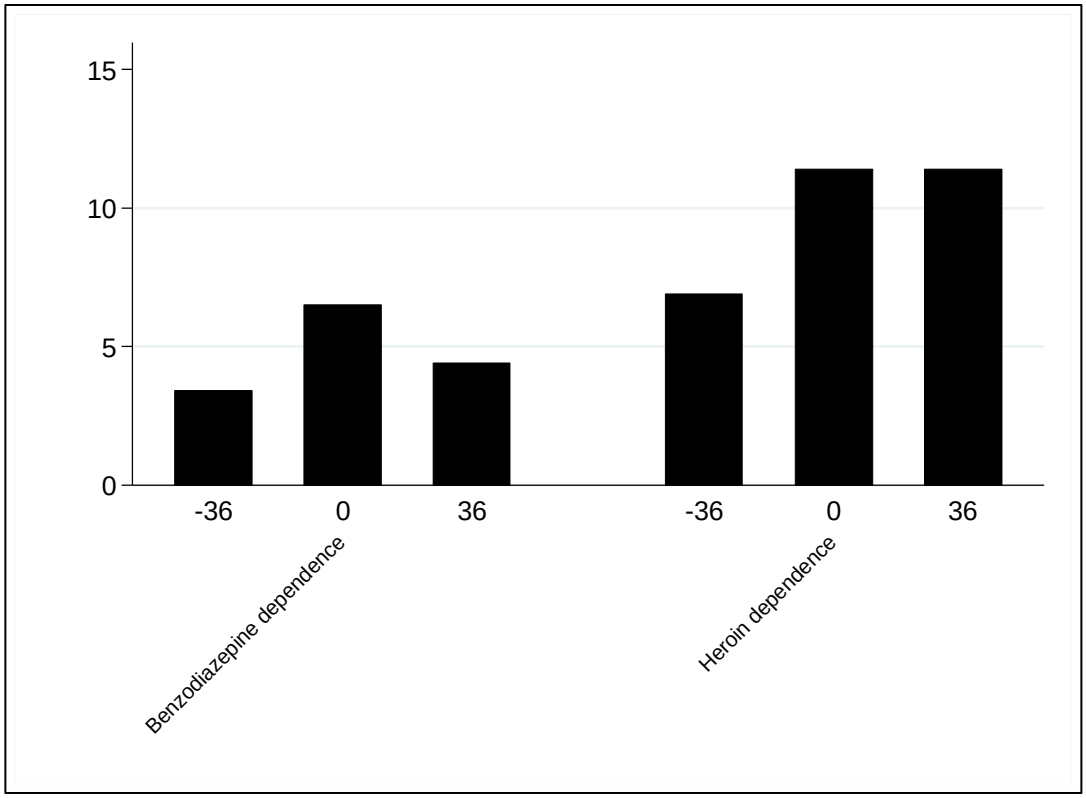


Figure 5:7: Most frequently used specific Read codes for drug use (-36=36 months before pregnancy, 0=during pregnancy, 36=36 months after pregnancy) Time-periods defined in methods section 5.6.1.2

Prescriptions for opioid substitution treatment

Approximately 40% of the prescriptions for opioid substitution treatment were for methadone in and around pregnancy. Whilst 20% of the prescriptions were for buprenorphine (Figure 5:8).

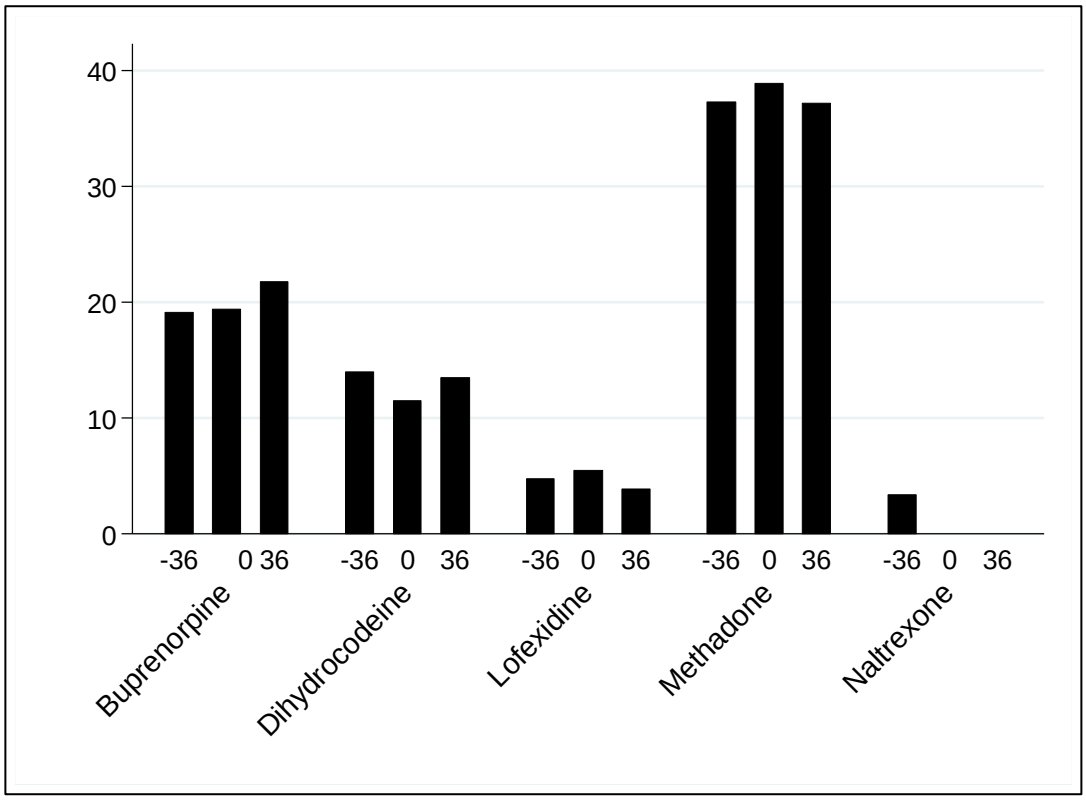


Figure 5:8: Five most frequently prescribed opioid substitution treatments used 36 months in and around pregnancy (-36=36 months before pregnancy, 0=during pregnancy, 36=36 months after pregnancy) Time-periods defined in methods section 5.6.1.2

Read codes for opioid substitution treatment

The most frequently used Read codes for opioid substitution treatment around and during pregnancy were “drug addiction therapy”, “drug addiction therapy-methadone” and “methadone dependence” (Figure 5:9).

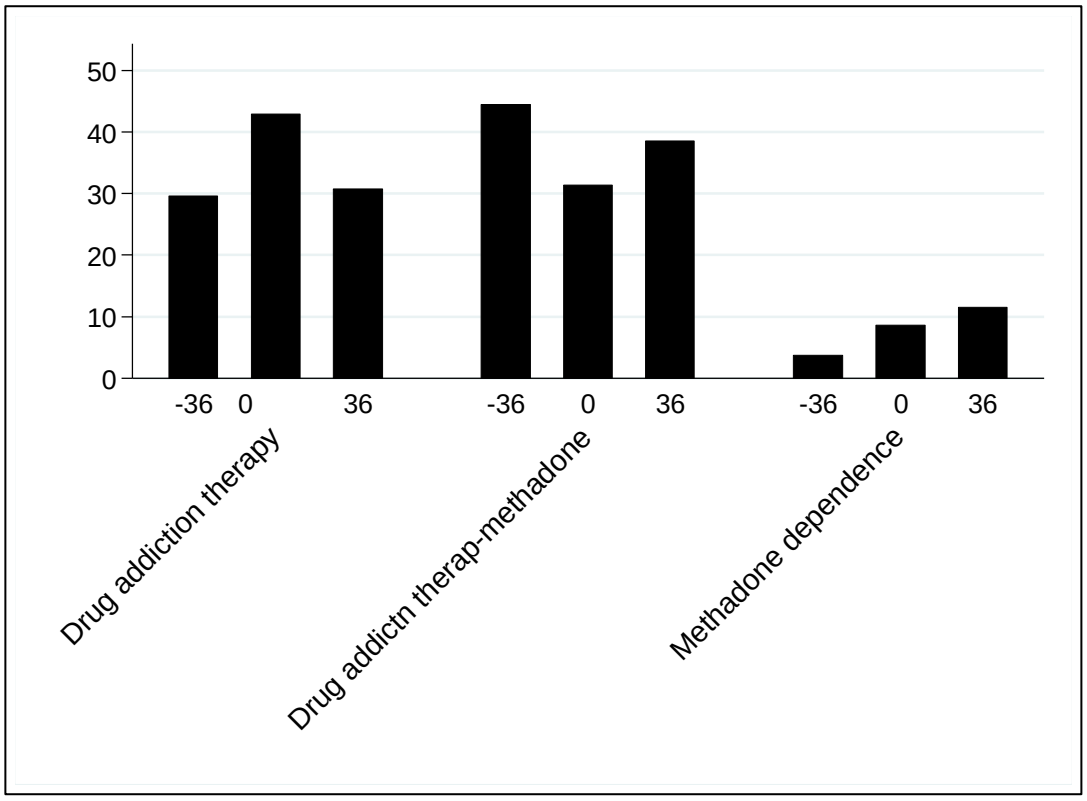


Figure 5:9: Most frequent Read codes for opioid substitution treatment used 36 months in and around pregnancy (-36=36 months before pregnancy, 0=during pregnancy, 36=36 months after pregnancy) Time-periods defined in methods section 5.6.1.2

5.7.4 Sensitivity analysis

Results from the cohort of women permanently registered nine months before, during and after pregnancy were similar to the results from the women in preg_81_cohort. I therefore did not include these results.

5.8 Discussion

5.8.1 Summary of results

A fifth of women in the THIN pregnancy cohort were permanently registered for 36 either side of and during pregnancy. One percent of these women had at least one recording for drug use and/or opioid substitution treatment. Both women with and without a recording for drug use and/or opioid substitution treatment had similar parity. However, women with a recording for drug use and/or opioid substitution treatment were 2 years younger compared to the women without a recording. Women less than 24 years, from the most deprived areas and residing in the North East or East Midlands regions of England were more likely to have a recording for drug use and/or opioid substitution treatment compared with women aged over 40 years, from the least deprived areas and residing in London.

Compared with the time-period during pregnancy, recording of drug use occurred 12% and 13% less during the time periods of 36 months before and 9 months after pregnancy respectively. Approximately 24% more prescriptions for opioid substitution treatment were given 18 to 36 months after pregnancy, compared with during pregnancy.

GPs used both specific and generic Read codes to record drug use in and around pregnancy. The generic Read code, “drug dependence” and the specific Read codes, “heroin dependence” and “benzodiazepine dependence” were used most frequently. GPs prescribed methadone mostly in and around pregnancy for opioid substitution treatment. Finally, GPs used the Read codes “drug addiction therapy” and “drug addiction therapy-methadone” most frequently for recording opioid substitution treatment in and around pregnancy.

5.8.2 Comparison to previous literature

5.8.2.1 Pregnant women who have a recording for drug use and/or opioid substitution treatment

One percent of the pregnant women in my study had a recording for drug use and/or opioid substitution treatment. My findings were similar to the study in the hidden harm report, where a mean of 1% (24 of 2,407, range 1-172) of women in midwifery units disclosed that they used drugs during pregnancy(Advisory Council on the Misuse of Drugs, 2011). However, my findings were lower than findings (range 6.8%-15.6%) from studies that used biological measures of drug use and self-reported questionnaires to measure drug use (Farkas *et al.*, 1995; Fergusson *et al*., 2002; Sherwood *et al.*, 1999). As previously mentioned, the reasons for the differences in these findings could be that disclosure of drug use could be more forthcoming when their identities are anonymous. Additionally the amount of women receiving opioid substitution treatment in my study seems relatively low, as the National Treatment Agency estimated that nearly half of women who were seen by drug treatment services had at least one child and 6% (914 of 16,277) of women who started treatment in 2011/12 were pregnant (National Treatment Agency for Substance Misuse, 2012b). This could indicate that opioid substitution treatment moves from general practice during pregnancy, however transfer of treatment seems to move back to general practice once the baby is born (*see section 5.8.2.3 for details*).

5.8.2.2 Parity and demographics of pregnant women with a recording for drug use and/or opioid substitution treatment

The parity of women in my study was similar to the total fertility rate of 1.85 pregnancies per woman in England and Wales (Office for National Statistics, 2014). Most (30.9%, 26,546 of 85,167) of the pregnant women in my study without a recording for drug use and/or opioid substitution treatment had their first pregnancy when they were between 25-30 years. This corresponds to the average

age for a mother at first birth (27.3 years ± 0.46) in England and Wales between 1994-2012 (Office for National Statistics, 2010). Pregnant women who had a recording for drug use and/or opioid substitution treatment were on average two years younger (26 years, ± 6.1) than women without a recording (28 years ±6.3). Similarly, Farkas *et al.* and Ferguson *et al.* all found that women in England who used recreational drugs during pregnancy were younger than those who did not (27 years compared to 28 years (no significance reported, 25.5 years compared to 27.8 years ($p<0.0001$) respectively) (Farkas *et al*., 1995; Fergusson *et al.*, 2002).

Women residing in the North East and East Midlands regions of England were more likely to have a recording for drug use and/or opioid substitution treatment in my study. Similarly, the highest reported prevalence rates of opioid use by women were in the North East region(9.51 per 1000 women) compared with the South East (5.27) and East of England (5.44) (Hay *et al*., 2013). Additionally, the North East of England has the highest number of emergency admissions (38 per 100 000) with a primary diagnosis of poisoning by illicit drugs among female adults aged between 16-59 years (Hay *et al*., 2013).

5.8.2.3 Timing of recording of drug use and/or opioid substitution treatment in and around pregnancy

The role of a GP in antenatal care has changed over the years in the UK (Smith, *et al*., 2010). Before the 1920s GPs played an integral role in perinatal care and the majority of deliveries were conducted at the mother's home (Smith, *et al*., 2010). The high rate of maternal deaths and stillbirths led to the Confidential Enquiry into Maternal and Child Health in 1952 (Smith, *et al*., 2010). Following this enquiry, recommendations were made which led to an improvement in perinatal care and subsequently both maternal deaths and stillbirths decreased significantly (Smith, *et al*., 2010). Subsequently maternity units were set up in community hospitals in the early 1950s, where GPs worked closely with midwives to provide antenatal care

(Smith, *et al*., 2010). GPs started being less involved in intrapartum care, and by 1970, most of the GP maternity units either closed or became midwife-led units (Smith, *et al*., 2010). Presently there are approximately 243 obstetric units and 116 midwife-led units in the UK (Smith, *et al*., 2010). NICE recommends that all women are referred to antenatal services and women with further difficulties require additional care (National Institute for Clinical Excellence, 2010b). One of these categories that requires additional care are women with "complex and social factors" which includes women who use drugs during pregnancy (National Collaborating Centre for Women's and Children's Health (UK), 2010). Therefore GPs should refer women who use drugs during pregnancy either to the midwife service or directly to the midwife team (National Collaborating Centre for Women's and Children's Health (UK), 2010). Women who are referred to the midwife team are subsequently triaged to the specialist midwife team.

It was evident in my study that there was a higher proportion of recording of drug use and/or opioid substitution treatment nine months before the start of pregnancy. In other words, GPs may have been enquiring about drug use before pregnancy and/or women may have disclosed information about drug use more before conception. Even though GPs may not provide care during pregnancy, the Royal College of General Practitioners recommended that GPs should provide pre-pregnancy counselling and support for women of child bearing age, especially if the woman has existing medical or mental health issues (Royal College of Obstetricians and Gynaecologists, 2010).

In contrast, recording for both drug use and prescriptions for opioid substitution treatment decreased during pregnancy. This decrease in recording could be due to four factors. Firstly, some of the care of women regarding her pregnancy moves from general practice into the midwifery services during pregnancy (National Institute for Clinical Excellence, 2010b). A referral letter should be sent by the GP

to the service and a discharge letter should be sent back to the GP at the end of the pregnancy (Perinatal Institute, 2015). Although the information is in letter form and may be scanned into the patient's electronic health records, however, the GP may not always record the information from the discharge letter using Read codes. Secondly, a specialist midwifery team usually takes over the management of the individual and prescribes appropriate opioid substitution treatment, which would not be coded in the patient's electronic records during pregnancy (National Institute for Clinical Excellence, 2010c). Thirdly, a woman may underreport or chose not to disclose drug use, as there is a fear that the baby would be taken away by social services (National Collaborating Centre for Women's and Children's Health (UK), 2010). Lastly, evidence suggests that women may reduce their drug intake during pregnancy as it is a critical time where women may be more motivated to modify their behaviour in order to decrease adverse effects on her unborn child (Australian Institute of Health and Welfare, 2015; Crozier *et al*., 2009; Ebrahim and Gfroerer, 2003; Moore *et al*., 2010). Behaviour change during pregnancy was highlighted by the Southampton Women's study (self-reported questionnaire, n=1490) where women decreased adverse health behaviours, such as smoking, drinking alcohol and drinking caffeinated drinks. However, women in the study, who were younger and less educated were less likely to change these negative behaviours (Crozier *et al*., 2009). Moore *et al.* (n=171, self-reported questionnaire) found that pregnant women in London were more likely to decrease alcohol and ecstasy use during pregnancy, however, they did not reduce smoking or cannabis use (Moore *et al*., 2010). Furthermore, Ebrahim and Gfroerer analysed the National Household Survey in the USA between 1996-1998 and found that 28% of women who previously used drugs, stopped during pregnancy and this increased to approximately 93% in the third trimester (Ebrahim and Gfroerer, 2003). Women in my study who had a recording for drug use were also younger. Although there is some evidence that women change their drug behaviour during pregnancy, the cessation of drug use can be difficult, especially if the woman has become a problem drug user (*see section 1.3.2.4*).

Finally, prescriptions for opioid substitution treatment increased after pregnancy. This may indicate that the care and treatment of the women moves back into general practice after the baby is delivered (National Collaborating Centre for Women's and Children's Health (UK), 2010).

5.8.2.4 Codes used most frequently by GPs to record drug use and/or opioid substitution treatment in and around pregnancy

Read codes for drug use

GPs used generic Read codes more for recording drug use; however, the specific codes for heroin and benzodiazepine dependence were also frequently used in and around pregnancy. This is different to other studies who all found that most of the pregnant women who tested positive for drug use, used cannabis (Farkas *et al*., 1995; Fergusson *et al*., 2002; Sherwood *et al*., 1999). Sherwood *et al.,* also found that 0.5% (4/807) of women tested positive for benzodiazepine use, and Farkas *et al.* showed that 1.4% (14/1000) of the women tested positive for opiate use (Farkas *et al*., 1995; Sherwood *et al*., 1999). However, as mentioned before, both these studies were in a clinical rather than a primary care setting and signed consent was not required. Two specific Read codes for drug addiction therapy and opioid drug dependence were only used after pregnancy, which could indicate that the GP coded this information from the discharge letter. The reason that GPs may be using generic codes is that poly-drug use is common in people who use drugs (Drugscope, 2015c; National Treatment Agency for Substance Misuse, 2010). However, both heroin and benzodiazepine dependence have serious and conclusive consequences for the baby including neonatal abstinence syndrome (Hudak *et al*., 2012).

Prescriptions for opioid substitution treatment

Methadone was the most common opioid substitution treatment prescribed. Buprenorphine and dihydrocodeine were also prescribed, but at a lower frequency.

Methadone is the recommended opioid substitution treatment for pregnancy, as buprenorphine is not yet licensed for use during pregnancy in the UK (Whelan and Remski, 2012). However, there is increasing evidence that buprenorphine is safe to use during pregnancy (Jones *et al*., 2010; Unger *et al*., 2011). Therefore the recommendation in the UK for women who are stable on buprenorphine before pregnancy is that they should remain on buprenorphine during pregnancy (Johnson *et al*., 2003). My study suggests that this occurs for some of the women receiving opioid substitution treatment. Results from my study also show that some GPs are prescribing dihydrocodeine in and around pregnancy. Dihydrocodeine is not licensed for opioid substitution treatment in the UK, however, it has been used to wean the patient off opioids (Mawhinney *et al*., 2006; Robertson *et al*., 2006; Swadi *et al*., 1990).

5.8.3 Conclusion

The findings illustrate the tip of the iceberg with regards to drug use and opioid substitution treatment in and around pregnancy. Although many women may not have contact with their GP during pregnancy, the majority have contact at the beginning of and after their pregnancy. These may be critical time-points when GPs could ask about drug use. If GPs chose to record in the electronic health records, the records could contribute to the continuation of care and support to both mother and child.

5.9 How Does This Chapter Support My Thesis?

Drug use and/or opioid substitution treatment during pregnancy is a multifaceted public health problem which can not only impact seriously on the health of the mother, but also for her foetus and developing child. An indirect way of measuring drug use during pregnancy is to observe the outcomes of a newborn baby. Neonatal Abstinence Syndrome (NAS) has been found to be a definitive indicator of drug use and/or opioid substitution treatment during pregnancy. Infants born from women who take opioids, benzodiazepine and barbiturates are at risk of

having NAS. In the second study Read codes for heroin dependence benzodiazepine dependence were frequently used and methadone and buprenorphine were the most common opioid substitution treatments prescribed. I will therefore examine the recording rate of NAS in THIN in the next chapter to ascertain an indirect measure of drug use during pregnancy.

CHAPTER 6 STUDY 3: GP RECORDING OF NEONATAL ABSTINENCE SYNDROME

6.1 Content and Structure of Chapter 6

In this chapter, I describe and discuss my third study, which focuses on recording of Neonatal Abstinence Syndrome (NAS). I include infants that are permanently registered with a practice within the first 6 months of their life and link them to the pregnant women in the second study (Chapter 5) to ascertain if any of these women with a recording for drug use and/or opioid substitution treatment also have an infant with a recording for NAS. I also compare the rates of recording of NAS in both primary and secondary care and assess how much information regarding NAS is being transferred to primary care in electronic health records. This chapter contains the introduction, aim, specific objectives, methods, results and discussion for the third study.

This study addresses the third objective of my PhD (*see section 2.4 for details*) and will also contribute to answering the second part of my main research questions as NAS could be an alternative method for examining drug or opioid use during pregnancy (*section 2.3*):

1. *Can a large primary care database (The Health Improvement Network (THIN)) be used as a surveillance tool for understanding drug use and opioid substitution treatment in the general population and specifically during pregnancy (in England and Wales)?*
2. *Can a large primary care database (THIN) be used as a tool to research drug use and opioid substitution treatment in general practice in the general population and specifically during pregnancy (in England and Wales)?*

Part of this chapter has been published in the *Archives of Disease in Childhood-BMJ*, 2015 (*Journal article is included in Appendix 11*)

6.2 Introduction

Misuse of addictive drugs, particularly opioids during pregnancy is a multifaceted public health problem (Madgula *et al*., 2011; O'Donnell *et al*., 2009). Opioid use during pregnancy can have serious adverse effects on both the mother and her foetus, including NAS which affects an estimated 60-80% of babies born to opioid users (Doberczak *et al*., 1991). Causes of NAS include prescribed opioid replacement therapy (namely methadone or buprenorphine) and/or heroin and other opioids (Hudak *et al*., 2012). Foetal exposure to benzodiazepine, barbiturates, selective serotonin reuptake inhibitors (SSRIs) also contributes to a small proportion of NAS. (Hudak *et al*., 2012; Klinger and Merlob, 2008).

Babies affected by NAS present with symptoms within hours of birth such as feeding difficulties, irritability, seizures and respiratory distress, due to the effect of drug withdrawal on multiple organs (Lloyd and Mysercough, 2006; O'Donnell *et al*., 2009; O'Grady *et al*., 2009). Neonatal treatment of NAS can require intensive care and prolonged hospitalisation (Johnson *et al*., 2003; O'Donnell *et al*., 2009; Uebel *et al*., 2015a). Opioid misuse during pregnancy is associated with preterm birth and poor foetal growth, but it is not clear whether these effects are caused by opioid misuse, other drug misuse or maternal mental health problems and/or an adverse environment (Abdel-Latief *et al*., 2013; Hudak *et al*., 2012). Compared with the general population, children born with NAS are at increased risk of neglect and other forms of child maltreatment during their childhood and their mother is more likely to die during their childhood (Kahila *et al*., 2010; O'Donnell *et al*., 2009; Uebel *et al*., 2015a). There is also a risk of the infant being taken away from the mother however, if the child remains with the mother and the mother is identified by the GP, the GP has a unique advantage of identifying the child too and could provide continuous support to both mother and child (Advisory Council on the Misuse of Drugs, 2011).

Information on the burden of NAS is important for maternity, neonatal, child health and welfare services, primary care and policy on drug prevention and treatment (O'Donnell *et al*., 2009). The prevalence of NAS has been examined in Scotland, Western Australia and the USA in secondary care (National Statistics Scotland, 2012; O'Donnell *et al*., 2009; Patrick *et al*., 2012). There was however, no population-based information on the prevalence of NAS in primary and secondary care in England and Wales. To achieve this, the infant needs to be diagnosed and recorded for NAS in secondary care initially. This information should be on the discharge records, and the GP should receive a summary of these discharge records. NAS is a definitive outcome and therefore an indirect measure of drug or opioid use during pregnancy. As a result, I wanted to explore if recording of NAS in electronic health records could be an approach to estimating the incidence of opioid drug use during pregnancy. In order to calculate recording rates of NAS, I used Read codes in primary care and International Classification of Disease-10 codes in secondary care to compare trends over time. I also examined demographic and other factors associated with a recording of NAS and examined how many mothers with a recording for drug use also had a baby with a recording for NAS.

6.3 Aims of Study 3

To explore recording of NAS, a symptom of drug use during pregnancy in primary and secondary care.

6.4 Specific Objectives of Study 3

1. Develop a list of Read codes for NAS in primary care
2. Identify infants who have a Read code indicated for NAS and examine the demographics of infants with and without a recording for NAS in primary care

3. Calculate the recording rate of NAS per 1,000 live births in primary care
4. Calculate the recording rate of NAS per 1,000 live births in secondary care and compare how much of this information is entered in primary care electronic health records

6.5 Hypotheses for Study 3

Hypothesis 1: Recording rates of NAS are the same in THIN and HES between 1997-2011

Hypothesis 2: The time-trends for recording of NAS are similar compared with HES

6.6 Methods

I only had access to births in England from Hospital Episode Statistics (HES) and therefore restricted my analysis in THIN to infants born in England.

6.6.1 Methods for THIN

6.6.1.1 Read code list for Neonatal Abstinence Syndrome (NAS)

I developed a Read code list according to the methods described by Davé and Petersen, 2009, in order to identify infants who had a recording for NAS. I used search terms from the literature to develop my Read code list (O'Donnell *et al*., 2009; Patrick *et al*., 2012) (Table 6.1).

Table 6.1: Search terms for developing a Read code list for Neonatal Abstinence Syndrome

Search terms used for Read codes for Neonatal Abstinence Syndrome	
neonatal abstinence syndrome	withdrawal syndrome
neonatal withdrawal syndrome	maternal drug use
NAS	drug use during pregnancy
abstinence syndrome	

Once I had developed the Read code list for NAS, with clinical guidance from a GP, I manually examined the list and took out any duplicates or any Read codes that had an ambiguous meaning.

Defining the denominator (Infants aged between 0-6 months) in THIN

I obtained records for infants aged between 0-6 months and permanently registered in the same general practice in England. I will refer to this group of infants as the THIN_birth_cohort. I retained the electronic health records for all infants who were born between the financial years of 1997 and 2011 (31 March 1997-1 April 2012). This time period is slightly different to the time-period used for the first two studies (1994-2012 *see section 4.4 and 5.4*). The reason for the difference is that birth records in HES were only available between the financial years of 1997 and 2011 and I therefore decided to examine infants for the same time period in THIN. I used the live births for each calendar year as the denominator when calculating the recording rate of NAS per 1,000 live births in THIN.

6.6.1.2 Defining the numerator (Infants with a Read code for Neonatal Abstinence Syndrome) in THIN

I merged the THIN_birth_cohort with the Read code list for NAS to obtain the number of infants with and without a recording for NAS. I used the number of infants recorded with NAS for each calendar year as the numerator when calculating the recording rate of NAS per 1,000 live births in THIN.

6.6.1.3 Demographics for infants with and without a Read code for Neonatal Abstinence Syndrome.

6.6.1.3.1 Demographics

I examined the gender, deprivation and strategic health authority (region) for infants with and without a recording for NAS.

6.6.1.3.2 Infants with and without NAS linked to a mother

Mothers and infants can be linked in THIN, if both records have the same family identifier codes, delivery month (mother) and birth month (infant). In order to identify how many infants with and without a recording for NAS had a mother with a recording for drug use and/or opioid substitution treatment, I merged the THIN_birth_cohort with the preg_81_cohort (from my second study*, section 5.6.1.2*). I examined the women who were identified as a mother of an infant in the THIN_birth_cohort to see if they had a recording for drug use and or opioid substitution treatment.

6.6.2 Methods using Hospital Episode Statistics (HES)

6.6.2.1 Defining the denominator (Infants 0-6 months) extracted from HES

I used pseudonymised data from HES(see *section 3.5.1*) for all infant admissions (up to the age of 6 months) to the NHS in England in financial years of 1997 to 2011 (Health and Social Care Information Centre, 2012).

The denominator population was all singleton live birth admissions to the NHS in England (comprising 96% of all births) (Birthplace in England Collaborative Group *et al*., 2011; Health and Social Care Information Centre, 2012). I excluded all births identified as stillborn based on method of discharge or birth status (Health and Social Care Information Centre, 2012). To minimise the risk of double counting cases, I restricted analyses to single births and in addition, excluded duplicate records by searching for the same HES identifier (HES ID) or for identical clusters of characteristics (e.g. birth weight, date of episode start, age, birth order) with different HES IDs (Health and Social Care Information Centre, 2012; Murray *et al*., 2013). I used the live births for each calendar year as the denominator when calculating the recording rate of NAS per 1,000 live births in HES

6.6.2.2 Defining the numerator (Infants with a recording for NAS)

I searched the ICD-10 code dictionary (*see section 3.5.1*) and literature for codes that indicated NAS (O'Donnell *et al*., 2009; Patrick *et al*., 2012; World Health Organisation, 2010). Together with a neonatologist (Dr Kathryn Johnson) and clinical paediatric epidemiologist (Professor Ruth Gilbert), we examined and kept the following relevant codes: P96.1 ("Neonatal withdrawal symptoms from maternal use of drugs of addiction", or P04.4 ("Foetus and newborn affected by maternal use of drugs of addiction"). These codes detect any neonatal abstinence syndrome and have previously been shown to be specific for NAS managed by clinicians in studies of clinical records (O'Donnell *et al*., 2009; Patrick *et al*., 2012). For the numerator, I identified singleton babies with records for NAS based on the ICD-10 diagnostic codes up to 6 months of age (Health and Social Care Information Centre, 2012; World Health Organisation, 2010). I used the number of infants with a recording of NAS for each calendar year as the numerator when calculating the recording rate of NAS per 1,000 live births in HES.

6.6.3 Statistical Analysis

All data was analysed using STATA (version 13) statistical software (Stata Corp LP, College Station, Texas).

6.6.3.1 Statistical analysis for THIN

I calculated the following for infants (0-6 months) in THIN_birth_cohort:

1. Most frequently used Read codes used for recording NAS
2. Number of infants with and without a recording for NAS
3. Distribution and unadjusted and adjusted odds ratios with 95% confidence intervals for gender, deprivation, region for infants with and without a recording for NAS. I examined if there was effect modification by gender, deprivation and region (Kirkwood and Sterne, 2003). If there was evidence

of effect modification, I stratified the covariate. In order to select which model fitted the data the best, I carried out hypothesis testing using likelihood tests (Kirkwood and Sterne, 2003).

4. Recording rate per financial year (1997-2011) for NAS per 1,000 live births

6.6.3.2 Statistical analysis for HES

1. I calculated the annual recording rates for NAS per 1,000 live births in England (1997-2011) infants in HES.
2. I compared recording rates of NAS in THIN and HES by comparing intercepts and 95% confidence levels and beta coefficients using the *suest* command in stata

6.7 Results

6.7.1 Results for THIN

6.7.1.1 Possible Read codes for neonatal abstinence syndrome (NAS) in primary care

There were four Read codes available for GPs to record NAS in primary care. The most commonly (0.04%, 254/637,707) used Read codes that GPs used to record NAS was “Neonatal abstinence syndrome” (Table 6.2).

Table 6.2: Frequency of Read codes used to record Neonatal Abstinence Syndrome (NAS)

Read code	Description	Frequency (%) N=637,707
14I6.00	H/O: neonatal abstinence syndrome	3 (0.0004)
Q485000	Neonatal withdrawal symptom from maternal use of drugs	109 (0.02)
Q485200	Neonatal abstinence syndrome	254 (0.04)
Q485.00	Newborn drug withdrawal syndrome	120 (0.02)

Total	486 (0.08)

N=number of infants in cohort

6.7.1.2 Infants who have a Read code indicated for NAS and demographics of infants with and without a recording for NAS in primary care

There were 809,227 infants who were born and registered with the same practice in the UK for the first six months of their lives. Of these infants, 637,707 (79.3%, 637,707 /809,227) were from England and born between 1 April 1997 and 31 March 2012. I will now refer to this group of infants as the THIN_birth_cohort. Within the THIN_birth_cohort, 486 (0.08%, 486/637,707) infants had a recording for NAS (Table 6.3).

6.7.1.3 Statistical model

I observed no effect modification by any of the covariates. There were slightly more males than females, but this was not statistically significant. Infants from the most deprived areas were two times (Unadjusted OR=2.18, 95% CI: 1.59-2.98) more likely to have a recording for NAS compared with infants in the least deprived areas. Additionally, infants from the North East region of England were 3.5 times (Adjusted OR=3.59, 95% CI: 2.28-5.66) more likely to have a recording of NAS compared to infants in London.

Table 6.3: Demographics of infants with and without a recording for Neonatal Abstinence Syndrome (NAS)

Infants born between 1 April 1997 and 31 March 2012 in England (N=637,707)						
	No NAS recording N=637,221(99.92%)	Rate per 1000 live births	NAS Recording N=486 (0.08%)	Rate per 1000 live births	Unadjusted OR (95% CI)	*Adjusted OR (95% CI)
Gender	**N (%)**		**N (%)**		**OR (95% CI)**	
Male	326,190 (51.2)	999.19	265 (54.5)	0.81	1	
Female	311,027 (48.8)	999.29	221 (45.5)	0.71	0.87 (0.73-1.04)	
Deprivation	**N (%)**		**N (%)**		**OR (95% CI)**	**OR (95% CI)**
1 least deprived	135,292 (21.2)	999.50	68 (13.8)	0.50	1	1
2	111,108 (17.4)	999.32	76 (15.5)	0.68	1.36 (0.98-1.88)	1.36 (0.98-1.89)
3	126,941 (19.9)	999.21	100 (20.4)	0.79	1.56 (1.15-2.13)*	1.64 (1.21-2.24)*
4	129,203 (20.3)	999.10	117 (23.8)	0.90	1.80 (1.34-2.43)*	1.89 (1.39-2.55)*
5 most deprived	97,892 (15.4)	998.95	**103 (22.0)**	**1.05**	**2.09 (1.54-2.84)****	**2.18 (1.59-2.98)****
Missing	36,785 (5.8)	999.40	22 (4.5)	0.60		
Region	**N (%)**		**N (%)**		**OR (95% CI)**	**OR (95% CI)**
London	94,604 (14.8)	999.60	38 (7.8)	0.40	1	1
East Midlands	25,043 (3.9)	998.80	30 (6.2)	1.20	2.99 (1.85-4.84)**	3.29 (2.03-5.33)**
East of England	72,388 (11.3)	999.13	63 (11.9)	0.87	2.17 (1.45-3.25)**	2.54 (1.69-3.83)**
West Midlands	73,440 (11.5)	999.27	54 (11.3)	0.73	1.87 (1.24-2.83)**	2.05 (1.35-3.11)**
North East	25,804 (4.0)	998.57	37 (7.6)	**1.43**	**3.59 (2.28-5.64)****	**3.59 (2.28-5.66)****
North West	71,880 (11.3)	999.00	72 (13.4)	1.00	2.52 (1.70-3.73)**	2.69 (1.81-3.99)**

Infants born between 1 April 1997 and 31 March 2012 in England (N=637,707)						
	No NAS recording N=637,221(99.92%)	Rate per 1000 live births	NAS Recording N=486 (0.08%)	Rate per 1000 live births	Unadjusted OR (95% CI)	*Adjusted OR (95% CI)
Y&H	27,585 (4.7)	998.91	30 (6.8)	1.09	2.76 (1.73-4.39)**	2.99 (1.84-4.84)**
South Central	97,555 (15.2)	999.35	63 (13.1)	0.65	1.61 (1.08-2.41)**	1.94 (1.28-2.92)**
South East Coast	75,268 (11.8)	999.40	45 (9.2)	0.60	1.49 (0.96-2.29)	1.74 (1.12-2.71)**
South West	73,654 (11.5)	999.27	54 (10.9)	0.73	1.83 (1.20-2.78)**	2.10 (1.38-3.19)**

*Adjusted for deprivation and region **significant, OR=Odds Ratio, Y&H=Yorkshire and Humberside

6.7.1.4 Infants with and without NAS linked to a mother

Of the infants in the THIN_birth_cohort, 17.6% (112,283 of 637,707) were linked to a mother in the preg_81_cohort. Within the group of infants linked with a mother, 0.03% (29 of 112,283) had a recording for NAS. Additionally only half (55%, 16 of 29) of the mothers who were linked with an infant with NAS had a recording for drug use and/or opioid substitution treatment (Figure 6:1).

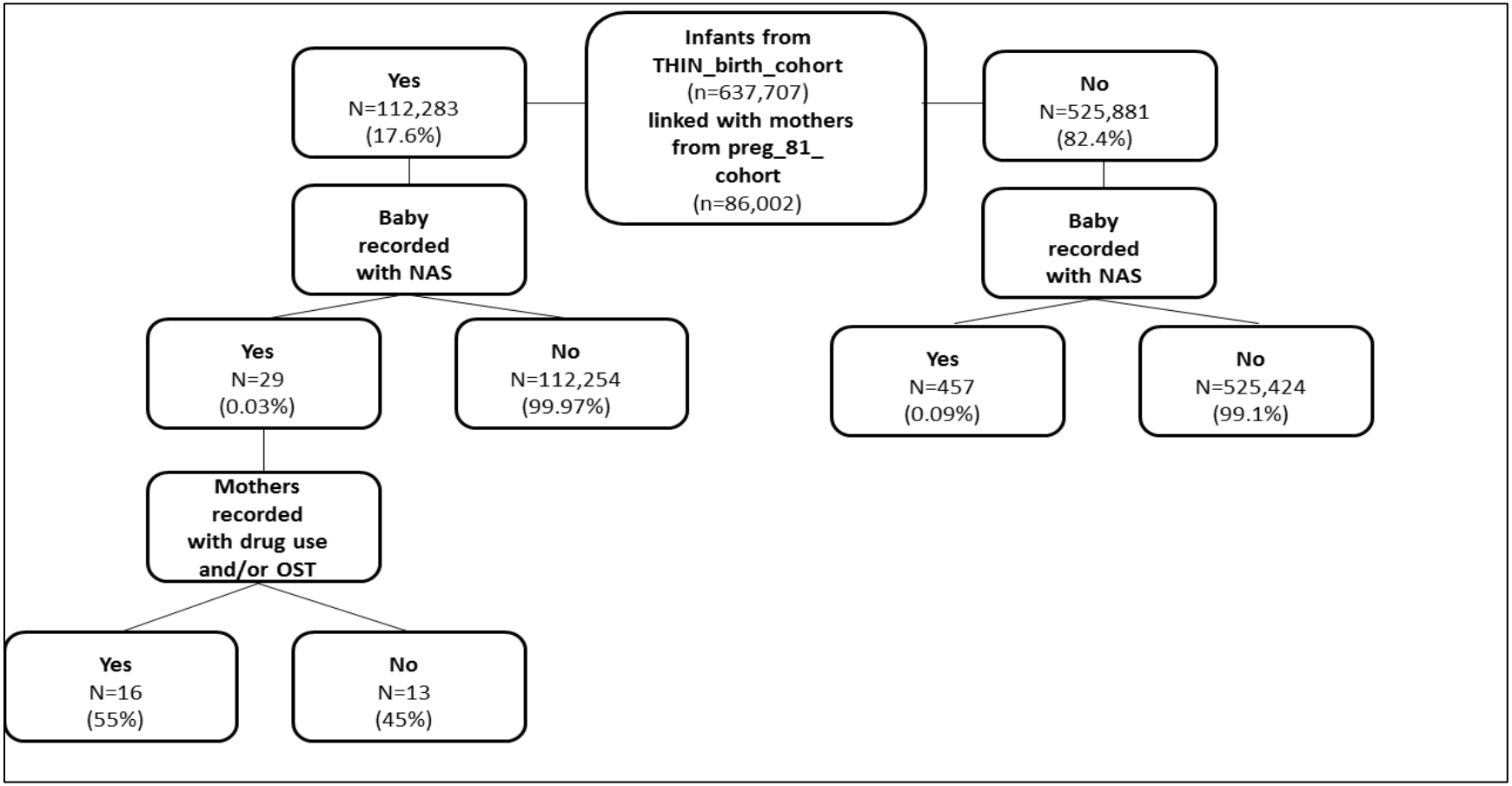


Figure 6:1: Infants linked with mothers in THIN with a recording or no recording for NAS (OST=Opioid substitution treatment)

6.7.1.5 Recording rate of NAS per 1,000 live births in primary care

Of the 637,707 infants born between the financial years of 1997-2011 in England, 0.08 (486 of 637,707) had a recording of NAS. A mean of 30.4 (sd = ± 13.2) babies had a recording for NAS per year. The mean recording rate of NAS was 0.78 (sd = ± 0.33) per 1000 live births for the entire period and 1.03 for the most recent year, 2011. The recording rate increased six fold between 1997 and 2005. The rate then fluctuates until it reaches a five-fold increase (compared with 1997) in 2011 (Figure 6:2).

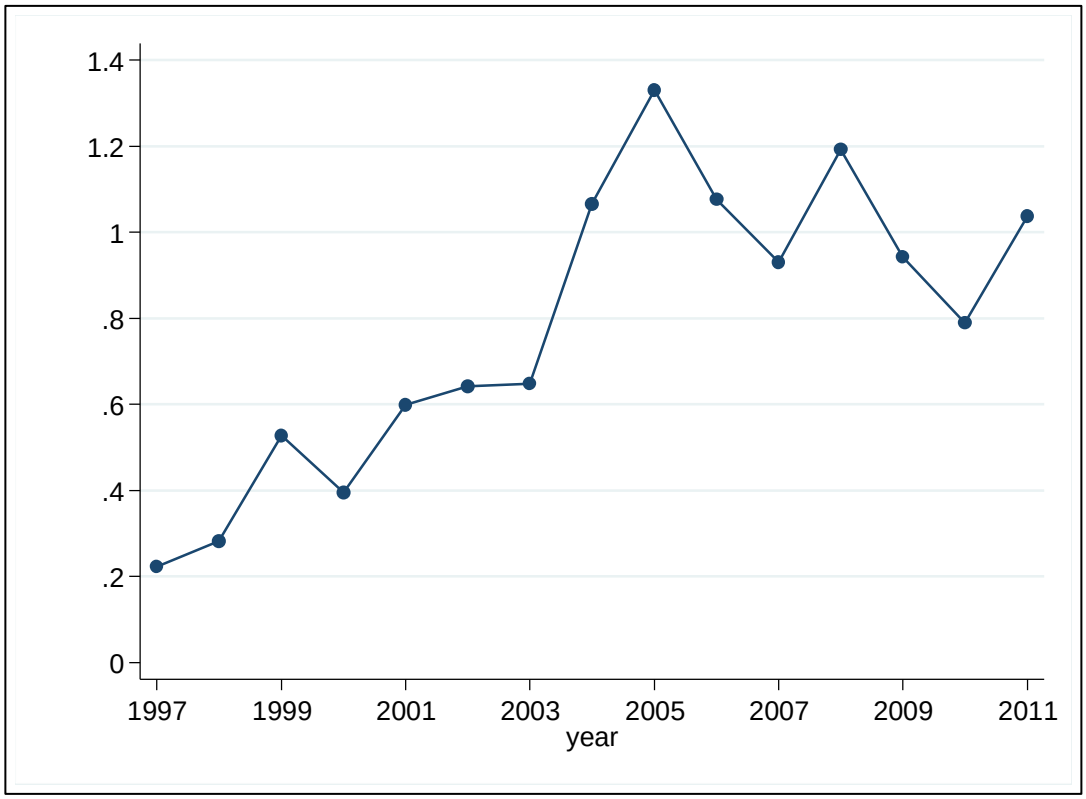


Figure 6:2: Recording rates of NAS per 1000 live births in THIN (1997-2011)

6.7.2 Results for HES

6.7.2.1 Recording rate of NAS per 1,000 live births in secondary care

There were 8,956,382 live births deliveries in hospital between 1997 and 2011, of which 22,681 neonates had records indicating NAS (a mean of 1,515 (sd = ± 254)

babies per year). The mean prevalence rate of NAS was 2.6 per 1,000 live births for the entire period and 2.7 for the most recent year, 2011. Figure 6:3 shows a 2.5 fold increase in the prevalence of recorded NAS between 1998 and 2004. The rate then approximately remained stable until 2011.

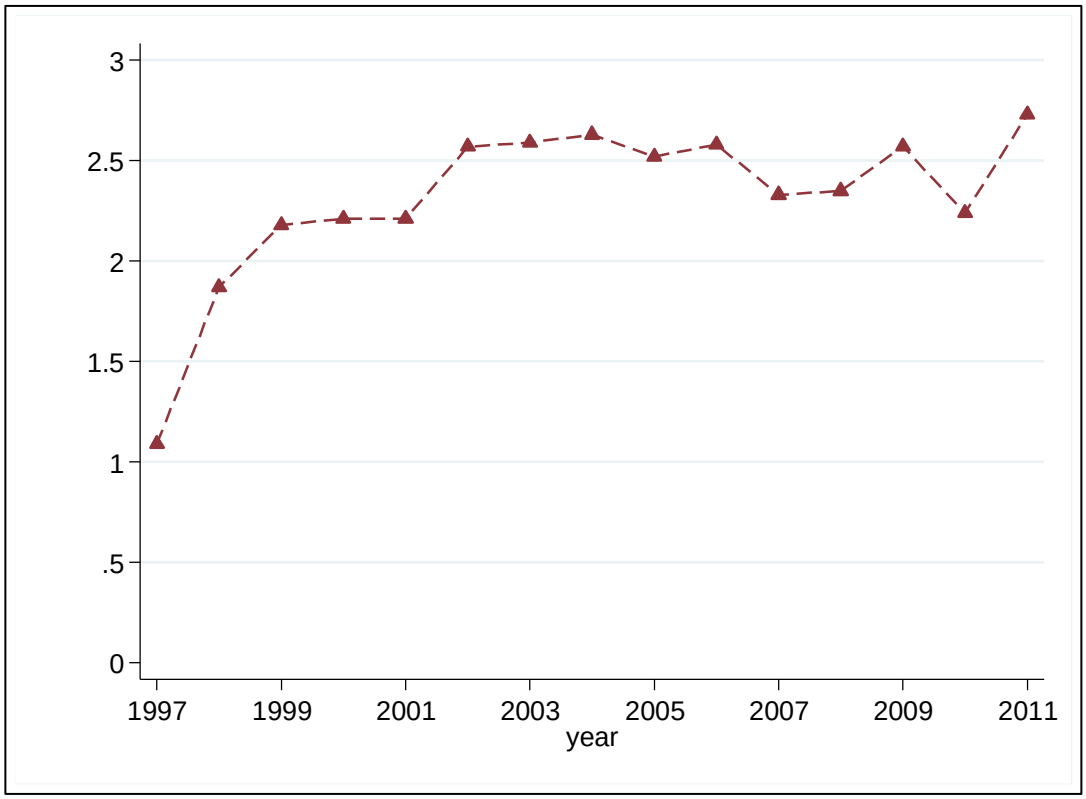


Figure 6:3: Recording rate of NAS per 1000 live births in HES (1997-2011)

6.7.2.2 External validation of the proportion of recording of NAS in both HES and THIN and accept or reject hypotheses 1 and 2

The total number of infants with NAS divided by the total births (between 1997 and 2011) was a third (0.32, 0.77/2.41) lower in THIN than in HES. I rejected the first hypothesis as the intercepts of the two models are significantly different as the confidence intervals do not overlap (HES: 1.89 per 1000 living birth 95% CI: 1.54-2.25) and THIN: 0.35 per 1000 living birth, 95% CI: 0.12-0.62) suggesting that recording rates were significantly lower in THIN compared with HES.

The Beta coefficients (the slope of the two models) were not significantly different (X^2=0.01, p=0.9415), therefore I accepted the second hypothesis as time-trends for the recording of NAS in THIN and HES are similar.(Figure 6:4).

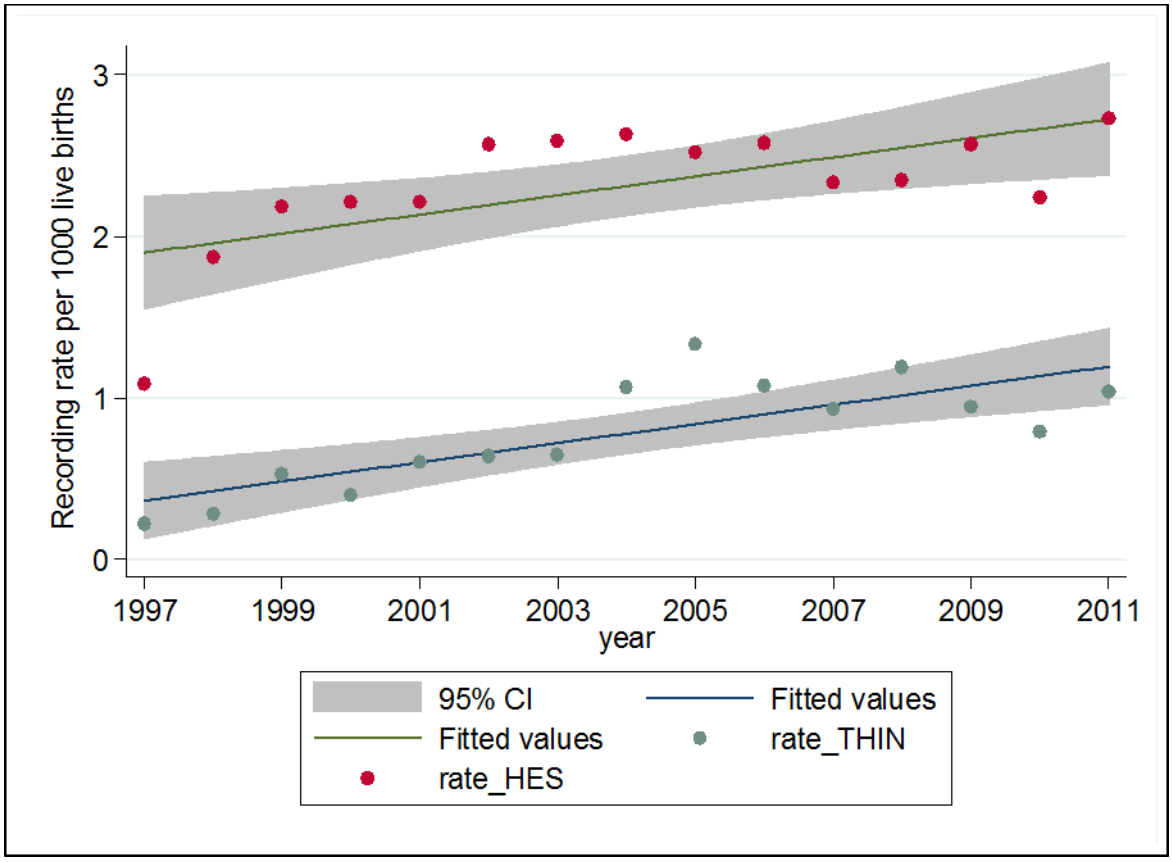


Figure 6:4: Recording rate of NAS per 1000 live births in THIN and HES (1997-2011)

6.8 Discussion

6.8.1 Summary of results

There were 637,707 infants registered permanently with a practice in England participating in THIN between the financial years of 1997-2011. Of these 0.08% had a recording for NAS. Infants in the most deprived areas and in the North East region of England were more likely (2 and 3.5 times respectively) to have a recording for NAS. Only 0.03% infants with a recording for NAS were linked to a mother and of those, only half were linked to a mother who had a recording for

drug use and/opioid substitution treatment. The mean recording rate of NAS in primary care was 0.78 (±0.33) per 1,000 live births and the most recent recording rate was 1.04 per 1,000 live births in 2011. In contrast the mean recording rate for NAS in secondary care was almost three (2.9, 2.3/0.78) times that of secondary care. Approximately a third of the recording of NAS in the hospital setting is recorded in primary care. There were four possible Read codes for NAS that were available for GPs to use in primary care and the most frequently used was "Neonatal Abstinence Syndrome".

6.8.2 Comparison to previous literature

6.8.2.1 Annual recording rates of NAS

The increase in recording of NAS seen in both primary and secondary care may reflect increased recognition or recording of drug use during pregnancy and/or recognition or recording of NAS. The increase in detection of NAS seen in both primary and secondary care in the late 1990s coincided with a Department of Health recommendation that obstetric departments establish good links with addiction centres, GPs and social services (Department of Health, 1999). The small decline in NAS in both primary (after 2005) and secondary care (after 2006) may reflect the declining number of women entering treatment for opiate addiction, which may relate to decreased use, or decreased contact with drug treatment centres and hence notification of obstetric and neonatal services (House of Commons Home Affairs Committee, 2013; National Treatment Agency for Substance Misuse, 2010). Furthermore, addiction services were vulnerable to funding cuts which may partly account for the variation in recent years (National Treatment Agency for Substance Misuse, 2012a).

The increase in recording of NAS in both primary and secondary care could also be attributed to increased analgesic opioid use. There has been a significant rise in recording of NAS in Scotland and the USA which is thought to reflect partly the

growing use of opiate analgesics (National Statistics Scotland, 2012; Patrick *et al*., 2012). Since 2000, prescription opioids have replaced heroin addiction as the main reason for starting methadone in Toronto.(Kuehn BM, 2007; Manchikanti *et al*., 2012). A national survey of drug use in the USA reported that sources of opioid analgesics included prescriptions for the women themselves, analgesics obtained from family members, and direct purchase of opioid analgesics over-the web or, in some US states (Kuehn BM, 2007; Manchikanti *et al*., 2012; National Institute of Drug Abuse, 2014). The increase of recording of NAS in Western Australia in the 1990s was attributed to increasing heroin and methadone use, which has since stabilised (O'Donnell *et al*., 2009). However, there is increasing evidence that a similar problem with regards to the misuse of prescription opioids is developing in Australia (Dobbin, 2014). Evidence is still lacking about whether maternal use of opioid analgesics is increasing in the UK (House of Commons Home Affairs Committee, 2013; Stannard, 2013). There is however evidence in my second study (*section 5.7.3*) which suggests that GPs are aware and record opioid use in and around pregnancy. One of the most frequently used Read codes for drug use in and around pregnancy was "opioid type drug dependence"; it is likely this Read code could be used for recording opioid type drugs other than heroin.

This is the first external validation study to illustrate how much of the recording of NAS from secondary care entered into the primary care electronic health records. My results indicated that a third of the information from secondary care is being entered into the electronic health records as Read codes in primary care. However, the fact that the infant had NAS may still be in the electronic health records but in the scanned discharge letter and not as a Read code.

6.8.2.2 Babies with NAS linked with mothers

Few infants with a recording for NAS could be linked to a mother through electronic health records in primary care. To date there are no other studies which link the

records of mothers who use drugs and or opioid substitution treatment and their infants in primary care in the UK. In Hospital Episode statistics mother and baby records are also not linked (Health and Social Care Information Centre, 2012). Primary and secondary health care systems in other countries vary and it is therefore difficult to make a direct comparison. An example of this is in Australia, where the infants can be linked to the mother's records using hospital administrative data (O'Donnell *et al*., 2009). O'Donnell *et al* linked 802 infants recorded with NAS with mothers who used drugs. With regards to primary care, the management of drug users by GPs is a complex and controversial issue (Advisory Council on the Misuse of Drugs, 2011). Nevertheless, my first two studies indicated that treatment of drug use is occurring in primary care. Likewise, the Hidden Harm report suggests that although there are primary care teams providing management for drug use, there seems to be less focus on the children (Advisory Council on the Misuse of Drugs, 2011). A reason for why my results indicated such a low number of linked infants with a recording for NAS and women who use drugs is that if the woman reveals information about drug use they run the risk of being separated from their baby (Advisory Council on the Misuse of Drugs, 2011). Their baby may then be taken into care, assigned a new NHS number, registered with a different general practice and their records would therefore not be linked.

6.8.2.3 Demographics and NAS

6.8.2.3.1 Gender

There was no difference with regards to gender and a recording of NAS in my study. This was the same in other countries which have looked at the gender of the infant and recording of NAS (O'Donnell *et al*., 2009; Patrick *et al*., 2012)

6.8.2.3.2 Deprivation

My study found that children in more deprived areas were more likely to have a recording for NAS. There are currently no other studies in the UK looking at the

deprivation of infants with a recording for NAS. However there are numerous studies in other countries highlighting that mothers who give birth to an infant with NAS are more likely to come from disadvantaged groups (O'Donnell *et al*., 2009; Patrick *et al*., 2012). Additionally, the Hidden Harm report suggests that the majority of children of drug users are from the most deprived areas (Advisory Council on the Misuse of Drugs, 2011).

6.8.2.3.3 Region

My results showed that infants in the North East were more likely to have a recording for NAS. Additionally the highest reported prevalence rates of opioid use by women were in the North East and North West (9.5 per 1,000 population) regions of England in 2011/12, compared with the lowest rate in South East and East of England (5.3 per 1,000 population) (Health and Social Care Information Centre, 2013). The North East of England also has the highest number of emergency admissions (38 per 100,000) with a primary diagnosis of poisoning by illicit drugs among female adults aged between 16-59 years (Health and Social Care Information Centre, 2013)

6.8.2.4 Read codes

To date there have been no previous studies looking at the specificity and sensitivity of Read codes used to record NAS in primary care. Nevertheless, the Read codes that I identified in THIN were clinically scrutinized by a GP and myself and any codes with ambiguous meaning were removed. Furthermore, if NAS is diagnosed and recorded in secondary care it should also be recorded in the discharge summary records of the infant which is later sent to the GP (British Medical Association, 2014). The discharge summary transfers the care of the individual from the hospital to the GP (British Medical Association, 2014). There are several objective scoring systems used to diagnose NAS (O'Grady *et al*., 2009). In a national survey of practice in the UK and Ireland, O'Grady *et al,* 2009,

reported the use of different protocols and screening tools in neonatal units and some units had no protocol in place (O'Grady *et al*., 2009). Where screening tools are used to detect NAS, inter-rater reliability coefficients of scoring methods ranged from 0.77-0.98 and small sampled studies have shown both specificity and sensitivity close to 100% (Bagley SM *et al*., 2014; O'Grady *et al*., 2009). Under-recording may however occur in secondary care if the mother is not identified as using drugs during pregnancy and the neonate is discharged soon after delivery (Osborn *et al*., 2010). Additionally a small percentage of mothers may avoid contact with health professionals in and around pregnancy in order to reduce the risk of her child being taken away and therefore these mothers are not identified as a drug user (Advisory Council on the Misuse of Drugs, 2011). Therefore there is a low risk of false positive diagnosis and recording for NAS in secondary care, which may later be recorded in primary care.

6.9 Conclusion

My findings illustrate the minimum estimate with regards to NAS in primary and secondary care. However, most infants are registered with a GP after birth and the electronic health records could contribute to the continuation of care. Both mothers and infants recorded with NAS could be monitored and supported.

6.10 How Does This Chapter Support My Thesis?

The results from my third study regarding recording of NAS link with my second study as the two most frequently used specific Read codes for drug use in and around pregnancy were for "heroin and benzodiazepine dependence"; "methadone" was the most frequently prescribed opioid substitution treatment; and finally the most frequently used specific Read code for opioid substitution treatment was for "methadone". Together with my first two studies, the third study will help establish if THIN can be used as a surveillance and/or research tool for drug use

and/or opioid substitution treatment during pregnancy. I will discuss this more in Chapter 8.

Additionally, as found in my first two studies, it is still unclear as to why and when GPs decide to use Read codes to record NAS. As previously mentioned in *sections 3.4.4*, the main strength of using a large primary care dataset is that it provides a large amount of data from real life primary care. However, meaning and understanding need to be incorporated into large datasets (Pope *et al*., 2014). This can be done by using qualitative methods to help understand the methods, classification and the circumstance for recording (Pope *et al*., 2014). My fourth study (Chapter 7) will therefore be a qualitative study to understand how and why GPs record drug use in the general population, in and around pregnancy and NAS in primary care.

CHAPTER 7 STUDY 4: FACTORS AFFECTING RECORDING OF DRUG USE – A QUALITATIVE STUDY

7.1 Content and Structure of Chapter 7

In this chapter, I present my qualitative research which encompasses the fourth and final study of the thesis. I used analysis from semi-structured qualitative interviews to assist in understanding GP recording of drug use and opioid substitution treatment and to aid in answering questions that arose from the previous three quantitative studies. This chapter contains the introduction, aim, specific objectives, qualitative data collection methods, analysis, results and discussion for the fourth study.

This study addresses the fourth objective of the thesis (*see section 2.4 for details*) and also contributes to answering the main research question by combining with data from the other studies to understand the reason for the gap in recording rates in a primary care database compared with national surveys, a hospital database and other studies (*section 2.3*):

1. *Can a large primary care database (The Health Improvement Network (THIN)) be used as a surveillance tool for understanding drug use and opioid substitution treatment in the general population and specifically during pregnancy (in England and Wales)?*
2. *Can a large primary care database (THIN) be used as a tool to research drug use and opioid substitution treatment in general practice in the general population and specifically during pregnancy (in England and Wales)?*

7.2 Introduction

Electronic health records can contribute to a longitudinal view about the individual and document continuous care, even if the individual is not always seeing the same GP (Freeman and Hughes, 2010). As previously mentioned in *section 1.3.4*,

the benefits of good record-keeping in general practice are summarised by the Department of Health's good practice guidelines for electronic patient records (Royal College of General Practitioners, 2011b). The primary purpose of the electronic record is to support the care of the patient and health professionals can also use the records to structure their thoughts and make suitable decisions in order to ensure patient-centred care (Freeman and Hughes, 2010). The electronic health record can also be shared amongst other health professionals who are involved in the same patient's care and include other documentations such as discharge letters from the midwifery services (Freeman and Hughes, 2010). Other uses for electronic health records include; clinical audit, research, education, service planning and contract delivery are also important (Royal College of General Practitioners, 2011b).

There are currently few qualitative studies exploring GP recording in primary care and no studies looking at how GPs record drug use and opioid substitution treatment in electronic health records. However, two qualitative studies have previously explored GP recording of other sensitive issues which may be difficult to disclose in primary care:, alcohol misuse and child maltreatment (Department of Health, 2005; Woodman *et al*., 2013) (previously mentioned in *section 1.3.12*). The first study, "*The Alcohol Needs Assessment Research Project*" used both qualitative and quantitative methods to explore GP recording of alcohol misuse in electronic health care records in England (Department of Health, 2005). The project included eight separate studies conducted for six months between 2004 and 2005 in the England. In order to try and establish the number of individuals with a record for alcohol misuse, they examined the General Practice Research Database (GPRD) and also telephoned 424 GPs to find out the number of patients who were recorded as misusing alcohol (Department of Health, 2005). Five times more GPs were aware of individuals who misused alcohol compared to the number that were recorded in GPRD (Department of Health, 2005). These results suggested that GPs were aware of alcohol misuse but did not always record it in

the electronic health records. The project also conducted six focus groups with Drug Action Team professionals (Department of Health, 2005). The findings indicated that GPs were reluctant to record alcohol misuse in health records and refer patients due to limited access of overstretched services and the lack of patient engagement with services (Department of Health, 2005). The second study was conducted by Woodman *et al*. who also used mixed methods to examine recording and responses to child maltreatment in primary care (Woodman *et al*., 2013, 2012). Using the THIN database, they found that child maltreatment was recorded in 1% of children's electronic health records in the UK. They acknowledged that the result was an underestimate compared with other data sources (Woodman *et al*., 2012) (*section 1.3.12*). GPs seemed to be cautious when recording child maltreatment in electronic health records and they subsequently conducted in-depth qualitative interviews with GPs (n=14), practice nurses (n=2) and health visitors (n=2) in England (Woodman *et al*., 2013). Their findings suggested that GPs used previously learnt skills for long term management of families who prompted concerns about child maltreatment (Woodman *et al*., 2013). Woodman *et al.* did not explicitly explore GP recording of child maltreatment however, they went a step further towards ascertaining and understanding the responses and actions of the health professionals regarding a very sensitive issue (Woodman *et al*., 2013). Although both studies looked at recording of other issues than drug use, there is a strong argument that the issues discussed above may be similar to drug use as they are also examples of sensitive and sometimes stigmatised issues that may have repercussions if recording in electronic heath records (Alcohol and Drugs Misuse Subgroup of the Changing Minds Campaign, 2003).

Even though there are no specific studies exploring GP recording of drug use, there two studies by McKewon *et al.* and McGillen *et al.* which explore GP attitudes to people who uses drugs which could impact on the recording of drug use (McGillion *et al*., 2000; McKeown *et al*., 2003). McKeown *et al.* conducted 48

semi-structured interviews to understand the attitude of GPs to drug misusers and drug misuse services in Scotland (McKeown *et al*., 2003). Their focus was on GPs who saw and treated problem drug users, mainly those treated with methadone (McKeown *et al*., 2003). The study highlighted that some GPs viewed drug use as more of a societal rather than a medical issue. Whilst most of the GPs were willing to treat drug users, the behaviour of the patient and the GP's confidence in managing addiction affected their decision of whether or not to provide treatment (McKeown *et al*., 2003). Shared care with other health professionals and specialist services was therefore considered the best way to treat drug users (McKeown *et al*., 2003). McGillion *et al.* sent a questionnaire to 206 GPs in the inner London area to examine their attitudes and knowledge towards management of problem drug users (McGillion *et al*., 2000). Most of the GPs who responded to the survey felt that general practice was an ideal place for drug use to be detected, however less than half felt that they had adequate and appropriate knowledge to treat drug use (McGillion *et al*., 2000). Both studies by McKeown *et al.* and McGillion *et al.* were conducted in the time-period when heroin was used more frequently and individuals who used heroin were often quite chaotic and needed long term treatment for their heroin addiction. GP attitudes may have changed with the variation in drug trends used over time. Both these qualitative studies contribute to the understanding of GPs' views of treating drug use. However they focus on problem drug users and do not include recreational drug users and drug use during pregnancy. The studies also do not give an indication of how, when and why GPs record drug use.

It was evident from my quantitative studies that GPs are recording drug use and opioid substitution treatment in the general population and during pregnancy. It is however, still unclear why recording is lower compared with national surveys, hospital data and other studies as well as to why, when, how and for whom they record. The main strength of using a large primary care dataset is that it provides a large amount of data from real life primary care (Pope *et al*., 2014). However,

meaning and deeper understanding need to be combined with large datasets (Pope *et al*., 2014). This can be done by using qualitative methods to help understand the methods, classification and the circumstance for recording (Pope *et al*., 2014). Methodological triangulation would strengthen the evidence of my quantitative work. This qualitative study therefore complements my existing studies by exploring the factors which determine recording by GPs of drug use and or opioid substitution treatment in primary care. It also aims to contribute to the landscape of literature regarding recording in primary care.

7.3 Aims of Study 4

To understand GP recording of drug use and opioid substitution treatment and to use existing literature to contextualise the findings.

7.4 Specific Objectives of Study 4

The qualitative study was based on interviews with a purposive and theoretical sample of GPs to determine how these GPs record drug use in primary care. My aim was therefore not to describe standard practice across the whole of the England and Wales. The specific objectives were:

1. To explore and generate an understanding of the factors determining GP recording of people who use drugs and/or receive opioid substitution treatment in primary care.
2. To examine if GPs use any specific protocols or codes for recording drug use and/or opioid substitution treatment
3. To examine and generate an understanding of the similarities and differences of recording drug use and/or opioid substitution treatment between the general population and pregnant women
4. To examine if GPs use any specific protocols or codes for referring individuals for treatment of drug use and/or opioid substitution treatment

7.5 Methods

7.5.1 Ethics

Ethical approval for the interviews was granted by UCL Ethics committee in June 2014 (Ethics approval number 5664/001) (*See Appendix 8.1*). Following the initial ethical approval, an amendment was applied for and granted (*See Appendix 8.2*):

1) Request to increase payment to participants from £20 to £30 (granted on the 18 June 2014)

The study was registered with UCL records office and is covered by the UCL Data Protection Registration, reference No Z6364106/2014/05/34, section 19, Research: Health Research.

7.5.2 Sampling of participants

Purposive sampling is a technique that involves selecting participants from a particular group who are likely to generate useful and appropriate data (Coyne, 1997). A researcher can select participants according to factors such as age, gender, status, profession, experience or location (Coyne, 1997). I decided to use purposive sampling for my qualitative study as I intended to interview GPs who had a special interest in patients who use drugs. The clinical director of Substance Misuse Management in General Practice agreed to contact GPs who had completed the RCGP Certificate in the Management of Drug Misuse (Royal College of General Practitioners, 2015a). However, after initial interviews, analysis and discussion during my data clinic (*see section 3.6.4 for details*), I decided to also use theoretical sampling (*section 3.6.2*) and include GPs who did not have a special interest in drug use, but who still treated patients for other clinical problems. I will now discuss my sampling process in more detail.

<u>Inclusion criteria 1:</u>

Participants (GPs) were selected if they fitted the following inclusion criteria:

- Currently work in a general practice in the England and Wales
- Has a special interest in treating patients who use drugs
- Had completed at least one module of the RCGP training in substance misuse
- Range of years of GP experience (from GP trainee to very experienced)
- Both males and females

Inclusion criteria 2

Following my data clinic (*see section 7.5.5*), I included the following criteria:

- GPs who did not have a special interest in drug use i.e. they saw individuals who use drugs, but did not treat them for drug use.

I recruited 11 GPs from different practices across the England and Wales. In order to select a purposeful sample the clinical director of Substance Misuse Management in General Practice (SMMGP) circulated a short summary of my study and contact details (*Appendix 9*) to GPs who had completed the course: she also broadcast the study more widely via the SMMGP twitter account. If a GP was interested in participating in the study, they could email myself directly. Once I received their email, I asked a few more questions about their location and type of work they did in order to ascertain if they fitted the inclusion criteria for my study. I also answered any queries they had regarding the study. There were a few GPs who did not fit the specific criteria (e.g. GPs who worked only in drug treatment clinics and not in general practice). If this occurred, I met with my supervisor to discuss if the GP could be included or not. Once I had confirmed that they were eligible for the study, I arranged a suitable time and place for the interview. I also sent the information and consent forms via email and informed the GP that I would bring two hard copies for both of us to sign and keep.

Pilot interview:

I initially conducted a pilot interview with one of the GPs working in the Department of Primary Care and Population Health, UCL. I sent an email to this particular GP, who was willing to participate. The GP was employed for four sessions per week at a practice in South West London and worked as an academic GP for the rest of the week. He did not have a special interest in drug use or a SMMGP certificate in the management of drug misuse, however the practice was located in a deprived area and he saw many patients who used drugs and presented to the practice for other reasons. After completion of my interviews, I decided with my qualitative supervisor to include the pilot interview in the analysis and obtained consent from the participant.

Following the pilot interview, I had three stages of sampling which allowed me to interview and analyse the data concurrently. I also intended to revise the topic guide iteratively in order to include new questions which emerged during the analysis.

Stage 1 sampling

The clinical director of the Substance Misuse Management in General Practice (SMMGP) sent the initial email to approximately 30 GPs who had completed the RCGP modules. I received responses from five GPs, however, two did not fit my inclusion criteria as they were GPs in drug treatment clinics rather than GPs working in general practice. One of the GPs worked as a prison GP, but had also recently worked in a general practice that registered homeless individuals. After a discussion with my supervisor, we decided to invite this GP to participate in my study. The three GPs from this first sampling stage were all from inner city practices.

Stage 2 sampling

A colleague who had recently conducted a qualitative study with GPs had several contacts from the RCGP. She offered to send an email to those GPs she was aware of who had completed the SMMGP modules. Two GPs responded to this email and both were eligible for the study. They were also from inner city practices.

Once I had completed five interviews, I held a data-clinic (*see section 7.5.5*). As previously mentioned, I decided to include GPs who saw patients who used drugs in their practice, but did not necessarily have a special interest in drug misuse.

Stage 3 sampling

I asked both the clinical director of SMMGP and two other colleagues to send additional emails, to include GPs who had not completed the SMMGP modules. Seven GPs responded but only five fitted the inclusion criteria. Two of the GPs were from inner city practices and had a special interest in drug use. A further three GPs did not have a specific interest in treating people who used drugs: two worked in outer city practices and one in an inner city practice (Table 7.1)

Table 7.1: Demographics of GPs interviewed

Gender	Years' of experience	Location	Sampling stage	No of GPs in practice (male :female)
GPs with a special interest in drug use and a SMMGP certificate				
#1-M*	>15	Inner city	1	8 (3:4)
#2-M*	>15	Inner city	1	4 (1:3)
#3-F*	>15	Outer city neighborhood	1	5 (2:3)
4-F*	5-10	Inner city	2	6 (2:4)
5-M*	5-10	Inner city	2	6 (1:5)
6-M*	>15	Inner city	3	4 (2:2)
#7-F*	>15	Inner city	3	7 (1:6)
#8-F*	>15	Inner city	3	7 (3:4)
GPs without a special interest in drug use				
9-M	5-10	Outer city neighborhood	3	8 (3:5)
10-F	5-10	Outer city neighborhood	3	7 (3:4)
11-F	GP trainee	Inner city	4	9 (3:6)
12-M	>15	Inner city	Pilot	8 (3:5)

*Completed at least one module of RCGP training
#Recruited through the clinical director for SMMGP

GPs were from a geographical spread of general practices across England. Unfortunately, I was unable to recruit any GPs working in practices in Wales (Figure 7:1).

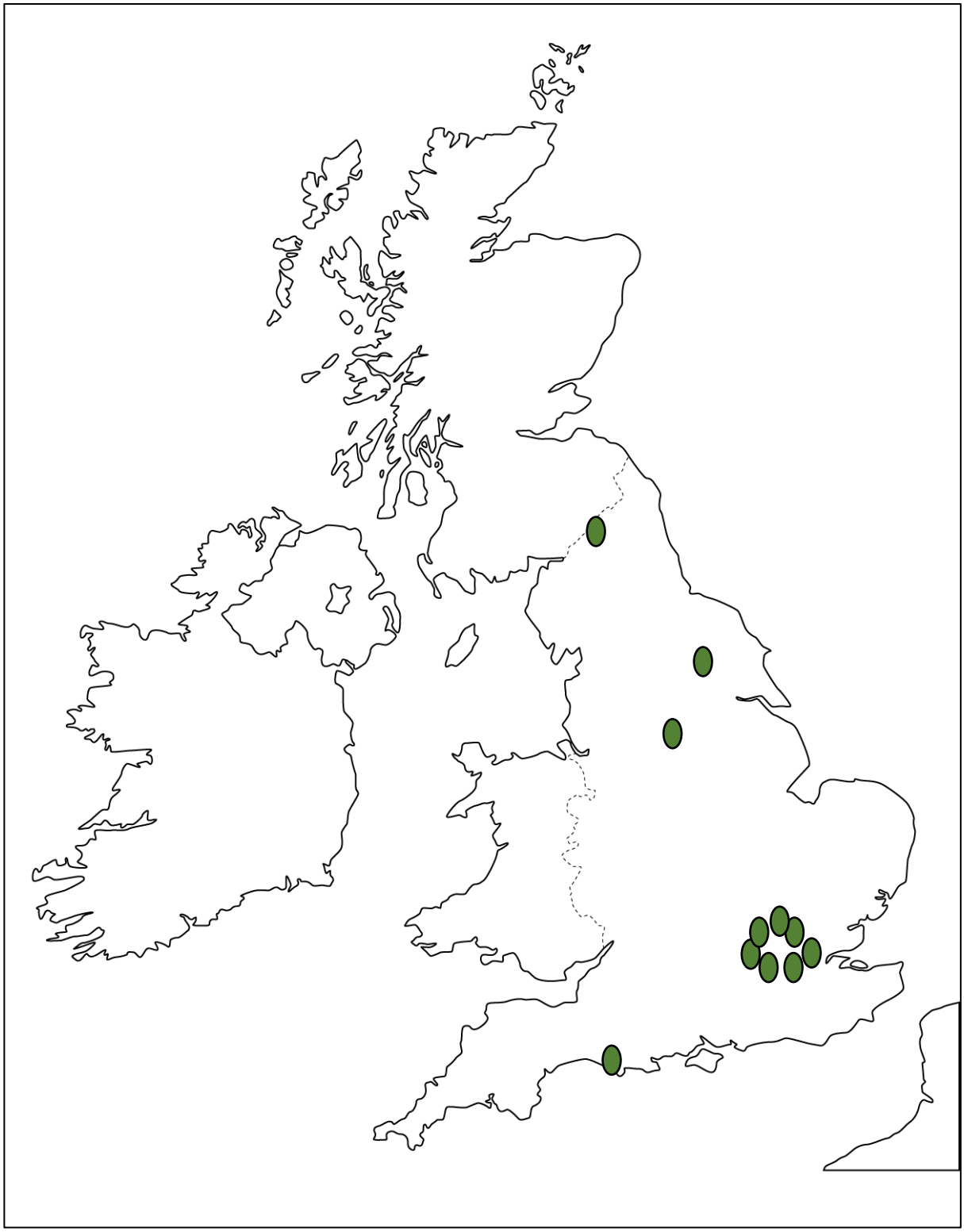


Figure 7:1: Location of general practices where participants worked in England

7.5.3 Interviews

After careful consideration and discussion amongst my supervisors and collegues, I decided to use face-to-face semi-structured interviews for my qualitative study (*section 3.6.1*). The main reason that I chose this method was that semi-structured interviews suited the type of data I wished to generate which reflected a specific, relatively self-contained action. I aimed to gain a deeper understanding of their perceptions, context and process of their recording practice of drug use. I also chose semi-structured interviews as there were some specific questions I needed to ask at the beginning of the interview, followed by more open-ended questions.

I asked each GP for permission to record the interview and all participants agreed. I also emphasised that the identity of both GP and patients would remain anonymous and that the general practice would only be identified at a borough or closest town level. I also asked all participants if they had any further questions about the study and then asked them to read and sign two copies of the consent form. Once this was done, I filled in the fact sheet that I had developed in order to record the time, date, location, special conditions and participant's demographics (see *Appendix 10*). Prior to the interview, I had developed the interview guide which contained key topics and open-ended questions (see *Appendix 10*). The interview questions initially covered the following areas for both the general population and pregnant women:

- if and why GPs record drug use;
- which methods GPs use for recording drug use;
- GP's actions if a patient asks for the information not to be recorded and
- GP's actions if they suspect a patient uses drugs but does not disclose the information.

I used an iterative approach and revised my topic guide after each interview. Versions of the first and last interview schedules can be seen in *Appendix 10.*

After each interview, I wrote my field notes, which included my thoughts and interpretations about the interview. I tried to do this as soon as possible after the interview, in order to reduce incorrect recall. I also typed these field notes up at a later date.

7.5.4 Transcription

I transcribed the first interview myself and sent the rest of the interviews to a professional transcriber who had previously transcribed interviews for other members of the department. I sent the audio file via Hightail software (https://www.**hightail**.com/), which is secure software for sending and sharing large files. Once the transcriptions were complete, I familiarised myself with the data by going through each interview with both the transcript and audio file to ensure that they had been transcribed accurately. If words had been left out, I revised the transcripts accordingly and analysed these final transcripts.

7.5.5 Improving reliability

In order to improve the reliability and rigour of my interpretation, I set up a data-clinic during the interviewing and analysis stages (Thomas and Magilvy, 2011). The clinic focused on discussing themes and codes that I had identified during my analysis (Bergman and Coxon, 2005; Green and Thorogood, 2004). Different researchers may not identify the same themes, due to their different backgrounds, experiences, interests, knowledge and theoretical approaches (Green and Thorogood, 2004). I therefore invited qualitative, mixed methods and quantitative researchers from a variety of disciplines from the department of Primary Care and Population Health. Six researchers with disciplinary backgrounds in sociology, psychology and epidemiology attended the data clinic in October 2014. One of my supervisors chaired the data-clinic, which meant I could focus on actively listening and taking notes during the discussion. However, on reflection and after attending

a different data-clinic - where the researcher recorded the conversation - I would record the session, so that I could review the dialogue in more detail.

Before the data-clinic, I sent each researcher a copy of a transcript from the third interview (Participant 3) and a summary of my PhD thesis. During the data-clinic, I began by outlining my PhD and describing how I intended to use the qualitative results to help understand the three quantitative studies. I also justified why I had chosen the particular transcript to discuss; the main reason was that I felt more confident with my interview technique by the time I conducted my third interview, furthermore, participant 3 was a female GP who was a similar age to me, and I felt more comfortable and at ease when interviewing her. Conversely, the previous two interviewees were older male GPs and I felt slightly intimidated during the interviews. In addition, participant 3 was an example of a GP who was not always following a specific protocol with regards to recording. She worked part-time as a GP and in a drug treatment clinic and consequently her experience working in the drug treatment clinic seemed to influence her way of recording and treating patients who use drugs.

I decided to focus on particular sections of the transcript to see if my interpretations were the same or different to the other researchers. We had an in-depth discussion about each specific section and after the data-clinic, I categorised the discussion into 4 sections;

- Questions that I could include in the next interviews
- Similar themes that came up
- Other themes that came up
- Actions to be taken

I found the data-clinic extremely useful for reinforcing the themes that I had identified, identifying new themes and introducing new questions into my topic guide. As mentioned previously, it also became clear that I needed to not only interview GPs who treated people who use drugs and who had a special interest in these patients, but to also include GPs who did not necessarily have a special interest in drug use and treated these individuals for other symptoms and co-morbidities. I therefore used both theoretical and purposive sampling in my sampling methods (*section 3.6.2*).

7.5.6 Reflexivity

Reflexivity is a central part to qualitative research (Cutcliffe and McKenna, 2002; Kingdon, 2005). It is a process whereby the researcher reflects on how their own perceptions, values and practice can influence the data collection and data analysis (Green and Thorogood, 2004). As mentioned in *section 3.6.4.5*, the researcher acts as the research instrument in qualitative research and therefore needs to monitor and critique their opinions, attitudes and interview techniques (Green and Thorogood, 2004). After I had completed my first quantitative study using THIN, it became apparent that recording of drug use was more complex than recording of other conditions such as diabetes. After discussion with my supervisors, we decided that I should include a qualitative study to explore the factors that influenced the GP recording of drug use. Before starting my quantitative study, I conducted a thorough literature review on drug use in the UK and recording in primary care. I also read English policy documents, training guides and Royal College of General Practitioners guidelines. I spoke to various GPs informally about their experiences of seeing people who used drugs in primary care. During this stage of my PhD, I had developed a set of beliefs and presumptions about drug use and the role of the GP with regards to recording. As part of the reflexive process, I wrote down the following assumptions in my field notes, before starting my interviews with GPs. I have included my initial

assumptions and how these assumptions (*In italics*) changed through the interview process.

1. Drug use is stigmatised in society and it may be difficult for a patient to be honest about their drug use
    - *Drug use may be stigmatised in society, but the general practices offered a non-judgmental place for the patient to discuss their drug use. Some GPs had developed a good rapport with patients and these patients may have felt more willing to disclose and discuss their drug use.*

2. Drug use was often combined with other social and medical issues
    - *This assumption remained the same and was supported by the evidence as most of the GPs described how individuals who used drugs came to see them about both medical and social problems other than their drug use, these included the following; depression, anxiety, job loss, homelessness*

3. Drug use during pregnancy often leads to children being taken away from a mother
    - *This was not always the case, but it did happen in some cases. Social workers were usually involved when a woman took drugs during and after pregnancy.*

4. People who use drugs can sometimes be difficult patients
    - *This was not always the case, although there were some patients who were more chaotic than others and who did not engage with services. Some patients were however more engaging and the GP and patient had developed a good rapport.*

5. Some practices chose to not treat individuals who use drugs

- *This assumption did not change, however the general practices choosing not to treat drug misuse, usually treated other medical conditions.*

6. GPs could be in an appropriate position to identify and treat people who use drugs
    - *This assumption did not change, and if the individual attended a consultation, GPs could be in a suitable position to identify individuals who use drugs. However barriers such as time and expertise may inhibit GPs from identifying individuals.*

7. GPs would usually record important information from a consultation and this should include drug use
    - *This assumption changed throughout the interview process as data emerged highlighting that GPs did not always record all information from consultations. Recording drug use was a particularly complex issue and was therefore not always recorded.*

8. GPs should be using guidelines and protocols for recording drug use in electronic health records
    - *This assumption changed as not all general practices had or were using specific protocols for recording drug use in electronic health records.*

9. Recording is important not only for research purposes but also for the continuous care of the individual.
    - *This assumption changed, as some of the GPs viewed trust and truth from the individual as more important for treatment of the individual rather than recording drug use.*

Looking back on my assumptions, I feel that I was slightly naïve in my thinking and beliefs. I felt that THIN was an effective tool for surveillance and research and that GPs would be at the forefront of accurate recording of their consultations. Reassessing the situation, I should have discussed these assumptions with my qualitative supervisor before the interviews, as after the first few interviews I gained a somewhat different perspective and understanding of GP recording of drug use. I tried to set my beliefs aside during the interview although I did find it difficult in the beginning to sit and listen rather than to interact with the conversation. After listening to the first few interviews, I realised that I was saying "ok" a lot in order to show understanding of what the participant had said. I tried to change this to a non-verbal nodding of my head and asking questions such as "could you tell me more about x". I also tried to summarise and repeat important points back to the participants to ensure that I had heard them correctly. I found that I was exhausted after each interview as I was trying to actively listen to each word carefully. I felt nervous during my first few interviews as they were both male GPs with over 15 years' experience. My third interview was with a female GP who was around the same age as me and this interview helped me gain more confidence and improve my interviewing technique. Frequent meetings with my qualitative supervisor and the data-clinic also helped me with both my confidence and including other questions in order to gain insight into other issues such as how changing computer software helped or hindered.

I made it very clear in my emails, the information sheet and at the beginning of the interview that I was a PhD student and that this was part of my PhD. I clarified that their identity and the identity of the general practice would be anonymous and I think that this put them at ease at the beginning of the interview. I noticed that most of the GPs described their experience rather than using guidelines for recording or not recording drug use in the patient notes. I found most of the GPs very easy to speak to. Although on one occasion, I had a migraine the night before one of my interviews. I woke up feeling very cloudy and thought about postponing

the interview. I decided against this as it had been quite difficult securing the interview time and the GP had agreed to be interviewed in-between his morning and afternoon sessions. The interview did not flow as previous interviews had and I think it was a combination of me feeling poorly and therefore not gaining rapport within the interview.

I wrote the following in my field notes:

> *"I had a migraine the night before and was feeling extremely foggy and exhausted on the morning of the interview. I almost cancelled the interview, but decided not to. I did feel that the interview was a bit flat, and I'm not sure if it was the interaction between the two of us, or because I was not expressing myself as clearly as I could have. On reflection and listening to the interview, it was ok, a bit slow to start though. I think that he had a slower way of talking and a very quizzical expression when I asked him a question which unnerved me slightly. He was also eating his lunch during the interview, so it was difficult for him to speak at times."*

I was aware of my role as a researcher and how this could potentially influence my interviews. During the first interview, the participant asked me a specific question about neonatal abstinence syndrome. By this stage, I had completed a thorough literature review and had written the introduction part of my chapter on neonatal abstinence syndrome. When he asked, it took me by surprise and my immediate reaction as a researcher was to give him the information from my literature review. I started to tell him and then felt that it would interfere with the interview and therefore stopped and said that I would email the relevant articles after the interview. When I was writing up my field notes, I reflected on the situation and decided that if a similar situation arose, I would tell the GP that I would be happy to discuss the matter after the interview, but not during it. As it happened, in the very next interview the GP asked about prescribing guidelines specifically during pregnancy, I therefore told her that I was happy to discuss the guidelines after the interview, and subsequently emailed her the most recent guidelines.

Most of my interviews took place in the GP's consulting room in the general practice. It was interesting for me to take note of the surrounding environment, not only inside the general practice but also the location. Some of the practices were located in very socially deprived areas, whilst others were located in relatively affluent areas. I did conduct two interviews in coffee shops as the GPs had suggested this and I found it a bit distracting during the interview. I did a sound check before each interview to ensure that I could hear the GP clearly.

I was aware of how busy all of the GPs were and was very conscious of the timing of the interviews. My information sheet had stipulated that the interview wouldn't take more than 40 minutes. Most of the GPs agreed to be interviewed on days when they were not seeing patients and two of the GPs actually came into the practice especially to see me. Most of the interviews ended naturally around 30-40 minutes but one or two continued for over an hour. I did interrupt the interview in order to check that it was ok for the GP to carry on with the interview.

In summary, there were many different aspects that contributed to my interview journey. My set of beliefs changed during the interview process and I felt that I became less judgemental of GPs who were sometimes putting patient care before accurate recording.

7.5.7 Analysis

I used inductive thematic analysis in order to analyse my data. Firstly, I coded the first few transcripts and developed a coding structure and together with my supervisor, we appraised the developing coding structure. I then used these codes to code the next transcripts and if any new codes emerged, I went back to the previous transcripts to ascertain if they contained any of the newly emerged codes.

I then organised the codes into emerging themes. Following this process, I met with my supervisor to discuss the emerging themes and how I would contextualize the themes. I also sorted the organising themes into two main global themes and arranged sub-themes into the organising themes.

Many themes emerged from the data and I had to be vigilant about including themes that were answering my research question about recording, namely:

- How does the GP record or not?
- How are decisions made in relation to the use of Read codes or free-text?
- How and why are they using templates or protocols?
- In what way is this different if a patient is pregnant?

In order to really ascertain if the themes emerging from the data were answering my research question, I went through each one carefully and decided whether it fitted with the four questions about recording. If it did not, then I decided to take it out of my findings as I wanted to focus on those themes.

It was evident from my quantitative studies, that GPs are recording drug use in the general population and in and around pregnancy. However, as previously mentioned in sections *4.9.2, 5.8.2 and 6.8.2*, the annual rates of recording drug use in my studies were lower than national surveys and this suggests that either people who use drugs are not going to see their GP and/or if they are seeing their GP, their drug use is not being recorded. It is unclear why, when, how and which circumstances GPs record drug use and why they use particular Read codes. Particular processes need to take place before a GP can record information into an individual's electronic health record. From the data, there were two clear processes that emerged so I decided to organise these two processes as global themes. The first global theme was "acquiring information about drug use" and the second was "management and treatment of drug use". There seemed to be

several factors that influenced these proceedings which can vary for different GPs, individuals and situations. I decided that these factors would be the organising themes. Three possible organising themes contributed to my first global theme and two organising themes contributed to the second global theme Figure 7:2. My first three studies were examining the end product of the two global processes; recording the information from the consultation.

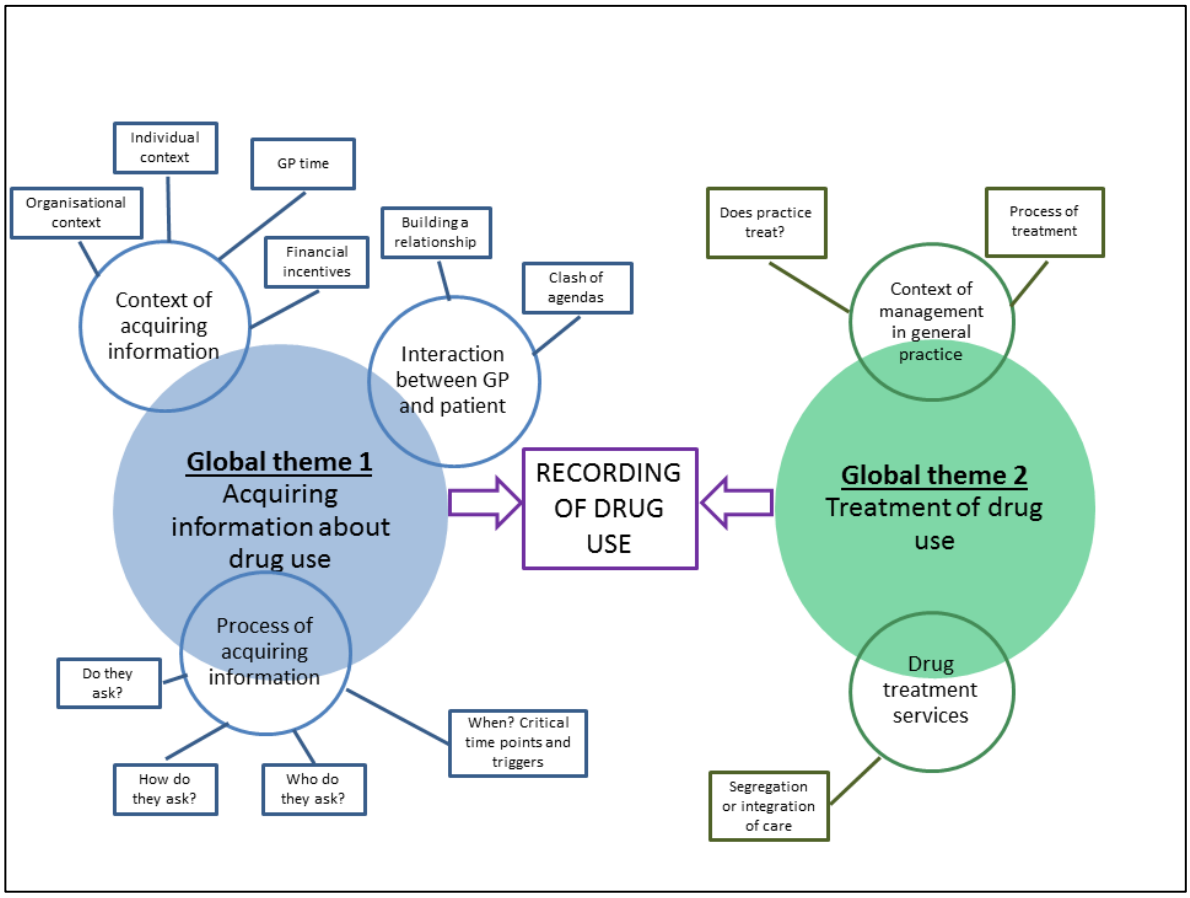


Figure 7:2: Global, organisational and sub-themes of recording

I will now discuss the findings of my qualitative work. I will do this in sequential order and discuss the global themes, organising themes and sub-themes.

7.6 Findings

To aid navigation of this section, I inserted a version of Figure 7:2 at the start of each section with the highlighted organising and sub-themes discussed in that section. I then introduce the findings, with quotes from the data to support the findings. I conclude each section with a summary of the key findings.

7.6.1 Global theme 1: Acquiring information about drug use

As drug use is legislatively an illegal action which can lead to adverse consequences, questioning about it is a sensitive topic. Additionally, negative attitudes and societal disapproval regarding drug use have created a stigma associated with it. The GP accounts from my qualitative study illustrated that asking patients about drug use is a complex and sometimes difficult issue. Consequently the first global theme that was identified and developed from my data was the topic of acquiring information. Two sub-themes ("the context of acquiring information" and "the interaction between GP and patient") transpired initially, which helped me to set the scene before I considered the third sub-theme of "the process of acquiring information about drug use".

7.6.1.1 The context of acquiring information

There were two distinct sub-themes incorporated in the "context of acquiring information". The first was the "organisational context" which focused on the environment and regulations of the general practice. The second sub-theme was the "individual context" which focused on the perceptions and experiences of the GP. Both the organisational and individual contexts influenced the reason and methods used for acquiring information from patients about drug use Figure 7:3.

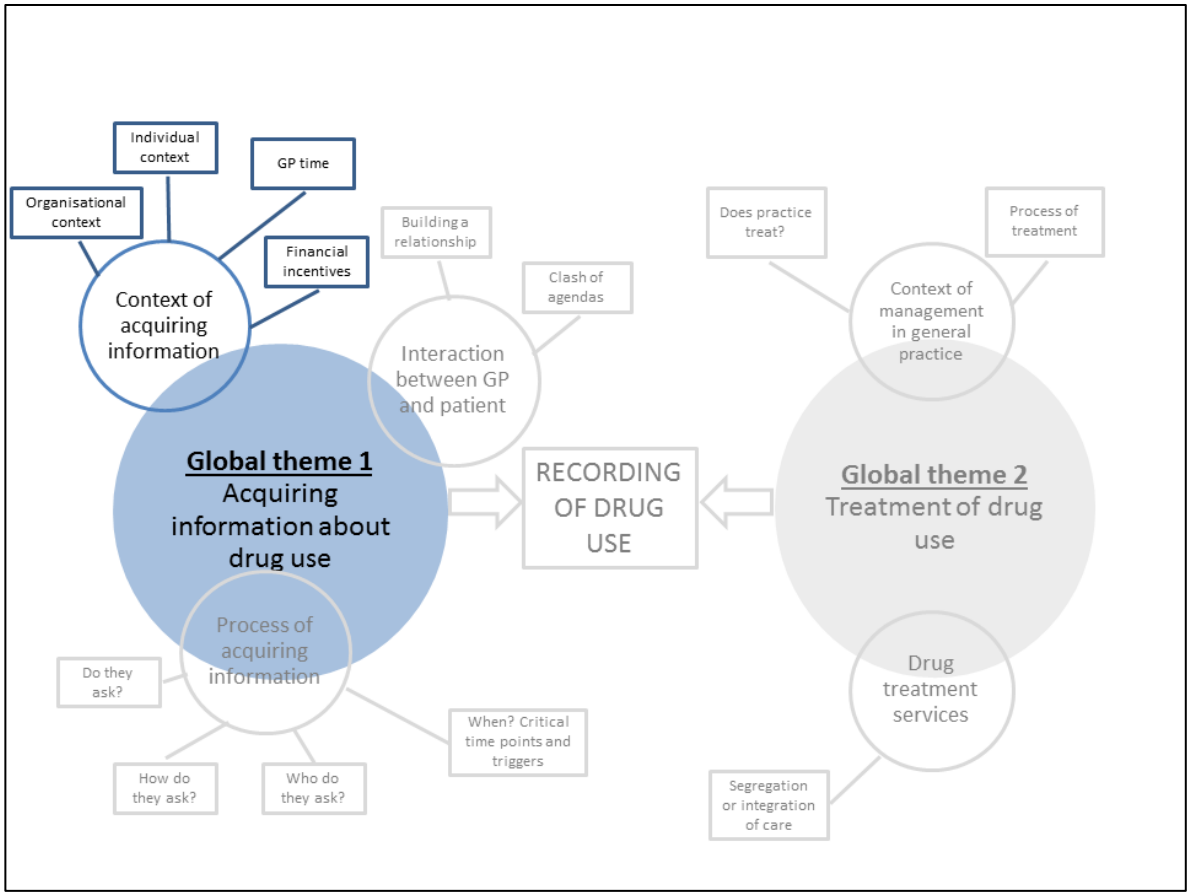


Figure 7:3: Context of acquiring information; first organising theme of Global theme 1

7.6.1.1.1 Organisational context

I will discuss three areas/topics which I identified from the data and grouped within the theme of "organisational context" of the general practice. These included the location and the size of the general practice, whether or not the general practice receives financial incentives for treating drug use and finally the time that GPs are allocated to see and treat patients.

Location and size of the general practice

The location of the general practice was significant to the convention of acquiring information. Practices located in areas where drug use was more prevalent, were more likely to have patients registered with the practice, who use drugs. The GPs

from these practices perceived that this made primary care more accessible for individuals who used drugs. Accounts from GPs from areas where drug use is relatively high (inner city) depicted that they had numerous patients registered with their practice whom they knew used drugs.

> *"Well, in [borough], we've traditionally been very keen, you know we've been very involved, quite a lot of GPs I think are involved, in terms of substitution prescribing, particularly for maintenance, but also for reducing and stopping. So I think we provide a very good place for managing the less chaotic people."*
>
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

> *"Our practice manager has set up the practice in such a way that it is quite attractive to people who want to join, particularly those who are having problems with access to their GPs, because we (sic) our practice is open for longer than average."*
>
> ***(GP, male, 5-10 years' experience, outer city, did not have a special interest in drug use)***

Consequently, these practices were accustomed to seeing patients for problems both directly and indirectly relating to drug use. The fact that patients who use drugs were regularly attending consultations in the practices seemed to desensitise the perception of drug use.

> *"But it's the same as smoking or alcohol or obesity, you know, it's a choice unfortunately that people can make, even though we can advise them. So I would bring it up, but I would basically say, you know, "Do you think that's something that you would be concerned about? Do you understand what it might do? Do you understand the risks you run?"*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

In comparison, one of the general practices located in an outer city area where drug use was less prevalent seemed to have fewer patients registered with the practice that they knew used drugs. The GP commented that as far as she was aware, not many of the patients registered with the practice used drugs.

> *"I imagine a GP practice that has loads of drug users or if they're doing clinics for homelessness and drug centres or whatever, I'd imagine they'd have systems set up. But I think possibly we don't, just because we don't see that many [people who use drugs]."*
>
> ***(GP, female, 5-10 years' experience, outer city, special interest in drug use)***

Not only does the location influence the organisational context, but the size of the general practice and the number of GPs in the practice appeared to influence the organisational context and continuity of care. I was unable to compare smaller and larger general practices as all of the GPs I interviewed worked in relatively large general practices which had at least 6 full-time GPs. A few GPs reported that a problem for recording drug use was that patients seen in larger practices did not always see the same GP at each visit.

> *"…because a lot of the time this isn't their regular doctor and they sort of say, "Well, if you were my own doctor I might tell you a bit more detail."*
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

However, some of these larger practices had a sufficient number of GPs to have the facility to appoint a lead GP for substance misuse. Patients who use drugs were therefore referred to and seen continuously by the same lead GP. This continuity of care was seen as especially important if the patient needed treatment for their drug use.

> *"So, we found that we had patients within the practice who had drug problems, nobody had any great expertise. There were different GPs working at that point in the practice, but different people were doing different things, so there wasn't a kind of co-ordinated response, and they weren't being seen by any dedicated person, or having any sort of input from secondary care. So it was because we felt we weren't looking after the patients well, that we decided, as a practice, we needed to develop more of an expertise. It then just fell on one of the partners to decide to do the course, so that was me"*
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

> *"So in general practice, people who are specifically presenting with concerns [about drug use] will get channelled into me."*
> ***(GP, female, 5-10 years' experience, inner city, special interest in drug use)***

The data indicated that the location of the general practice influenced the need for a lead GP in substance misuse. General practices located in areas where awareness of drug use was relatively high seemed to have more registered individuals who they knew used drugs. The data also suggests that although there is less continuity of care for most patients registered in larger general practices, patients who are identified as using drugs received continuous care from the lead

GP in substance misuse. Two of the inner city practices had an allocated weekly drug clinic, where the patient could see the same GP or drug worker each week.

> *"We've been running a specifically dedicated drug clinic, a substance abuse clinic, which is run in liaison with [local drug treatment clinic] who are the voluntary organisation that offer drugs workers support, and since 2006, that's how we've dealt with patients. So if a patient comes to us who isn't in that system, has a drug issue and wants advice or support, then the other GPs will refer that person to see me, depending on what drugs are involved, if it's something that needs substitution prescribing, so if we're talking heroin, or opiates, then we would refer to [local drug treatment clinic] for an assessment; they would be assessed for suitability for shared care and then we would be seeing them through my clinic."*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

As well as the location and size of the practice, financial incentives for recording and treating drug use seemed to influence the organisational context.

Financial incentives for GP practice

As mentioned previously in *section 1.3.8,* treating drug use is not in the GMS contract, however practices in certain areas where the need has been identified have a local enhanced service for treating drug use and are financially incentivised for treating individuals who use drugs. The GP lead in substance misuse from an inner city practice described how patients from other practices in the area who do not have a GP lead refer their patients to her practice. All the practices in the area are financially incentivised by a local enhanced service for treating drug use and she described how recording of drug use and treatment was mandatory. Consequently, recording of drug use was not only financially beneficial for all the practices in the area, but also facilitated continuity of care for the patient.

> *"…and locally the way our enhanced services have gone is that it isn't just for your own practice, it's actually for the whole of Southwark, as GPs; we all have to sort of reach that target for the whole group to be paid."*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

Conversely, one of the GPs from a practice that was not financially incentivised for drug use treatment, described how there were no Quality Outcome Framework (QOF) indicators for drug use. His view was that some GPs may not feel that it is necessary to record drug use unless there were financial incentives.

> *"Yeah, it will be great if it [recording drug use] did [get financially incentivised], but it's always been resisted because drug treatment isn't part of the current GMS contract.*
>
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

"My experience is that unless you've got some little incentive for making people ask, they don't"

(GP, female, >15 years' experience, inner city, special interest in drug use)

A general practice can choose not to treat patients who use drugs, however they are obliged to treat patients for other healthcare issues.

"They [GPs] have to provide medical care to people with drug problems, but they don't have to do drug treatment, and as long as that stays the situation, it won't go into QOF, I don't think, because it will be seen as an extra thing."

(GP, female, >15 years' experience, inner city, special interest in drug use)

It was interesting to see from the data that GPs perceive that recording of drug use is limited due to the GMS contract not including drug use and treatment, furthermore there are no QOF indicators for recording drug use.

<u>Allocated time for GPs to see and treat patients</u>

The final topic that I identified within the organisational context of general practice is the amount of time allocated for GPs to see and treat patients. GP time can influence whether or not a GP asks about drug use. The data indicated that the majority of the GPs perceived that they did not have enough time within their consultation time to enquire and if necessary treat a patient who uses drugs. GPs who were not leads in substance misuse expressed that time was a barrier for enquiring about drug use.

"From the moment you've finished seeing your last patient, you've tidied up and you want to see the next patient, you've got about 7½ minutes, and the first thing you'll do when you click on the file for your next patient is to just have a quick read of what's been going on before. It's nice if it's written in concise text so you can scan it in 15 seconds, rather than spend a minute trying to read through and work out, OK, what is actually the relevance of that!"

(GP, male, 5-10 years' experience, outer city, did not have a special interest in drug use)

"But I don't routinely ask. I mean to be honest, we just don't have time to do that."

(GP, female, GP trainee, inner city, did not have a special interest in drug use)

In most general practices, it seems that an inadequate amount of time is allocated for seeing and treating the patient and writing up the consultation. This lack of time could impact on whether or not GPs ask and record drug use in the electronic health records. I will now discuss the organising theme, "individual context."

7.6.1.1.2 Individual context

The second organising theme of "context of acquiring information" is the "individual context" of the GP who is seeing the patient. Two sub-themes that I identified from the data were the "experience and training of a GP" and the "perception of the role of a GP".

<u>GP experience and training</u>

The first topic that emerged with regards to the individual context was the experience and training of GPs. GPs with more experience who were the clinical lead for substance misuse and who had completed 1 or 2 modules of the RCGP training on substance misuse felt more confident asking individuals about drug use. One of the GPs in an inner city practice explained that she did the RCGP training when she was appointed as the clinical lead for substance misuse in her practice. She described how the practice needed to improve the service for drug use in their practice.

> *"Well, I did it specifically to set up a shared care service…so it was because we felt we weren't looking after the patients well, that we decided, as a practice, we needed to develop more of an expertise"*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

Another of the GPs, who was also a clinical lead, described how the RCGP training gave him more confidence to work with people who use drugs.

> *"I've done the certificate in Substance Misuse, Part 1 and Part 2… probably just in terms of more of confidence."*
>
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

It was evident from the interviews that most of the GPs who were clinical leads for substance misuse had completed one or both modules of the RCGP training in substance misuse. In contrast, a GP trainee felt that she was not as confident now but with experience she would gain more confidence which would enable her to ask about drug use more.

> *"I mean, in general, I'm not as confident as I imagine I will be in ten years' time when you've seen a lot more of this, and maybe as you get older you have more confidence to push an issue…"*
>
> ***(GP, female, trainee, inner city, did not have a special interest in drug use)***

It is possible for GPs to divide their work time between the general practice and working in a drug treatment clinic. GPs who worked in the drug treatment clinic seemed to be more aware of the signs and symptoms of people who use drugs.

> *"It [working in the drug treatment clinic] helps me suspect things earlier and address them I think, because a lot of people are nervous to ask."*
>
> ***(GP, female 5-10 years' experience, outer city, special interest in drug use)***

A GP's working week is divided into sessions and each of these sessions is approximately four hours. The narrative from a GP in an outer city practice with a special interest in drug use suggested that working in both a drug treatment clinic and general practice helps her to be more aware and to question about drug use earlier. This suggests that combining experience from working across both general practice and drug treatment clinics contributes to improved awareness of people who use drugs and will therefore influence if the GP asks about and records drug use in the electronic health records.

<u>Do GPs have a role in recording drug use?</u>

Some GPs who treated individuals who use drugs used words that had a slightly negative connotation with regards to drug use. One of the more experienced male GPs perceived that there are other GPs who may have an antiquated and negative

perception of people who use drugs. This was however a preconception rather than from direct experience.

> *"There is still some doctors I think out there, if they saw a long list of past medical history saying, you know, cannabis use, heroin use, whatever and then they automatically are thinking about how this is a druggie type patient, you know, and therefore will explain everything in terms of their past medical history.."*
>
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

A narrative from a female GP from inner city practice who is a lead in substance misuse, used words such as "cagey", "admit" "other "and "most" that suggested that she perceived drugs use as an illicit or forbidden behaviour.

> *"…but other people are a bit more cagey and most people wouldn't admit to it if they didn't want you to know it,…"*
>
> ***(GP, female, 5-10 years' experience, inner city, special interest in drug use)***

Although the words used in the narratives may have slightly negative connotations, most of the GPs I interviewed perceived that their role for treating individuals who used drugs was essential. They also described how they had become more accepting and desensitised to the stigma associated with drug use.

> *"I think we've got to get involved, it's a very satisfying area to get involved in. So it's an assessment in signposting them to the right service if you don't think you can deal with it here. A lot of the time it is getting them involved with others; there's voluntary sector agencies we work with for either drugs or alcohol, and trying to get them into treatment."*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

It was interesting to hear that a GP trainee with little experience of seeing individuals who used drugs also viewed her role with regards to identifying individuals who drug use as important.

> *"yeah, I think that GPs definitely have a role. I think one of the first things is actually uncovering that there's a problem"*
>
> ***(GP, female, trainee, inner city, did not have a special interest in drug use)***

GPs who were interviewed perceived primary care as one of the first points of contact for some individuals who use drugs. The views and perceptions seemed to be moulded by their experience and how they viewed their role in the treatment of drug use. Overall, it seemed that GPs perceived that they had an important role with regards to managing patients who use drugs. The role encompassed identifying the problem and working together with other health professionals and

services in order to manage and support individuals who use drugs. Perceiving their role as important could influence whether or not a GP asks and records drug use in the electronic health records.

7.6.2 Key points from the organisational theme "context of acquiring information"

Most of the points from this section were expected, however the fact that overall GPs thought that including drug use in QOF would be beneficial for enquiring, management, treatment and recording of drug use was surprising. General practices located in areas where awareness of drug use is higher seemed to be more likely to have funding from local enhanced services to manage and treat drug use in primary care. All the GPs I interviewed worked in larger practices which seemed to be better equipped to have a clinical lead in substance misuse. Many of the clinical leads in substance misuse had completed the RCGP training in substance misuse and perceived the training to be valuable for enquiring about, managing and treating individuals who use drugs. Time constraints and expertise were identified as barriers to questioning individuals about drug use. Most of the GPs felt that their role was important with regards to drug use, this included identifying patients and shared care with other health professionals and drug treatment services. It was evident that all of these contextual issues influenced recording of drug use in electronic health records through acquiring information form the individual. I will now move on to the findings from the organising theme; "interaction between GP and patient".

7.6.2.1 Interaction between GP and patient

Within the global theme of "acquiring information" the organising theme of "interaction between the GP and patient" developed from the data. I considered the following sub-themes were integral to this theme; "building a relationship" and "clash of agendas within the consultation" (Figure 7:4).

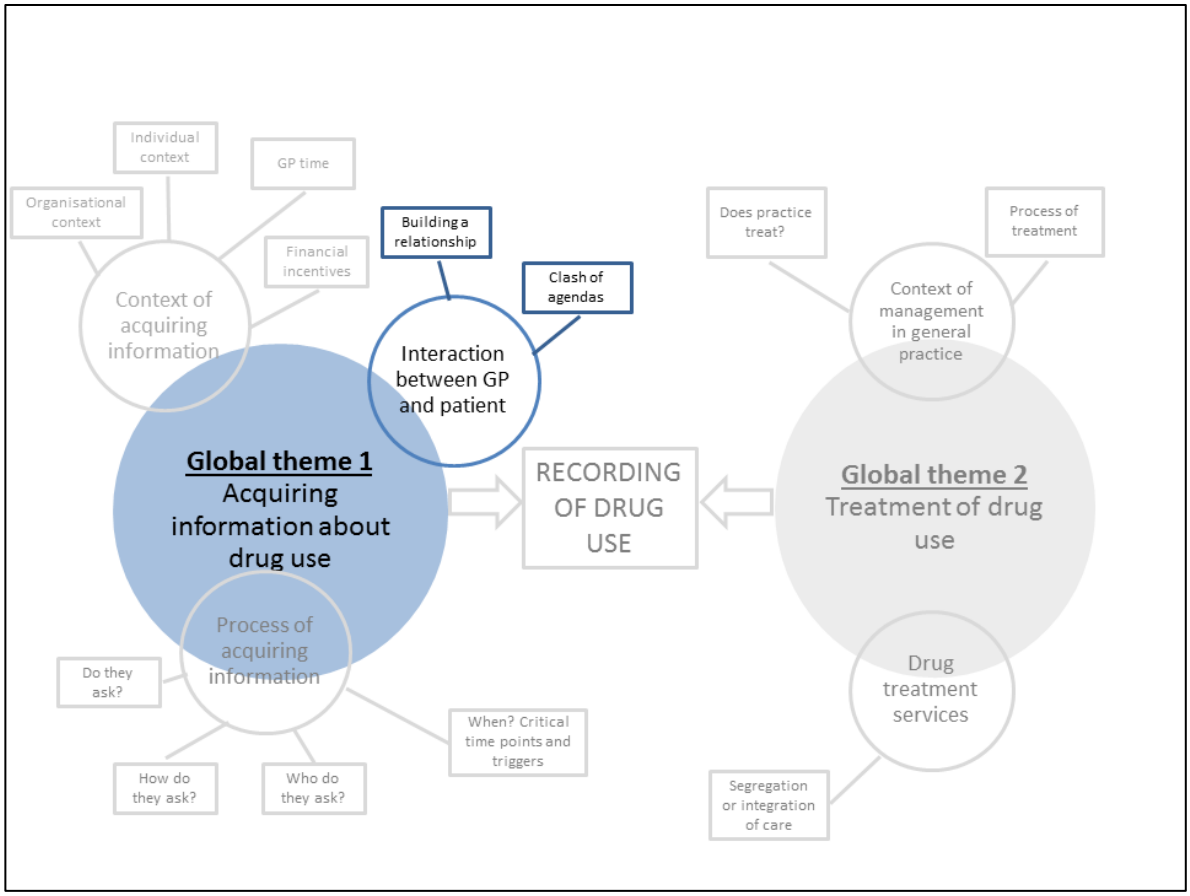


Figure 7:4: Interaction between GP and patient;second organising theme of global theme 1

7.6.2.1.1 Building a relationship between the GP and the patient

The first organising theme of "interaction between GP and patient" is the notion that a "relationship should be established and maintained between the GP and patient". Two sub-themes emerged from the data; "respect and patient choice" and "the clash of GP and patient agendas"

Establish and maintain a respectful and empathetic relationship

The continuity of the individual seeing the same GP at each visit can facilitate in the development of a relationship between the GP and patient and can also assist in the continuity of care for the patient. A GP who had a special interest in drug use described how it was beneficial for both her and the patient to establish a

respectful relationship and used words such as “rapport” “and “what is actually going on” to indicate this.

> *“We do actually encourage a bit of continuity, so they’d stick with one person because then you build up a* ***rapport*** *and you’re more likely to have an idea of what is actually going on at home and with their drug abuse” (emphasis added)*
>
> ***(GP, female, 5-10 years’ experience, outer city, special interest in drug use)***

It also seemed as though she was aiming to gain a deeper understanding of the patient’s situation outside of the general practice. A different GP who did not have a special interest in drug illustrated how he had empathy with regards to the patient’s social situation and was not there to judge the patient, but rather to help and support.

> *“But it’s never our job to preach and I’m very careful not to, because people have got tough lives, and for some of them, it’s just their way of coping really.”*
>
> ***(GP, male, 5-10 years’ experience, outer city, did not have a special interest in drug use)***

The narratives illustrate that GPs perceived that their relationship with patients is important and the relationship can be strengthened when the GP is empathetic. Furthermore, most GPs perceived that barriers to building and establishing relationships with patients were time constraints and continuity of care. However, as described in the sub-theme of organizational context where a general practice has a clinical lead for substance misuse, the patient may receive more continuous care and therefore allow time for rapport to be established.

At times GPs need to balance between clinically appropriate actions and the established relationship. This decision can impact the continuity of care as seen in the following narrative where a GP refused to give the patient additional medication on top of their opioid substitution treatment, and the patient then chose to see another GP.

> *“If I don’t give them what they want, they’ll try, some of them will try to just test another doctor out and see how far they’ll go and whether or not they will be prepared to modify the prescription. “*
>
> ***(GP, male, >15 years’ experience, inner city, special interest in drug use)***

The GP seems to be balancing between the needs, wants and requests of the individual and the appropriate clinical decision. The development of rapport can influence asking about and recording of drug use in electronic health records. This section leads me into the next sub-theme of trust from both GP and patient perspective.

Trust between GP and patient

The relationship that is established between the GP and patient requires trust from both parties in order for it to remain intact. An example of this is that the GP should trust that the patient is being honest whilst the patient should trust that the GP is going to use the information carefully and keep consultations confidential. The word "trust" was used frequently to illustrate that GPs viewed that in order to build a relationship, it is essential for them to accept what the patient is reporting as true and for the patient to have confidence about both their clinical and interpersonal skills.

> *"…once people establish a relationship, then it's easier for them to, you know, for trust to build up one way and another, and for things to work."*
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

The trust can be compromised if the GP needs to record information regarding drug use. Some of the GPs expressed that it was more important that the patient felt comfortable discussing issues in order to treat the patient appropriately, rather than to record the drug use.

> *"Because if they felt that to come and talk to you about something and that would require it being recorded would stop them coming to see you, then that would be detrimental to their care, so you've always got to be quite pragmatic."*
> ***(GP, female, >15 years' experience, outer city, special interest in drug use)***

Additionally, one of the GPs viewed that patients may perceive the trust to be damaged if the GP did not keep the information about drug use confidential and/or the GP chose to record the information about drug use, without their consent. A

GP with a special interest in drug use viewed that shared decision making regarding what was recorded was imperative.

> *"And you just have to reassure people about the confidentiality. If they don't want information shared on the NHS form, if they don't want that to go on, then they can decide not to. You have to tell people and let them know what their rights are, yeah."*
> ***(GP, female, >15 years' experience, outer city, special interest in drug use)***

However, GPs were aware that they did not always believe patients when they told them about the amount and types of drugs used. One GP described he is not always confident that the patients' accounts fully report drug use. This seemed to be parallel with patients' accounts of alcohol use.

> *"Erm, I think, generally, if people are willing to talk about it, then I've noticed people will, sort of, talk it down, and say something like "Oh, well, I just sort of, you know, occasionally might use."*
> ***(GP, male, 5-10 years' experience, inner city, special interest in drug use)***

The data from this section suggests that trust between patient and GP was essential for establishing relationships and improving the continuity of care.

<u>GPs' views about patient's choice</u>

The interaction between the GP and patient also includes how the GP views a patient's choice under certain circumstances. Some of the GPs respected the patient's choice by accepting the patient's request of drug use not to be recorded. These GPs described how they would not record if the patient had asked them specifically not to.

> *"…but if someone asked me specifically not to, then I wouldn't."*
>
> ***(GP, male 10-15 years' experience, inner city, special interest in drug use)***

Conversely, one GP, whilst respecting the patient's choice, still perceived that convincing the patient that they need to record the information was a priority.

> *"but I do think I would have the discussion with the person and make a judgement, and if it was really important, I'd try to persuade them that it actually is important to put on their medical notes."*

(GP, female >15 years' experience, inner city, special interest in drug use)

However the GPs' actions depended on the circumstances and GPs seemed more uncompromising about recording drug use if a woman was pregnant or if there was someone else involved (e.g. a child) and/or other agencies needed to be brought in. In these circumstances, most of the GPs were willing to discuss with the patient why the drug use needed to be recorded.

> *"there are some situations where I would record, regardless of the use; if there was, if it was relevant to the consultation or if there were children involved, or the person was pregnant, or situations where it would be relevant anyway, regardless of the extent of the use."*
>
> ***(GP, female, 5-10 years' experience, inner city, special interest in drug use)***

The narratives illustrated that most of the GPs respected the patient's choice, and if they did not want the drug use recorded, they would question this and in some cases highlight the importance of recording. Although overall GPs seemed unanimous in their actions with regards to recording when a woman was pregnant and a child was involved.

7.6.2.1.2 Clash of agendas

The final topic that was incorporated within the "interaction between a GP and patient" was the "clash of agendas" within a consultation. The GP may be aware of the patient using drugs or certain signs and symptoms may trigger their awareness, whereas the patient may be coming to see the GP for a problem other than their drug use.

<u>Awareness and triggers of awareness</u>

Firstly, the experience of a GP may help to enhance their awareness of a patient who uses drugs. GPs who worked in both general practice and drug treatment services perceived that they were probably more aware of the signs and symptoms

of an individual who uses drugs. The word 'suspect' was frequently used and may suggest that GPs are doing detective like work to establish if the patient uses drugs.

> *"It helps me suspect things earlier and address them I think, because a lot of people are nervous to ask"*
>
> ***(GP, male 5-10 years' experience, inner city, special interest in drug use)***

> *"I can think of a particular case where I suspected it for a long time, and I was right, but it took them a long time to actually sort of seek help, or admit to it"*
> ***(GP, male >15 years' experience, inner city, special interest in drug use)***

GPs with less experience of seeing patients who use drugs may be less likely to recognise relevant signs or symptoms. There were however some common signs, symptoms and co-morbidities that seemed to trigger the GP's awareness of drug use and prompt the GP to ask about drug use. Examples of these signs, symptoms and/or comorbidities included depression, anxiety, insomnia, stomach pain and chronic obstructive pulmonary disease.

> *"It's (drug use) potentially relevant to their you know to their stress or insomnia, I mean these are the main sorts of things they present with. Also social problems, work problems"*
> ***(GP, male 5-10 years' experience, inner city, special interest in drug use)***

> *"so they generally come along with emotional difficulties: symptoms of depression and anxiety, and have just been unhappy with the way they are really."*
> ***(GP, male 5-10 years' experience, inner city, special interest in drug use)***

Overall the GPs described similar signs and symptoms that triggered their awareness of drug use. The next section explains how this trigger of awareness could potentially be problematic for the relationship between the GP and patient.

<u>Patient seeking help for a specific problem and disclosure of patient</u>

There may be a "clash of agendas" when the patient consults the GP about a problem, unrelated to drug use, but the GP still questions about drug use. GPs described how a patient would come for one problem and the fact that he/she uses drugs might emerge during the consultation. The consultation may be sent in a

different direction and there could be a concern that the agenda of the patient is not properly met and an increased risk that the consultation may break down. The following narratives illustrate how the fact that the patient used drugs emerged during a consultation about a different problem and this may affect recording.

> *"…mostly in general practice, it's more kind of mostly an incidental thing that will come up as part of questioning during a consultation"*
> ***(GP, male >15 years' experience, inner city, special interest in drug use)***

> *"I think if someone was to come with a completely unrelated problem, say, a young person, a student or someone had come about something else, and admitted to maybe occasionally smoking cannabis, then I wouldn't [record] it would depend how relevant I thought it was."*
> ***(GP, male 10-15 years' experience, inner city, special interest in drug use)***

However, some patients may consult the GP in order to disclose their drug use as they are seeking help. This was illustrated by a male GP who had a special interest in drug use. He described a case where he had seen an individual frequently. He noticed that the individual had signs and symptoms of steroid use and ask about steroid use on several occasions. The patient always refuted the use of steroids. However when he disclosed a more serious problem of heroin use, he also disclosed his use of anabolic steroid.

> *"But later actually when he came for his heroin problem, he actually did say that he'd used anabolic steroids as well. "*
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

The data suggests that there may be an agenda clash when a GP focuses on a problem that the patient has not actually come to seek help about. This problem could then trigger a GP's awareness of drug use, and the GP may choose to focus on the drug use rather than the original problem, which could affect recording in the electronic health records.

7.6.3 Key points from the organisational theme "interaction between GP and patient"

It is imperative that GPs and patients establish and maintain a respectful relationship in order to have open communication during the consultation. Continuity of care and empathy seem to assist with the establishment and

maintenance of the relationship. The trust should be two-way, whereby the GPs should assume that the patient is disclosing the truth, whilst the patient needs to be confident that disclosure is kept confidential. Overall GPs agreed that they respected the patient's choice and found that shared decision making with regards to recording was good practice. Their decision to record drug use was different when a woman was pregnant or a child was involved. However recording may occur in the referral letter rather than as Read codes in the electronic health records. GPs who had a special interest in drug use seemed to be more aware of signs and symptoms that could indicate drug use, however other GPs were aware that certain signs and symptoms could trigger their awareness of drug use. GPs were not always aware that they prioritised their agenda over the patient's agenda and that could have a negative impact on the consultation. It was evident that the interaction between GPs and patients can impact GP recording drug use in electronic health records. I will now discuss my findings from the organising theme; "process of acquiring information."

7.6.3.1 Process of acquiring information

In the previous section, I have described the interaction between GP and patient, I am now going to describe and discuss the findings from the third organisational theme of "acquiring information"; "the process of acquiring information" (Figure 7:5).

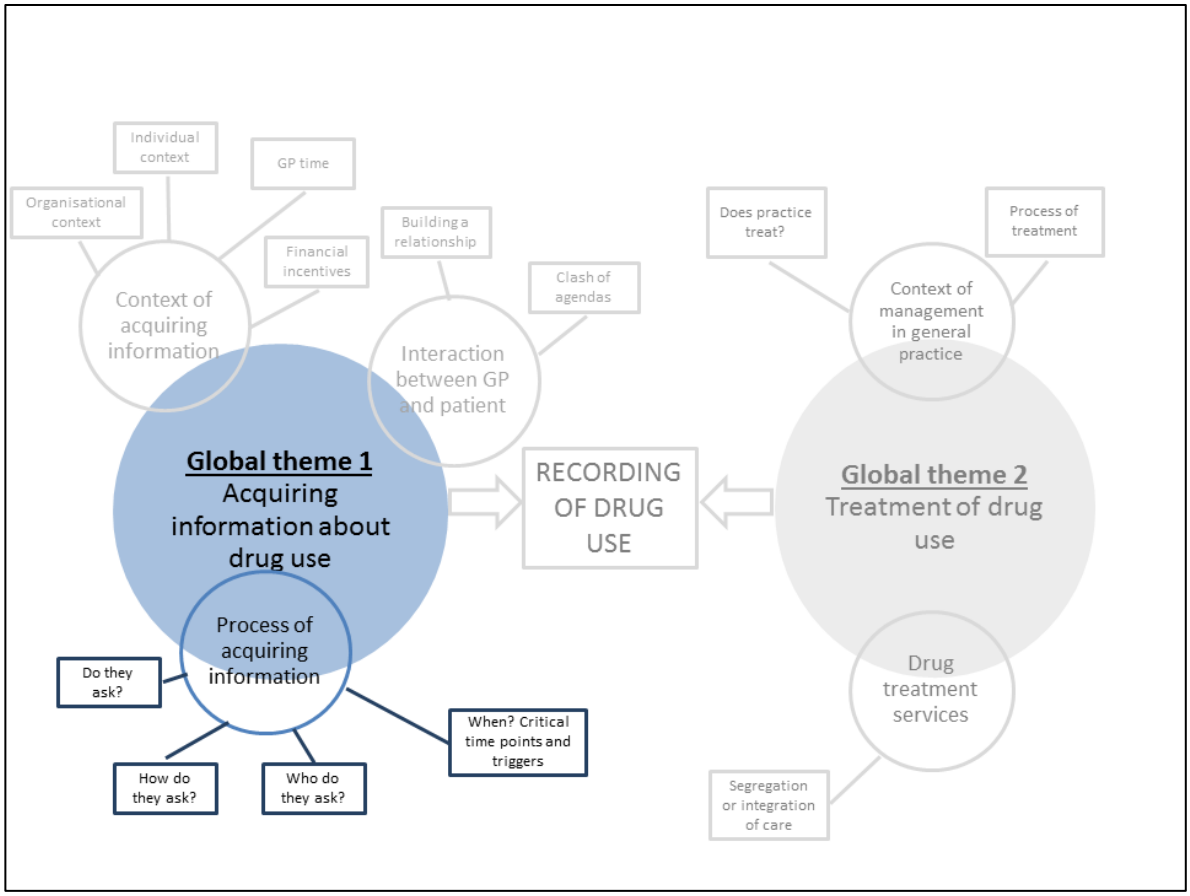


Figure 7:5: Process of acquiring information; third organising theme of Global theme 1

GPs ask about drug use?

The first organisational theme of the "process of acquiring information" is describing if, who, how and in which situations to the GP asks about drug use. The four sub-themes that emerged from the data were: "why does the GP ask about drug use?"; "who does the GP ask?"; "how does the GP ask?"; and "in which situations does the GP ask"

Why do GPs ask about drug use?

GPs did not appear to routinely ask individuals about drug use during consultations. The experience of both the number of years that a GP has practiced, and regularly seeing patients who use drugs, seemed to influence whether or not a GP asked a patient about drug use. GPs with more experience seemed more likely to question patients about drug use. Additionally, those GPs

who frequently saw patients who used drugs were more confident to ask about drug use. One of the GPs who also works in a drug treatment clinic, perceived that the question about drug use usually arises during the consultation about a different problem. She also suggested that GPs are quite nervous to ask about drug use, whereas they are more comfortable asking about alcohol as drinking alcohol is a societal norm.

> *"it's more kind of mostly an incidental thing that will come up as part of questioning during a consultation I mean, people ask all the time about alcohol and are quite confident and comfortable talking about that, but a lot of people I think are quite nervous to actually suggest to someone, especially not your typical you know, they might ask a guy in their twenties, but they probably wouldn't ask a pregnant woman in her thirties."*
>
> ***(GP, female, 5-10 years' experience, inner city, special interest in drug use)***

Conversely to GPs with a lot of experience, GPs with less experience seemed more hesitant and less confident to ask about drug use. This was previously mentioned in the section on GP experience and training. Additionally, GPs may not choose to ask about drug use for reasons other than their experience of working with patients who use drugs. It was interesting to hear the views of a GP with 25 years of experience of working in the same inner city practice. She perceived that GPs who were and were not leads in substance misuse differed with regards to asking patients about drug use. She alluded to the fact that it was like "opening a can of worms" and that the GP might not have time to help with the complex issues that emerged together with drug use at that point in time.

> "*Otherwise a lot of people [GPs] are just thinking they're going to open a can of worms and it's going to make a consultation twice as long if you start talking about it and they have a problem"*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

Despite concerns about managing disclosure about drug use this GP did suggest that the patients are actually relieved to be asked as they can then get the appropriate help.

> *"I think often people are relieved [to be asked or offered help] and actually quite pleased to sort of feel like there is some help, because a lot of people just don't realise there actually is help and maybe they have a problem."*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

It seems that GPs who had a special interest in drug use perceived that GPs not regularly seeing patients who use drugs, did not routinely ask about drug use. Additionally, if they did ask, they may have felt uncomfortable about asking. This could have been due to the fact that they may not have felt they had the expertise to deal with drug use, but also because it might reveal a myriad of other problems that the GP may not be able to deal with within the consultation time. One of the GPs suggested that GPs were more comfortable asking about alcohol rather than drug use. GPs are well positioned to query about drug use, however barriers such as time, experience and the complexity of the issue seem to have an impact on the number of patients GPs ask and therefore record in electronic health records.

Who do GPs ask? Stereotypical vs atypical

GPs are more likely to ask certain individuals about drug use in primary care. Most of the GPs recounted that they did not ask about drug use routinely and justified that the reason they only asked certain individuals was due to the fact that they lacked time to ask everyone.

Some of the GPs described how during their GP experience there were certain presenting characteristics of individuals who used drugs and they therefore directed their queries regarding drug use to those particular individuals. This was illustrated by a GP who does not have a special interest in drug use, but from her experience has found that men who have depression often use both alcohol and drugs. She therefore always asks about alcohol and drug use if a man presents with depression.

> *"There's one group that I do always ask and that's men who come to me with depression"*
> ***(GP, female, 5-10 years' experience, outer city, did not have a special interest in drug use)***

This was similar for GPs who had a special interest in drug use who also asked individuals with certain presenting characteristics such as depression or mental health issues.

> *"And anybody who comes in with depression or mental health issues we'd ask, regardless of age, in the same way as you'd ask about alcohol."*
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

GPs with a special interest in drug use perceived that the many individuals who used drugs also had mental health issues. GPs also appeared to consistently ask certain groups of people about drug use. These included young professionals, students, homeless people or people with insecure housing.

> *"I mean a lot of the time young professional people or students"*
> ***(GP, male, 5-10 years' experience, inner city, special interest in drug use)***

> *"They were homeless patients or they would be vulnerably housed, so in unstable housing"*
> ***(GP, male, >15 years' experience, outer city, special interest in drug use)***

> *"I think if I look back, I'd probably say it would be young professionals, if they come in with sort of anxiety or depression problems, or problems with alcohol, so that would be a trigger most often for me to ask the questions.*
> ***(GP, female, GP trainee, inner city, did not have a special interest in drug use)***

> *"the majority of people in this situation have got mental health problems, and a significant proportion have got personality disorder"*
> ***(GP, male, 5-10 years' experience, inner city, special interest in drug use)***

It appeared that certain types of people were triggers for GPs asking about drug use. However, a GP who also worked in a drug clinic argued that there was a risk that individuals may be missed if GPs only asked certain types of people. In her experience she had found some unexpected individuals used drugs

> *"They [GPs] might ask a guy in their twenties, but they probably wouldn't ask a pregnant woman in her thirties. Whereas there's no reason to think that she hasn't or isn't using recreational drugs; it may be less likely but it's not impossible and so I think that can probably get missed quite a lot."*
> ***(GP, female, 5-10 years' experience, inner city, special interest in drug use)***

Other GPs with and without a special interest in drug use described some patients that they asked about drug use even though they did not fit the typical stereotype of a drug user.

"He also was um different in that he was a professional and was in a job, and found it very difficult to keep going"

(GP, male, >15 years' experience, inner city, special interest in drug use)

"I can clearly recall one patient who was quite well-to-do, in quite a senior management job, and in that case was taking cannabis, and not someone I'd have expected or anticipated"

(GP, male, 10-15 years' experience, outer city, did not have a special interest in drug use)

It was interesting to see that both of the GP accounts above described how they asked certain individuals, not fitting their perception of stereotypes who use drugs, but presented with similar characteristics (insomnia, depression, anxiety) during a consultation. Barriers such as time inhibit GPs from asking everyone about drug use, however, the data highlighted that there may be individuals who do not necessarily fit GPs' perceptions of someone who uses drugs. It may therefore be necessary for a GP to ask about drug use, if an "atypical" person presents with certain symptoms. A GP who has a special interest in drug use perceived that some of individuals who use drugs and are in certain professions may not present to GPs.

"I think some of the party drugs male patients are not presenting, not being honest about it, and maybe that's because they're in sort of more professional roles such as solicitors and barristers, than our typical drug user in the past"

(GP, female, >15 years' experience, inner city, special interest in drug use)

GPs therefore do not always have the opportunity to ask and therefore record certain individuals. GPs did not report routinely initiating discussion about drug use, but if they did, they tended to ask certain people about drug use or people with particular signs and symptoms. A key difference that emerged between GPs who saw and did not see patients regularly who used drugs, was that the former viewed that there was a risk that individuals may be missed if the GP only focused on asking particular groups of patients.

7.6.3.1.1 How do GPs approach asking about drug use?

<u>Direct versus indirect styles questioning style</u>

GPs have developed different styles of questioning in order to ask about drug use. GPs seemed to have reflected on their experience and found a style of questioning

that worked and fulfilled the purpose of acquiring information about drug use. Some GPs used a gentler indirect approach to try and explore the issue more and elicit information from the patient. A male GP from an outer city practice who did not have a specific interest in drug use discussed how he had read and reflected on a journal article about questioning styles and decided to change the way he asked about sensitive topics such as drug use.

> "*I don't ask people directly whether they are taking or misusing substances. I ask them permission to ask it first, and so they have a 'get out' clause, before saying, you know, "Are you taking any recreational drugs?"*
>
> ***(GP, male, 5-10 years' experience, outer city, did not have a special interest in drug use)***

Conversely a female GP from a different outer city practice used a more factual, direct and closed question approach to asking about drug use.

> *I think you have to ask your question to the point, because otherwise you might not get the answer and people might not understand your questions either. So, normally I'd say, you know, "Have you been using any illicits while you're in prison?" You know, "Are you taking your medications as they're prescribed?" So, I'm not quite sure how you could ask those questions otherwise.*
>
> ***(GP, male, >15 years' experience, outer city, special interest in drug use)***

It was interesting to hear about the different questioning styles from various GPs. Their experience and reflection seemed to have shaped their questioning style and it seemed to fulfil the purpose of acquiring about drug use. Some found it easier to be more direct, whilst others find they obtain more information if they use a gentler indirect style of questioning. Questioning style may influence if individuals tell about their drug use and subsequently if GPs record it in the electronic health records.

<u>When are the critical time-points for asking?</u>

There were distinctive and significant time points where GPs reported questioning about drug use. These include during registration of a patient, asking together with another sensitive issue and life changing events such as pregnancy or when a child is involved.

Health check on registration

Patients usually have a health check and answer a health questionnaire when they register with a new general practice. Most of these questionnaires ask about alcohol use and smoking, but some also ask about drug use. A lead GP in Lambeth described how the information from the questionnaire would be coded (using Read codes) in the patients' electronic health records. However he perceived that patients were not always honest with the amount of alcohol they consumed and even less honest with regards to drug use.

> *"This is our new Patient Health Questionnaire, and on it, it has a section, 'Do you misuse any of the following drugs or substances? Alcohol is slightly easier than substance misuse, and, you know, in a questionnaire, I probably don't get the whole details of alcohol and less of drugs"*
>
> ***(GP, male, >15 years 'experience, inner city, special interest in drug use)***

It seems that although the patient questionnaire may be an opportunity for the GP to indirectly ask about drug use, there was some scepticism about the validity of the results. Although registration of a new patient may be a critical time for asking about drug use, it may not be the right time for an individual to disclose and therefore affects recording of drug use in electronic health records.

Asking together with another sensitive issue

Asking about drug use together with another sensitive topic may also be helpful. A GP trainee without a special interest in drug use described how she does not routinely ask about drug use on its own, but found it easier to ask about drug use together with sexual health issues.

> *"I guess the other situation that's come into it in the other time when I would have asked those questions would have been thinking back, sort of, sexual encounters or people who'd come in for the Morning After Pill, and you're kind of asking the protective questions about, you know, "Was this a sexual encounter that you wanted?" I may ask, "Was drugs or alcohol involved?" you know, those sorts of questions."*
>
> ***(GP, female, GP trainee, inner city, did not have a special interest in drug use)***

Consultations regarding other sensitive but maybe slightly less stigmatised issues may present and opportune time for asking about drug use.

Perinatal period

When a woman finds out that she is pregnant, she usually sees her GP who will refer her to the midwife services. If the woman sees her GP, it is an opportune time for a GP to ask about certain health behaviours such as smoking, alcohol and drug use. If she answers positively regarding drug use, GPs unanimously agreed that they would record this information as the drug use not only impacts the mother, but the foetus too.

> *"I think my recording for somebody who is pregnant is much more thorough; just historically it's always more thorough because you want as much information as possible.*
> ***(GP, female, >5-10 years' experience, inner city, special interest in drug use)***

> *And I guess the other area would be in pregnancy, so for example if I'm concerned that either someone might be smoking or could potentially be using, or in their notes it says that they've had some usage in the past, then again that's another trigger to ask, is that a problem now, or is that a new problem.*
> ***(GP, female, >trainee, inner city, did not have a special interest in drug use)***

GPs rarely see pregnant women during the gestation period. Evidence from my second study (Chapter 5) supports this. However, once the woman is discharged from the midwifery service, GPs receive a detailed discharge letter. A GP trainee who did not have a special interest in drug use mentioned that she would record drug use in the woman's electronic record if it was mentioned in the discharge letter.

> *"I would certainly record if I got that [drug use in the discharge letter] letter back,"*
>
> ***(GP, female, >trainee, inner city, did not have a special interest in drug use)***

Pregnancy is a critical and opportunistic time for the GP to ask a woman about drug use. GPs ask many other questions, some of them quite sensitive and therefore drug use could be included.

7.6.4 Key points from the organisational theme "process of acquiring information"

Most GPs did not routinely ask individuals about drug use. Time, expertise and opportunity costs seemed to be the main barriers for not asking. GPs targeted particular individuals when asking about drug use. However keeping an open-mind was perceived to be important. GPs have developed different questioning styles when asking about a sensitive topic such as drug use. There are critical time-points when GPs may be more likely to ask about drug use, these include registration of a patient, when the patient presents with another sensitive issue and during the perinatal period. It is evident that asking about drug use is a multifaceted issue and can influence recording in electronic health records. I will now move onto discuss recording of drug use in electronic health records.

7.6.5 Recording of drug use

From the previous section, my data clearly indicates that "acquiring information about drug use" is influenced by many factors. As "acquiring information about drug use" precedes recording, it follows that GP recording is indirectly impacted by these factors. Recording of drug use is therefore a complex process (Figure 7:6).

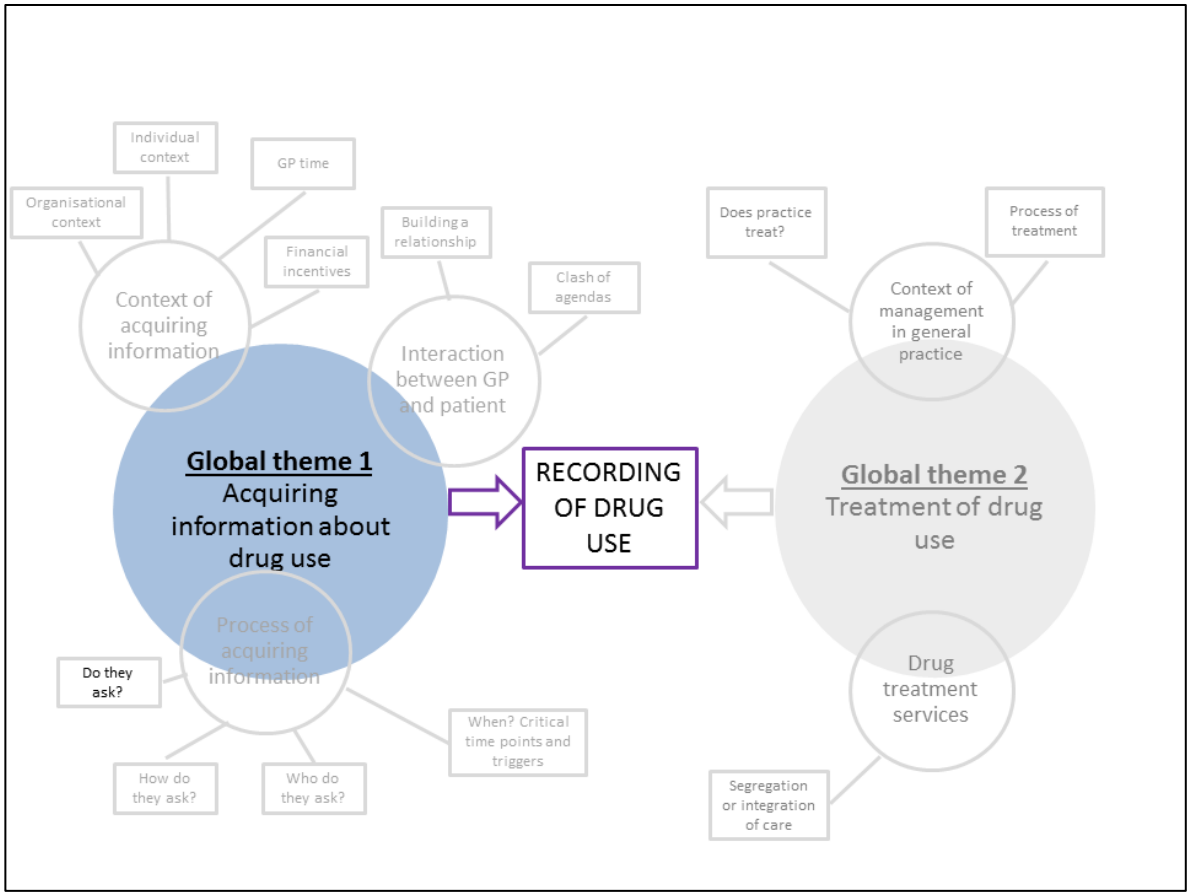


Figure 7:6: Factors from Global theme 1 influencing recording of drug use

7.6.5.1.1 When and who do GPs record

GPs may ask certain individuals about drug use, but whether or not they record drug use for these same individuals seems be dependent on the situation. Similarly recording also depends on the context and how relevant it is at that time.

<u>Permission from patient to record and requests not to</u>

GP opinions' differed with regards to when and how to record drug use in a patient's electronic health record. Some GPs did not feel that it was necessary to ask a patient for their permission to record and a GP trainee described how she

records on the computer once the consultation is finished and doesn't discuss this decision with the patient.

> *"No, it's whenever the patient has left; I always record notes after they've left….Erm … no, I probably wouldn't routinely ask someone [if I can put it in their notes] because I guess you would everything that's told in the medical consultation, you know, is sort of confidential between you and them, really. So I wouldn't necessarily, no. No, I've never asked someone whether I could put it in their notes."*
>
> ***(GP, female, GP trainee, inner city, did not have a special interest in drug use)***

Similarly a GP whose practice was to record information whilst the patient was still in the consulting room, reported not asking for the patient's permission to record. She assumed that the patient was consenting to her recording by being in the consulting room.

> *"I suppose, yeah, I always have to write something when somebody comes in. So if somebody comes in about a drug issue, they would see me writing during the consultation. So I guess that's implied consent."*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

In contrast, some GPs seemed to respect the patient's choice and reported asking or making the patient aware that about recording the drug use. A GP indicated that recording drug use on the electronic health record was a serious matter as it would be on the patient's record eternally.

> *"I don't know, I think that's something we'd have to discuss with the patient because the problem is that once it's on their record, it's on their record forever."*
>
> ***(GP, female, > 15 years' experience, inner city, special interest in drug use)***

> *"I think I'm always aware that what goes into people's medical records follows them. I think you can expand it from substance misuse to mental health, because people worry about mental health problems being recorded in their notes, sort of, and that's from across the spectrum of care provision, so in mainstream general practice as well.*
>
> ***(GP, female, 10-15 years' experience, outer city, did not have a special interest in drug use)***

Two of the GPs who both had special interests in drug use viewed that it was more important to obtain accurate information regarding drug use rather than recording it and he would explain this to his patients.

> *"I've asked somebody about their drug use and said to them that they, it's not, you know, I'm not looking to record this, I think it'd just be useful to know cos it's potentially relevant to their stress or insomnia"*
>
> ***(GP, male, 5-10 years' experience, inner city, special interest in drug use)***

If a patient asked for the drug use not to be recorded, some GPs asked why and then decided depending on the answer whether or not to record. A female GP from an outer city practice expressed how recording in the electronic records was permanent and compared drug use to being recorded with mental health problems.

In contrast, a different GP described how he would try and explain to the patient why it was essential for them to record the information, especially with regards using the electronic health record to help with continuous care of the individual.

> *"So I usually say to them, "Look, if you're seeing somebody and they don't know something about you that's going to influence how they treat you, then it's in your interest to have it on the record."*
>
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

There was an interesting argument with regards to not recording drug use in the records because of the impact to future insurance applications. A GP from an outer city practice who did not have a special interest in drug use described how he felt torn between his role as a GP and role as providing information.

> *"I mean, it always does concern me, any type of recording of anything, you know, that influences people's ability to apply for insurance or things like that subsequently. And I think that's where there's this interface between acting as a care-giver and also acting as a provider of information sometimes, which, you know, I have concerns about."*
>
> ***(GP, male, 5-10 years' experience, did not have a special interest in drug use)***

This reflection illustrates how GPs also act as bureaucratic gatekeepers in primary care. In contrast to his argument, a female GP from an inner city practice with a special interest in drug use perceived that it was important to record for insurance purposes, as if she chose not to record, the records would not be legally valid.

> *"Well, I would explain to them that actually … well, I suppose why they wanted that, I suppose I would want to find out why. Was it for insurance or what exactly, and I'll try and get people to actually let us record it because it's very important information. And even if you don't do it, I would be liable if say it's an insurance report, it's still if you know the information then it would make their insurance thing null and void if it was a fact that it was known that they had a problem, you know, that they've been injecting drug users, say, and they hadn't been checked for blood borne viruses, and I knew it and I hadn't put it into there, it would make their health insurance void."*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

However her account did not distinguish between individuals who used drugs occasionally for recreation purposes compared with those who used drugs persistently. It seemed that the decision to record was a balancing act with regards to patient care. There were however critical times where GPs unanimously said that they would record the fact that the person uses drugs. One of these times was during pregnancy as the drug use not only impacted on the mother, but on the foetus as well. GPs may not record the information as a Read code, but rather in the referral letter to the midwifery service. Additionally GPs perceived that they write a lot more detail in the referral letter compared to a patient who was not pregnant on the patient's electronic health record.

> *"I don't know if we take a robust approach or if we're more harder [sic] on people (who are pregnant), but we wouldn't give people much leeway. I mean, we would say, "If I know about it, then I have to pass that information on."*
>
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

> *"Usually when I'm doing a consultation with someone who is pregnant or if I was doing a consultation where I thought that it would be a social work concern, I'd be more structured and detailed I think than just my usual rambling free-text"*
>
> ***(GP, female, 5-10 years' experience, inner city, special interest in drug use)***

The other critical time that GPs would record drug use was when a child was involved. All the GPs were unanimous about recording in detail if a child was affected by drug use of the mother and/or the father. GPs viewed it as their duty and responsibility to record any adverse situations if it affected a child. If the problem was severe they described how they would usually refer the case onto social services. A GP described how the communication between different agencies such as social services was extremely important and that recording helped with this.

However this was not the case with Neonatal Abstinence Syndrome (NAS). NAS was not always recorded in the child's electronic health record. The GP accounts were divided with regards to the long term implications of NAS. Some GPs perceived NAS to be a medical problem which was dealt with in the hospital

setting. These GPs were more reluctant to Read code the fact that the child had NAS.

> *"It would be recorded. Well, I mean, it isn't that relevant for us because the baby will be over it."*
>
> ***(GP, female, 15 years' experience, inner city, special interest in drug use)***

Conversely other GPs viewed it more as a continuous social problem that could have effects on the child later in life.

> *"I think it is and the chances are, this baby will be on the 'at risk' register, so I think almost undoubtedly, this baby would be well known to Social Services, and it's important that all professionals are aware that this baby is potentially at risk, so that we can look for signs of whatever, relapse on the mum's part or neglect or whatever it may be."*
>
> ***(GP, female, 5-10 years' experience, outer city, did not have a special interest in drug use)***

A GP trainee described how when she was doing her training in obstetrics, they would always include the fact that the baby had neonatal withdrawal syndrome in the discharge letter. She said that she would always therefore use a Read code to record NAS in the baby's primary care electronic health record.

> *"Oh, all of the letters that we wrote in paediatric, it will all have that in there, yeah. "Certainly if I got that letter back, one of the jobs as a GP if you get a letter through that you code it, or if you don't code it, then you send it to the admin to code it. And I would certainly code as much as I could in terms of that, and I'd put it on the baby's and the mother's records. That's what you should do."*
>
> ***(GP, female, GP trainee, inner city, did not have a special interest in drug use)***

It was interesting to hear the account of a GP who described a case where he did not know that the woman was using drugs until he saw the discharge letter and saw that the child had NAS.

> *"I had one many years ago: went through the pregnancy (she's still a patient of ours) and the first time I knew that this person was using drugs was when the child was admitted to the special care baby unit with a drug withdrawal."*
>
> ***(GP, male, > 15 years' experience, inner city, special interest in drug use)***

In summary GPs views' differed with regards to recording drug use. Some GPs viewed that it was more important for the patient to be honest about drug use rather than recording it. Most of GPs were sensitive to the fact that recording drug

use on an individual's electronic record may have a future impact and were therefore sometimes reluctant to record as Read code. There were critical time points when all the GPs agreed that they would record the drug use, this included the perinatal period and when a child was involved. Neonatal abstinence syndrome however was not always recorded as it was sometimes perceived as a medical rather than a social problem and treated in the hospital setting rather than in primary care.

7.6.5.1.2 How do GPs record information about drug use?

Finding specific Read codes to use for recording drug use can be time consuming and it is sometimes easier and quicker for a GP to use free-text rather than Read codes. Some GPs who did and did not have a special interest in drug use, expressed that there were too many Read codes to use and it was often easier and quicker for them to record the information using free-text or generic codes.

> *"So, yes, I think that's very true of EMIS that it probably needs to be cleaned, but I guess there's often one to find, but whether you can find the exact thing you're looking for and you just don't have the time to search. So you'll use a couple of key words and then if they're not bringing up what you need, then I'll just put it in the notes in another way, which is probably a problem because then if you were specifically looking for it, it won't come up the same way or as easily for someone like you doing a random search."*
>
> ***(GP, female, GP trainee, inner city, did not have a special interest in drug use)***

> *And sometimes that's I mean it's not because I shouldn't be (slight laugh) but I do it just because mostly I would just be freetexting everything, rather than specifically looking for Read codes for it.*
>
> ***(GP, female, 5-10 years' experience, inner city, special interest in drug use)***

A GP trainee described how the whole Read code system needed to be sorted and inapplicable codes needed to be removed.

> *"Erm, I think that everyone will get into a pattern of finding a new thing, the ones that they know are there. I think there are a lot of silly ones, and I think it really needs to go through a kind of, er … a sort of … Well, just I think a clean-up, yeah."*
>
> ***(GP, female, GP trainee, inner city, did not have a special interest in drug use)***

Both GPs with and without a special interest in drug use described how they would Read code the primary problem that the patient had come about rather than record drug use.

"Otherwise it's you know they be [sic] coded as we normally include the main thing that we see them for so you know like other bits and pieces"

(GP, male, 5-10 years' experience, inner city, special interest in drug use)

"In general practice it would just be what you thought the main problem was or something, so either the one that has been coded before"

(GP, male, 5-10 years' experience, outer city, no special interest in drug use)

GPs described how information in the discharge letter was scanned into the woman's electronic health records once a woman was discharged from the midwife services. A GP trainee recounted how she usually highlighted the important symptoms or diagnoses from the letter and then enters these as Read codes. It was interesting to hear that she knew of more experienced GPs, who due to time constraints, had the practice administrator choose and enter the Read codes. There was no indication from my data that practice administrators received any training on how to choose particular Read codes.

"Well, to be honest, I don't do that, because it's not my habit to do it, but I know certainly some of the older GPs in the practice I think who have the greater work burden, they highlight what the issues are and then send it back to say, these are it. But I think in my practice certainly and in what I do, I would open up the mum's records, I would open up the kid's records, and pick a Read code and put it in."

(GP, female, GP trainee, inner city, did not have a special interest in drug use)

Some general practices have developed templates or protocols to use specific Read codes to record drug use. GPs who worked in these practices perceived that using these templates was easier and more time efficient as they did not need to spend time scrolling through the many Read codes. The template also offered more opportunity for auditing the information regarding drug use in their general practice, as the same Read codes would be used. Larger practices seemed more likely to have developed a template or protocol.

"this lady I saw yesterday. I would have used our template to record her illicit drug use"

(GP, female, 5-10 years' experience, inner city, special interest in drug use)

"Yeah, well, they have to because as long as they use the template they're using those. So the only way you're going to get people to use similar Read codes is to make them use a template."

(GP, female, 5-10 years' experience, inner city, special interest in drug use)

I will go into more detail with regards to templates in the next section. To summarise there are many different views with regards to using Read codes to record drug use. Some of the GPs found using Read codes time-consuming as they had to scroll through to find the most appropriate Read code to use. There was an overall perception that free-text was a quicker and easier way to record. There seemed to be a view that there were too many Read codes and this could be revamped to get rid of unnecessary codes. GPs described how discharge letters are usually scanned, but some important information is regularly recorded as Read codes in the electronic health records. GPs may sometimes rely on the practice administrator to choose and enter the Read codes. Some practices have templates for recording drug use which seems to make the recording more organised and systematic.

7.6.6 Key points from accounts of recording drug use

GPs reported that they do not always record drug use if the patient discloses the information during a consultation. They will normally look at the context and make a decision on whether or not to record. GPs usually recorded the primary problem (e.g. insomnia, depression) as a Read code rather than drug use. The timing of recording in consultations differed with GPs and they did not always explicitly tell the patient that they are recording drug use in the electronic health records. GPs unanimously record more when a woman is pregnant or when a child is involved, but the recording may be in the free-text and not necessarily a Read code. However, there was a difference of opinions with regards to the importance of recording NAS. There are numerous Read codes to choose from and consequently GPs find it easier to free-text rather than Read code. Practice administrators are sometimes also choosing and entering Read codes highlighted by the GP. Some practices have developed templates for recording drug use which means that they are consistently using the same Read codes to record drug use.

I will now discuss the findings for the second global theme that emerged from the data.

7.6.7 Global theme 2: Management and treatment of drug use

The second global theme I identified and developed from the data was "management and treatment of drug use". In order for recording regarding treatment to take place, an individual needs to be managed and treated in the general practice or in a drug treatment service. Consequently, two organising themes emerged; "management and treatment in general practice" and "other drug treatment services"

7.6.7.1 Management and treatment of drug use in general practice

Within the organisational theme of "management and treatment in general practice", I identified two sub-themes, these were the "context and the process of the management" and "treatment within the different practices".

7.6.7.1.1 Context of management and treatment

The context within the general practice emerged as an imperative aspect with regards to recording as not all general practices treat drug use and subsequently have the opportunity to record in the electronic health records (Figure 7:7).

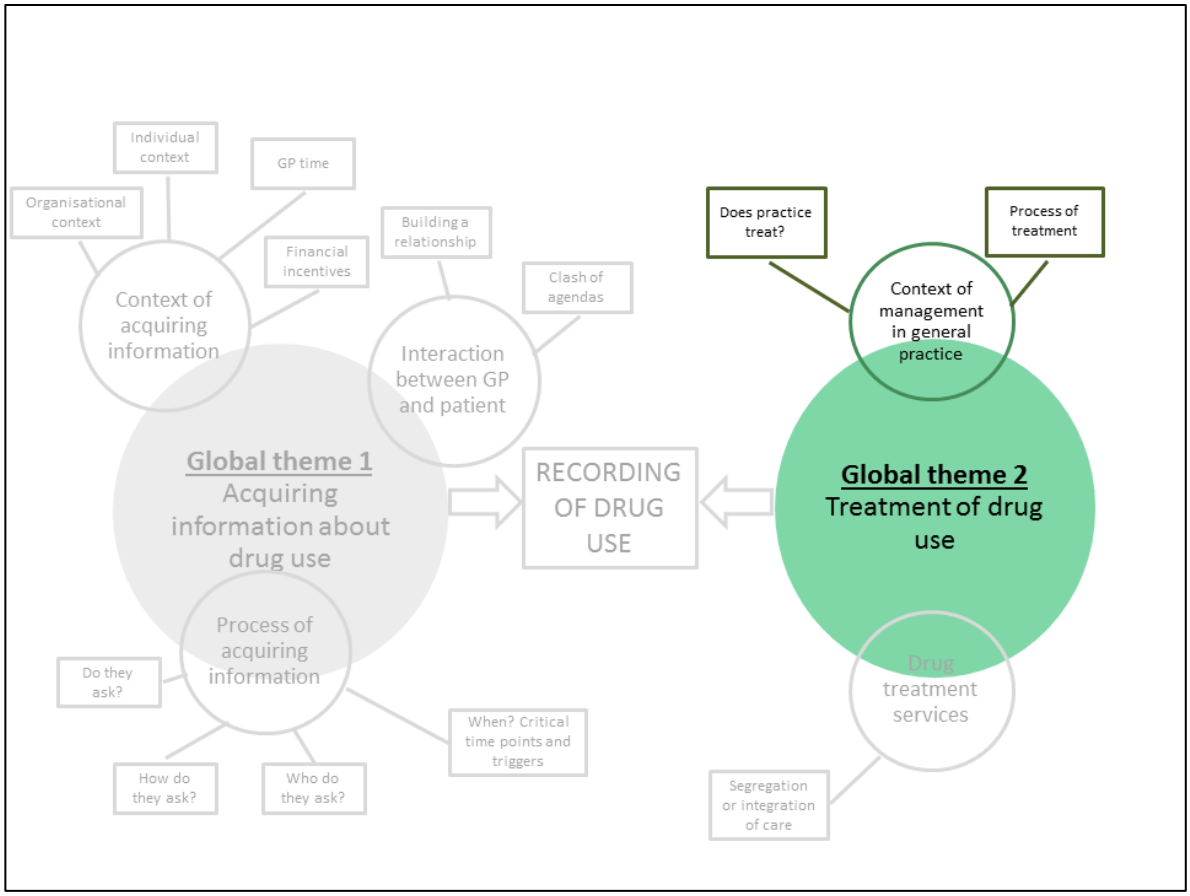


Figure 7:7: Context of management and treatment in general practice, first organising theme of Global theme 2

Does a general practice treat or not?

Treatment of drug use is not part of the General Medical Service (GMS) (*section 1.3.8*) contract and therefore general practices are not obligated to treat individuals who use drugs. However, if a general practice does not treat drug use, the practice should still be responsible for the medical care of individuals who use drugs. General practices that do treat drug use have usually been commissioned by and are funded by local enhanced services (*section 1.3.8.2*). A GP working in an inner city general practice perceived that they had a relatively high percentage of individuals who used drugs because they treated drug use in the practice.

"And our practice has had, if you like, probably a disproportionately high number of patients, because we take part in the Level 2 Enhanced Service, so that's one thing"

(GP, male, >15 years' experience, inner city, special interest in drug use)

As previously mentioned in the section "financial incentives for general practices", the data also indicated that some areas have one specific general practice that served the area, rather than treatment taking place in all the general practices. A female GP from an inner city practice described how patients from other general practices were referred to and treated for drug use in her general practice.

"We do quite a lot of drug work. We look after our own patients, 30 something, 33, 35 or maybe 36, patients who are on methadone or buprenorphine. We also look after another 30-40 who are registered at other practices where their own GP won't prescribe; we do the prescribing of the opiates and drug clinics."

(GP, female, > 15 years' experience, inner city, special interest in drug use)

It is evident that there are a few options available for general practices with regards to treating drug use. General practices are not obligated to treat drug use and it may be more beneficial that individuals are treated in either practices that have the expertise and confidence to treat individuals or treated in specialised drug treatment service. It is also evident that GPs should have a clear understanding of where to sign-post or refer individuals in order that they receive the most appropriate treatment. However whether or not the general practice treats individuals for drug use will have an impact on recording of drug use and treatment in the electronic health records.

GPs may not see or treat individuals during pregnancy

GPs may not have much contact with a woman during her pregnancy which impacts recording in the electronic health records. GPs refer pregnant women via a referral letter to either normal or specialist maternity services. Additionally, the specialist maternity services usually take over treatment if a woman requires treatment for drug use. One of the GPs described that she would always put a greater amount of detail into these referral letters to the midwifery services than if

the referral was to a different service. These referral letters are sometimes scanned onto the patient's electronic health records, but Read codes are not always used. The same GP also explained that she would always indicate if the woman smoked, used alcohol or drugs as she perceived that this information was imperative in order for the pregnant women to obtain the correct treatment.

> *"But in general practice, I can think of one woman recently who was a cannabis user, but she wasn't using any opiates, so I put that in her letter because that had been picked up during her pregnancy and a social worker had been involved in the pregnancy"*
> ***(GP, female, 5-10 years' experience, outer city, did not have a special interest in drug use)***

In one region, the specialist antenatal service is incorporated into the local area addiction unit. Therefore GPs refer straight to the addiction service and pregnant women will be seen within the unit.

> *"They would have been transferred to the local … within [place] there is the [place] Addiction Unit, and the [place] Addiction Unit at that time were, and still are, commissioned to provide the antenatal specialist prescribing. So we would have had to have referred into them."*
> ***(GP, female, >15 years' experience, outer city, special interest in drug use)***

The treatment of drug use during pregnancy seems to be unanimously transferred to the midwifery services. The referral is either directly to the specialist midwife service or to the generic midwife services, which may then be triaged to the specialist service. As mentioned in *section 5.8.2.3*, once a woman is discharged from the maternity service, GPs should receive a discharge letter. Information from these letters is usually scanned into an individual's electronic health record. Important information from these letters can be recorded as a Read code, but this does not always occur in the electronic health records.

<u>Is there shared care?</u>

Some general practices who offer treatment for drug use have a designated drug worker and/or drug nurse working with the GP lead. This model of shared care seemed to work effectively and GPs viewed the working relationship with either the drug worker and/or drug nurse as very beneficial. An effective working relationship

allowed good communication between GP and drug worker, however meetings can be relatively informal and not always recorded in the electronic health records.

> *"I think that we have to get better at recognising the need for good communication, and for multidisciplinary care and continuation of care as well, and that's about developing services So it takes time and I think it starts with people coming in and taking ownership of that, that group. And bringing expertise in and bringing experience in and sharing experience, and then looking at how we can do things."*
>
> ***(GP, female, > 15 years' experience, outer city, special interest in drug use)***

> *"She's a practice nurse, but she sort of was a specialist nurse before she became a practice nurse in substance misuse, and she does all my alcohol detoxes as well, we usually communicate face to face and might not record all the information"*
>
> ***(GP, male, > 15 years' experience, inner city, special interest in drug use)***

There was however a setback when either the drug worker or practice nurse left the practice and was not replaced.

> *"We had a very good substance misuse worker working with us when we first started doing it, so I learnt a lot from her. She's unfortunately not here now"*
>
> ***(GP, female, > 15 years' experience, inner city, special interest in drug use)***

In two of the inner city practices, they offer a weekly clinic for patients requiring treatment for drug use. The patient will see either the lead GP or drug worker on alternate weeks. The consultations are recorded using a standardised template (discussed more in section 7.6.10.1).

> *"Yes, we do, yes. We do based on … for a small group of patients. We have about 20-ish patients who attend the clinic; they come and they go but it's about 20. They're either seen weekly, fortnightly or monthly, depending on their stability. We use a template to record each week"*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

In contrast some practices did not have been a designated drug worker and/or practice nurse. In these instances some of the GPs had formed a good communication relationship with other health professionals involved in treatment of drug use outside the general practice. However, the data shows that one of the GPs who has a special interest in drug use conducts most of her communicating with health visitors over the phone as the health visitors are located away from the general practice. Not all of the conversation is recorded.

"The health visitors are really good actually, the health visitors in our practice, so they keep quite a close eye on people in their postnatal period, and we have quite good links and communications with them, if they had any concerns. They're based slightly, they're not based in the exact same part of the practice as we are, so I do a lot of my communication with them just over the phone, which isn't ideal either, because we're both obviously having to make a summary of our discussion."

(GP, female, 5-10 years' experience, inner city, special interest in drug use)

Shared care is beneficial, however, much of the communication occurs on the phone or in meetings and it is not always documented and entered into the electronic health records. Recording of management and treatment seems to work in the inner city practice that has developed a protocol together with drug workers. It was not always seen as time efficient, but that could be because GPs have so much other information to record. I provide more detail about this recording template in *section 7.6.10.1*.

7.6.8 Key points from the organisational theme "management and treatment in general practice"

Not all general practices chose to manage and treat drug use. General practices choosing not to treat, are still responsible for the patient's medical care and for referring to and signposting patients for the most appropriate treatment which they may record using either Read codes or free-text. GPs may not see women during their pregnancy, but referral and discharge letters from midwifery services are usually scanned, however Read codes are not always used to record important information in the electronic health records. Some general practices that manage and treat drug use have a shared care model of practice which can be beneficial in delivering patient centred care, however communication between health professionals regarding the patient is often informal and not recorded.

7.6.8.1.1 Process of management and treatment

Who can GPs refer to?

If a general practice does not offer treatment for drug use, a GP has a few different referral options. GPs described how they can refer a patient to the drug treatment clinic or in some cases, another GP practice where treatment takes place. They

may use Read codes or free-text to record the referrals. Two GPs described how they suggest to the patients that they refer themselves to the drug treatment clinic. The first quote indicates that he perceived that patients were more likely to attend the drug treatment clinic if they referred themselves rather than being referred by the GP.

> *"I tend to get people to self-refer for most things that they can self-refer for, because I think they're more likely to actually attend if they self-refer themselves. I usually record this as free-text"*
>
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

> *"they can self-present, so that's why I think it's rare and a lot of people don't want their GPs necessarily at first to know they've got drug addictions so they go to the services separately"*
>
> ***(GP, male, 5-10 years' experience, inner city, special interest in drug use)***

The second quote illustrates that if a patient self-refers without the GPs knowledge, the GP cannot record this information in the electronic health records. There are some cases when a GP chooses not to treat the patient in the general practice, even though treatment for drug use is offered. One of the GPs explained that she referred more chaotic patients, to the drug treatment services. She perceived that patients who did not adhere to their clinic appointments may get more support and be managed more appropriately in the drug treatment services and she would either use a Read code or free-text to record the referral.

> *"And the ones we might refer on, they get too chaotic, they're drinking too much, they're just not able to manage their own shared care in terms of totally unable to turn up for appointments, injecting their neck or some really dangerous practices, where we think they might benefit, we've got a local injecting clinic so we might send them to that. So where they're just not able to engage with our service, we refer on and I may use a Read code or just free-text."*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

In summary the data highlighted that there are various options for GPs to refer to or sign post the patients to for self-referral. GPs who saw patients more frequently who used drugs and who were involved in shared care seemed to be more aware of the referral processes and options for referrals. If GPs made the referral, they reported using either Read codes or free-text.

7.6.9 Other Drug treatment services

There are various drug treatment services that GPs can refer individuals to. There seems to be either segregation or integration of care between general practices and services (Figure 7:8).

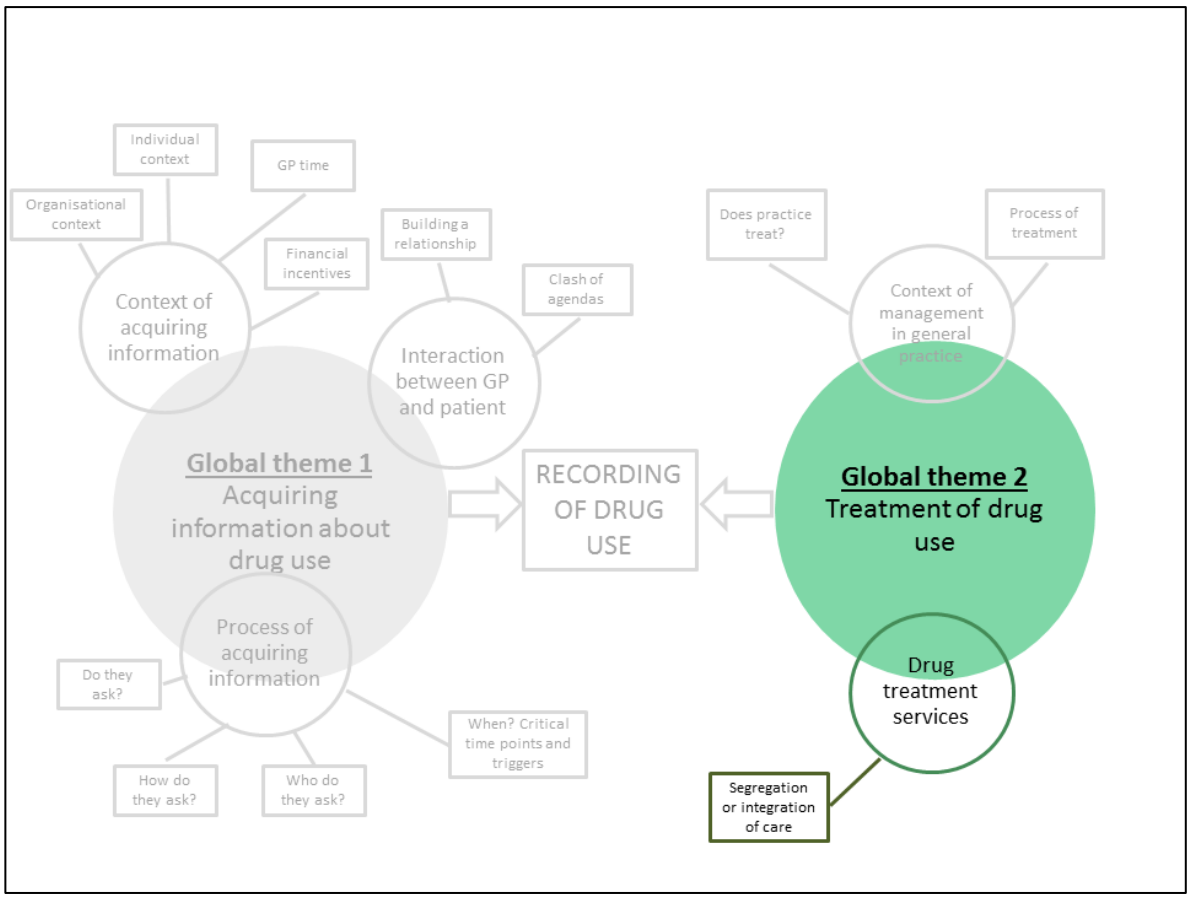


Figure 7:8: Other drug treatment services; organising theme of Global theme 2

7.6.9.1.1 Segregation or integration of care

<u>Communication between the services and the GPs</u>

In some circumstances there seems to be more segregation rather than integration of care. Once the patient goes to the drug treatment service or maternity service there may not be much communication between the GP and the service regarding the patient. A GP explained how the lack of communication could be detrimental; as a patient could be receiving opioid substitution treatment from the drug

treatment services without the GP knowing and the patient may then try to obtain additional medication from the GP.

> *"But that's generally a problem with our secondary care service anyway, the drugs service, they don't communicate they don't write letters. They're not very good at sort of communicating back to us."*
>
> **(GP, female, >15 years' experience, inner city*, special interest in drug use*)**

GPs are therefore not able to record information regarding treatment in the patient's electronic health record because of the communication gap between services. There are also areas where good communication and integration of care between the drug treatment service and the general practice occurs. The data showed evidence of good practice of integration of care in a region where drug use is highly prevalent. The regional addiction service use the same software system (system One) as the general practices in the area. If a patient gives consent, the GP can access a patient's electronic records from the drug treatment service and see the quantity of medication being prescribed. This then decreases the risk of over-prescribing.

> *"The nice thing is we're on the same computer system, so we can see when they've been seen there and we can see what's been going on as well"*
>
> ***(GP, male, 5-10 years; experience, outer city, did not have a special interest in drug use)***

It is evident that there are examples of both integration and segregation of care with regards to communication between other services and general practice. It seems that different services are using different recording systems which are not usually linked to the general practice. The GP will only hear about the information if they get a discharge letter, communicate directly with the other services or if the patient tells them the information. As mentioned in the previous section, some of the GP practices recording systems are set up, so that the GP can link into the records of the patient at the treatment centre. The general practices that are using the same electronic systems as the drug treatment services seem to be benefitting from this ongoing communication. As long as the patient consents to their records

being shared, the GP has a more accurate picture of the patient's care in other services.

7.6.10 Key points from segregation or integration of care

There seems to be more segregation rather than integration of care when the patient's care is transferred to other services and communication regarding the patient is not always adequately fed back to the GP. Finally, there are regions in the UK who have set up the same electronic systems and therefore information regarding the patient is shared between the drug treatment service and the general practice. These aspects all impact GP recording of drug use in the electronic health records.

7.6.10.1 Recording drug use and treatment using templates

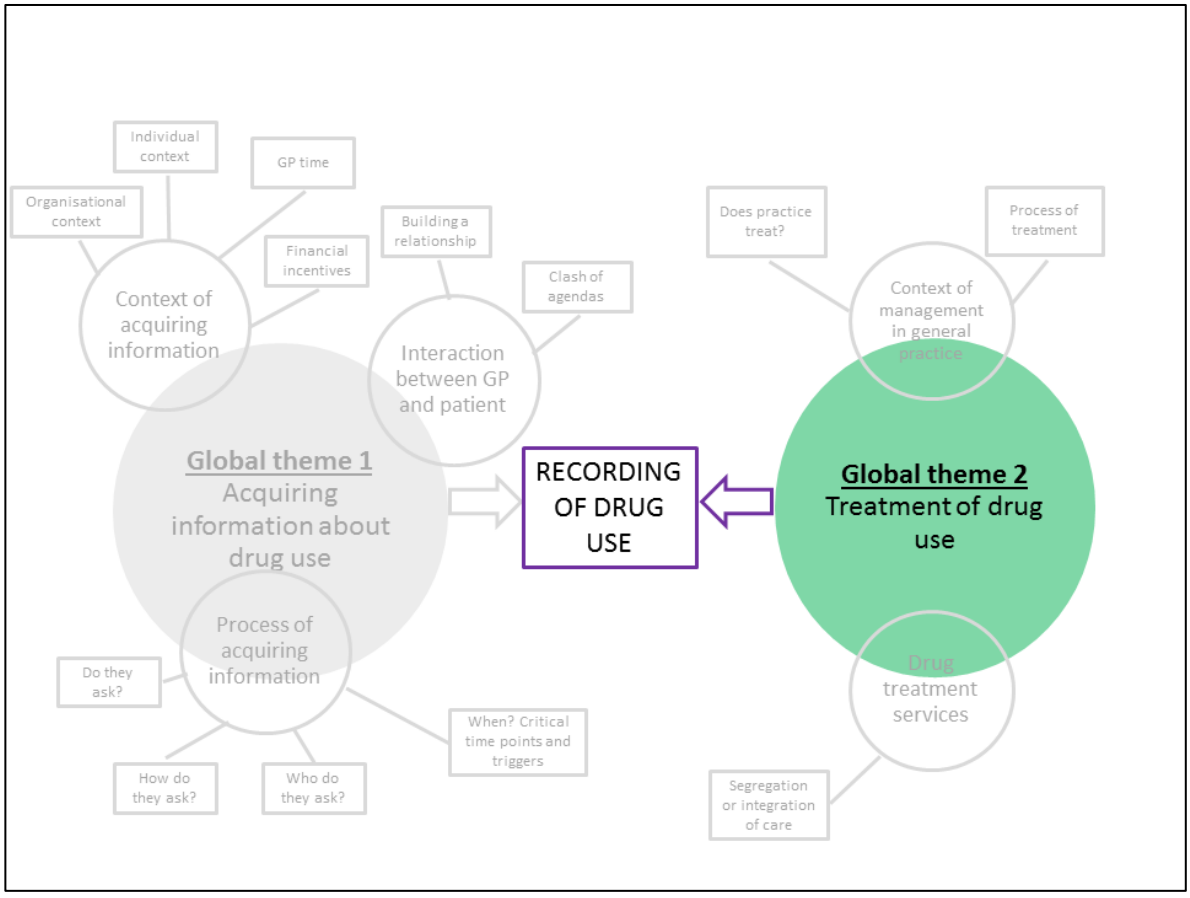


Figure 7:9: Recording of drug use 2

Some general practices have developed templates for recording drug management and treatment. A lead GP in an inner city practice described how over the years there was a need for her to develop a template for recording drug use, especially to ensure that they were receiving the correct payment for treatment.

> *"So our template for substance misuse is that one, and so because we get a payment for drug addiction treatment, so to use this template, you have to use the drug addiction, one of these three codes"*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

The template was linked to various Read codes in the patient's electronic health record, but the drug workers and GPs also had the opportunity to free-text additional information.

> *"Then there's a thing underneath it where you can free-text the amount of illicit use that there has been."*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

She had worked together with other GPs, drug workers and an IT specialist to develop the template. She also described how the template was annually updated to ensure that appropriate information was being recorded.

> *"I had an opportunity to work with the IT guy to improve the template .So I did quite a bit of work with them [drug workers] to make sure that what was on the template would be useful for them as well, for their templates. So it works quite well because we did actually consult quite a lot of people, the people who were frontline in making sure that we had what they wanted in the template. I worked it out so that the drug workers would be able to record stuff onto the computer and we'd be able to search for it. So when it comes to recording illicit use, this is the thing."*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

I interviewed another GP who was using this particular template, and she perceived the template as extremely useful with regards to recording and the continuity of care of the patient. She did however express how she had found it bit time-consuming to complete.

> *"It's a template developed by them (the other GP practice) which we use, usually in each consultation, but actually it's quite repetitive."*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

This particular template is only used in this particular London borough and has not been rolled out to other general practices. After viewing the template and observing how quickly a vast amount of relative information could be entered and then linked to Read codes, I asked the GP if she had thought about rolling it out to other general practices. She unfortunately has not had the time, initiatives are at a local level and reliant on individuals for roll out.

> *"I've done an awful lot locally, but I've never really got hugely involved in the RCGP or stuff nationally, because, well, I had kids and I haven't time, and I was more interested in working locally"*
>
> ***(GP, female, >15 years' experience, inner city, special interest in drug use)***

A different inner city GP had developed a template for recording. During the transfer of computer systems his template disappeared. He described how frustrating it had been and he was trying to find the time to develop a new template but he felt that he did not have the IT expertise and did not have any IT support.

> *"I have got a template, but it's all a bit of a mess, because for 20 years, I've been using Emis and we had our templates, but they were mainly templates that I built myself and used all the time. And now we've transferred to System One and all that data is actually lost. Um, I'm really at sea at the moment, because I'm so used to coding my information, at the moment I feel I cannot make any proper notes! "*
>
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

> *"It was actually one of the reasons why we were very cautious about not switching to Emis Web because Emis Web said it couldn't be done. SystemOne, under false pretences, said that it could be done and they could adapt all my codes, and I could build the templates again with the old codes. But, no, so we're not quite sure how to solve it."*
>
> ***(GP, male, >15 years' experience, inner city, special interest in drug use)***

Templates seem to be very useful and efficient with regards to recording management and treatment of drug use in general practice. They do however take individual commitment to develop, but there are no process to help roll out.

7.7 Discussion

7.7.1 Summary of findings

I have included the key summaries after each organising theme in the findings section. Many factors appear to influence recording of drug use is general practice. I have produced an algorithm to illustrate the various ways that recording of drug use can be captured in electronic health records in THIN (Figure 7:10).

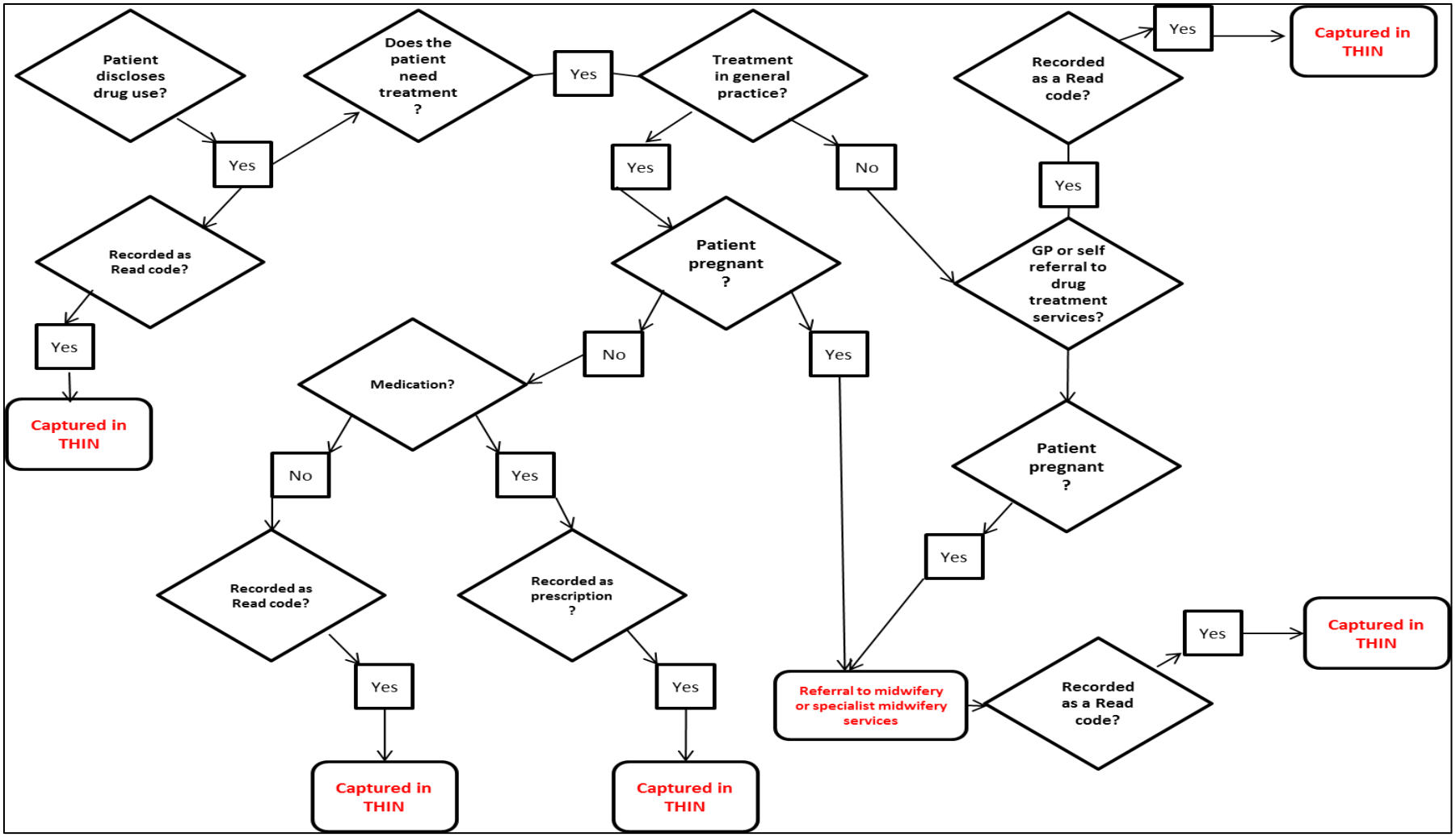


Figure 7:10: Algorithm illustrating how drug use is recorded in THIN

In order for recording to take place, the patient has to see a GP and the GP needs to either ask or the patient needs to disclose that they use drugs. Decisions are made at all points (figure 7.10) as to whether or not to record drug use and if so whether or not to use Read codes or free-text. As mentioned previously, it is more useful and practical to extract and examine Read codes than free-text when using THIN as a surveillance or research tool. It is difficult to capture information using free-text as to date, only a third (35%) of free-text comments have been anonymised in THIN (CSD health research, 2015).

7.7.2 Comparison with previous literature

In this section, I have analysed all the data together with regards to pregnancy, NAS and GPs who did and did not have a special interest in drug use. The analysis identified and explored different levels that influence recording of drug use in electronic health records which fitted into the following conceptual framework; the first level was the individual GPs, the second being the general practice, the third, the CCG and finally how government policies can impact recording (Figure 7:11).

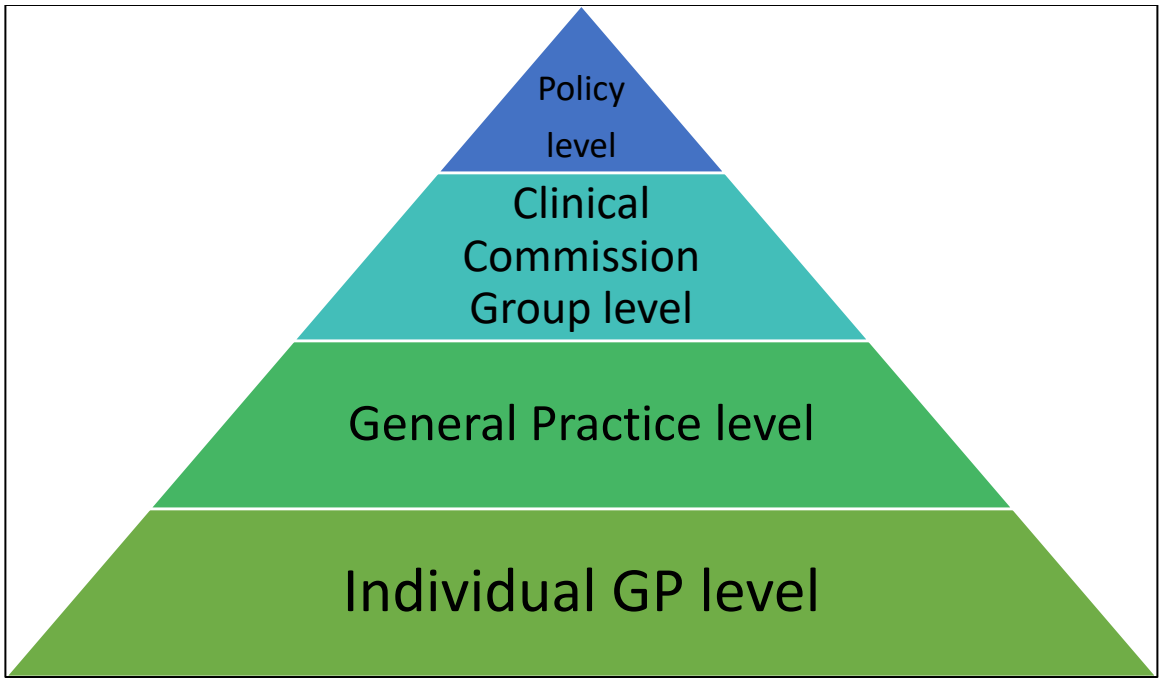


Figure 7:11: Interpretation of findings

General Practitioner level:

Primary care may be the first point of contact for some individuals who use drugs. When a GP sees an individual who uses drugs, many factors (mentioned in previous section) seem to influence if and how they record in the individual's electronic health record. Most of the GPs interviewed in this study with and without a special interest in drug use perceived that their role for managing and treating individuals who use drugs was essential and important. Some of them also described how they had become more accepting and desensitised to the stigma associated with drug use. These perceptions echo the Royal College of General Practitioners (RCGP) recommendation that GPs should try to maintain a non-judgemental attitude towards patients (Royal College of General Practitioners, 2010). The GPs' views and perceptions seemed to be moulded by their experience and how they viewed their role in the treatment of drug use. Their role encompassed identifying the problem and working together with other health professionals and services in order to manage and support individuals who use

drugs. It can be clearly seen that recording of drug use is potentially affected by how the GPs view their role with managing and treating individuals who use drugs.

GPs' experience and training also seemed to influence how they recorded drug use in electronic health records. A GP's working week is divided into sessions which are approximately four hours each. Data from this study supported the fact that GPs who worked in both general practice and drug treatment felt that they were more aware and therefore asked individuals about drug use more frequently, which then influenced if the GP recorded or not. The RCGP offers standardised training in substance misuse in the form of two modules (Royal College of General Practitioners, 2015a). Once the two modules are complete, the GP is awarded a certificate in the Management of Drug Misuse (Royal College of General Practitioners, 2015a). It was evident from the data that most of the GPs who were clinical leads for substance misuse had completed one or both modules of the RCGP training. This highlights adherence to RCGP guidelines which recommends that "practitioners with special interests" should undergo specific training and accreditation (Department of Health (England), 2007; Ford *et al*., 2013). Currently there are no guidelines regarding recording in the modules (Dr C Ford, 2014: personal communication (email) 8 Dec). I will discuss this in more detail in the clinical implications (*section 9.8*)

Development of good rapport can influence the information the individuals tells the GP during a conversation. The narratives from this study illustrated that most of the GPs perceived that developing rapport with a patient was important and the relationship can be strengthened when the GP is empathetic. These opinions resonate with Goold and Lipkin's argument that the doctor-patient relationship is an imperative aspect of patient care and is possibly as important as therapeutic treatment (Goold and Lipkin, 1999). If a GP incorporates empathy into the relationship, it allows the patient to feel heard and they may then open up more to

the GP and develop a relationship which could impact on their decision to stay with the same GP (Goold and Lipkin, 1999). However, Gott *et al.* found that GPs felt that there was insufficient time to build rapport with the patient when they asked about another perceived sensitive topic; sexual health, which the GPs perceived as a sensitive issue (Gott *et al*., 2004). The GP accounts from my study also suggest that GPs aim to create a balance between the needs, wants and requests of the individual. Unfortunately relationships between GPs and patients can decline, which could be exacerbated if a patient is requesting something that the GP cannot concede to. Furthermore, most of the GPs in my study perceived that the main barriers to building and establishing relationships with patients were time constraints and continuity of care. According to the GP service report, patients value a long term and continuous relationship with their GP (Monitor, 2015). If the general practice has a clinical lead for substance misuse, the patient should be seeing the same GP and therefore receiving more continuous care. This continuity of care should therefore allow time for rapport and interpersonal continuity of care to be established between the GP and patient. Continuity of the individual seeing the same GP could influence what the individual tells the GP and therefore influence if the GP records the drug use in the electronic health records or not.

Building rapport can also aid in developing trust between the GP and an individual. The narratives in this study illustrated the value GPs placed on the trust of the patient. The opinions regarding trust echo with Croker *et al*, who rationalized that the trust patients have in their GP is essential for effective and efficient consultations (Croker *et al*., 2013). This is especially evident when the patient is disclosing sensitive information and may feel a sense of vulnerability (Croker *et al*., 2013). Goold *et al.* reasoned that a patient who does not trust or like their GP will not disclose all the information efficiently during a consultation (Goold and Lipkin, 1999). Furthermore, it was also interesting to hear that most of the GPs did not always seem to think that the patient was openly communicating and disclosing the whole story and therefore GP's could start to distrust the information they receive

from the individual. It is evident that the development of trust between the GP and patient can impact on the patient disclosing drug use and whether or not the GP records drug use.

Together with gaining the patient's trust, respect for each other is also imperative to the consultation. The narratives in this study illustrated how most of the GPs respected the patient's autonomy by not recording the drug use in the electronic health records if the patient asked them not to. However in some cases GPs tried to highlight the importance of recording to the individual. Shared decision making and a sense of partnership can help to maintain the patient's trust in a GP (Croker *et al*., 2013; Little *et al*., 2001). Although overall when a woman was pregnancy or a child was involved, GPs in this study seemed unanimous in their actions with regards to always recording drug use. Woodman *et al.* found that the role of health professionals identifying children who have been maltreated or neglected was increasing in primary care (Woodman *et al*., 2013). Furthermore, perinatal exposure of illicit drugs during pregnancy has recently been included in the definition of child neglect (HM Government, 2013). Therefore GPs may be inclined to record drug use more in electronic health records when a woman is pregnant or a child is involved. In summary GPs used their judgement on whether or not to record drug use in the electronic health records.

Individuals presenting with certain signs and symptoms may trigger a GP's awareness of drug use. This trigger of awareness could potentially be problematic for the relationship between the GP and patient as the patient may be seeking help for a problem other than their drug use. Overall GPs with and without a special interest in drug use described similar signs and symptoms that triggered their awareness of drug use, which sometimes resulted in the GP asking about drug use. Medical practitioners play an important role as a first point of contact for people who are seeking help (Royal College of General Practitioners, 2010).

Hamilton and Britton argued that the agenda (problems) that the patient present to the GP may clash with the GP's prioritisation (Hamilton and Britten, 2006). Prior to consulting a GP, patients have usually judged the seriousness of the issue (Hamilton and Sharp, 2004). If this problem then triggers a GP's awareness of drug use, and the GP focuses on the drug use rather than the original problem, the patient could become frustrated and not feel heard. Goold *et al.* described how three factors determined how the consultation would be successful to both GP and patient (Goold and Lipkin, 1999). The three factors were the following; the GP's agenda, the patient's agenda and the outcome and plan of the consultation (Goold and Lipkin, 1999). They theorised that if the three factors overlapped considerably, the consultation could be deemed productive by both GP and patient, however if there was little overlap, one or both of the parties could deem the consultation as unsuccessful (Goold and Lipkin, 1999). This conflict of interests could contribute to of the demise of the GP-patient relationship and therefore influence if the GP decides to record drug use in the electronic health records or not.

In order to record drug use, GPs usually need to first ask the individual. Asking about drug use seemed to differ between GPs who did and did not have a special interest in drug use. GPs who did not have a special interest in drug use in this study seemed to see patients who use drugs infrequently and therefore did not ask about drug use routinely. Additionally, if they did ask, they seemed to feel uncomfortable about asking. This seemed to be because they may not have felt they had the expertise to deal with drug use, but also because asking about drug use may reveal a myriad of other problems that the GP may not be able to deal with within the consultation time. McGillion *et al.* and McKeown *et al.* found similar issues with regards to expertise and time when they interviewed GPs and practice nurses regarding managing individuals who used drugs (McGillion *et al*., 2000; McKeown *et al*., 2003). Similarly, Gott *et al.*, found a similar issue when they interviewed GPs and practice nurses regarding barriers to talking about sexual health (Gott *et al*., 2004). The same phrase "can of worms" as well as "pandora's

box" was used in both my study and the study by Gott *et al.* to illustrate how a sensitive and complex issue was difficult to discuss within the time and resource limitations present (Gott *et al*., 2004). It could be considered an opportunity cost if the GP decides not to ask about drug use. Furthermore, if a GP decides to ask they risk learning about the patient's various complex issues and would then be required to help and support the patient.

Some GPs in this study suggested that GPs were more comfortable asking about alcohol rather than drug use, however, Lock *et al.* argued that GPs are not routinely asking patients about alcohol in primary care, and most only ask in response to certain physical signs and symptoms (Lock *et al*., 2009). Even though alcohol may be seen as a slightly less sensitive and more acceptable to ask about, it seems that GPs are still not always asking about alcohol use and even less about drug use. GPs are well positioned to query about drug use, however barriers such as time, experience and the complexity of the issue seem to have an impact on the number of patients GPs ask and therefore the number they record in electronic health records.

GPs in this study reported not routinely initiating questioning about drug use, but if they did ask, they tended to ask certain people about drug use or people with particular signs and symptoms. My findings echo the survey conducted by Lock *et al.* who found that 64% of GPs who answered their survey acknowledge they would ask about alcohol use if the patient presented with certain physical, psychological or social symptoms (Lock *et al*., 2009). A key difference that emerged in my findings between GPs who had a special interest in drug use and those who did not was that the former viewed that there was a risk that individuals may be missed if GPs only focused on asking particular groups of patients. The fact that some patients who used drugs could be missed would consequently affect recording of drug use in electronic health records. GPs could possibly be made

aware of this to ensure that they are not missing opportunities to ask certain people about drug use.

My findings showed that GPs seemed to develop their own style of questioning about drug use. Some found it easier to be more direct, whilst others find they obtain more information if they use an indirect style of questioning. The RCGP recommend that two of the core competencies of a GP consultation should be to "Adapt communication skills to meet the needs of the patient" and to "Demonstrate focused questioning and examination to obtain sufficient relevant information to diagnose, manage and refer appropriately" (Royal College of General Practitioners, 2015b). Both of these competencies were demonstrated by all GPs in my study when asking about drug use. Some GPs found it easier to question together with another sensitive topic, such as sexual health. This echoes Mitcheson *et al.'s* findings that suggest individuals engaging in risky sexual behaviours, should also be asked about drug and alcohol use (Mitcheson *et al*., 2008). Questioning style and context could have an indirect effect on recording of drug use, depending on how the patient reacts to the questions.

GPs views differed with regards to whether or not it is important to record drug use. Health professionals sometimes view coding as a complex sociotechnical issue (de Lusignan *et al*., 2003). Some GPs in this study felt that it was more important for the patient to be honest about drug use rather than recording it. My data echoes the findings of the Department of Health study exploring recording of alcohol misuse where some GPs expressed that they would rather build a trustful relationship than be intent on recording the alcohol misuse (Department of Health, 2005). Most of the GPs with and without an interest in drug use were sensitive to the fact that recording drug use on an individual's electronic record may have a future impact and were therefore sometimes reluctant to record drug use as Read code. Similarly, Woodman *et al.* also described how GPs would think twice before

and were very careful before coding a child with a maltreatment code as the code was effectively there for life (Woodman *et al*., 2012). As mentioned previously, there were critical time points when all the GPs in this study agreed that they would record the drug use, this included the perinatal period and when a child was involved. Pregnancy is a critical and opportunistic time for the GP to ask a woman about drug use. GPs ask many other questions, some of them quite sensitive and therefore drug use could be included. Although GPs seem to not have much contact with a woman during her pregnancy, if the fact that she is using drugs is flagged up and recorded, the GPs could then monitor and support her once she is discharged from the midwifery unit. Once a woman is discharged from the midwifery service, GPs receive a detailed discharge letter. These discharge letters are usually scanned into the electronic health records, but only some of the information is Read coded. Neonatal abstinence syndrome (NAS) however was not always recorded in the child's electronic health records as some GPs perceived NAS as a medical rather than a social problem. Most of the GPs were not aware of any long term complications of NAS and they felt that treatment was completed in hospital and it was therefore not necessary to record in primary care records.

There were many different views with regards to using Read codes to record drug use. Some of the GPs in this study found that using Read codes was time-consuming as they had to scroll through to find the most appropriate Read code to use. Some GPs also felt that there were too many Read codes to choose from and it would be helpful if the list of Read codes could be revised and unnecessary codes could be excluded. GPs with and without a special interest in drug use felt that free-text was a quicker and easier way to record. Discharge letters are usually scanned into the electronic health records, and only important information from the letters is recorded as a Read code. Some GPs however may rely on the practice administrator to record these Read codes and therefore practice administrators are deciding which Read codes to use. Some GPs have templates for recording drug use which seems to make the recording more organised and systematic. Similarly,

Maisey *et al.* and Dixon *et al.* found that if a disease is included in QOF and the disease or outcome would be recorded more systematically (Dixon *et al*., 2010; Maisey *et al*., 2008).

In summary, in deciding whether or not to ask the patient about drug use - and subsequently if and how this information should be recorded - GPs must weigh up many factors and competing priorities. GPs act at an individual level, but GPs are also required work within the general practice level.

General Practice level

The organisational and contextual aspects of different general practices can indirectly influence GP recording of drug use in electronic health records. The data in this study indicated that the location of the general practice could influence the need for a lead GP in substance misuse. A lead GP is a GP with a special interest in a certain area of medicine and patients with the specific medical condition are usually channelled to the lead GP (Royal College of General Practitioners, 2015c). The recognized needs of the local population usually inform which specific services in a general practice need to have an allocated practitioner with a special interest to help implement and deliver these services (Royal College of General Practitioners, 2008). The data in this study also suggested that although there was less continuity of care for most patients registered in larger general practices, patients who were identified as using drugs received continuous care from the lead GP in substance misuse. This may influence recording of drug use at a practice level as one GP would make the decision whether or not to record drug use in the patient's electronic health record.

Time was identified as a barrier for building rapport and asking individuals about drug use in the previous section on GPs. In most general practices, ten minutes

are allocated for seeing and treating a patient and writing up the consultation (Hamilton and Britten, 2006). GPs are expected to work within these time constraints and some general practices encourage patients to make more than one appointment if they have several problems that they need to see a GP about (Hamilton and Britten, 2006). Time limitations seemed to be critical for GPs who were not leads in substance misuse as they felt they had limited time to explore issues other than the primary reason for the patient attending the consultation. Patients who use drugs often have more complex problems and the normal consultation time may not be enough for acquiring information about drug use. In contrast, GPs who were leads in substance misuse did not suggest that time was a barrier. In previous studies, time has been found to be a barrier for involvement of GPs with patients with other complex issues such as alcohol (Lock *et al*., 2009), sexual health (Gott *et al*., 2004) and other risky lifestyle behaviours (Pocetta *et al*., 2015). However, GPs have to work within time constraints and therefore it may save time if a patient who uses drugs and has complex problems sees the same GP. This may then influence whether or not the GP records the drug use in the electronic health records.

New patient registration forms could be an opportunity for general practices to indirectly ask about drug use. However, it appears that patients are not always willing to disclose drug use in the form and if they do disclose, they may not have an opportunity to disclose the whole story. There does not seem to be any clear guidelines on what to include in new patient registration forms. Forms seem to have been developed and evolved in different practices. The forms are generally short and ask for generic information. The high turnover of patients and increased administration time warrant the forms to be succinct and consequently questions regarding drug use are not always included in the form (Dr G Rait and Dr S Singh,2015, personal communication (face to face conversation) 30 November).

It was evident from the data that there are a various options available for general practices with regards to treating drug use. General practices are not obligated to treat drug use and it may be more beneficial that individuals are treated in either practices that have the expertise and confidence to treat individuals or treated in specialised drug treatment services (McKeown *et al*., 2003). Drug treatment services are commissioned by CCG (discussed in more detail in the next section on CCGs). The model of shared care has been implemented in these areas, where the general practice works together with statutory NHS and voluntary sector drug treatment services (National Treatment Agency for Substance Misuse, 2006). The individual can therefore either receive treatment at a specific general practice, be referred or they can self-refer to the drug treatment services (National Treatment Agency for Substance Misuse, 2006). It is essential though that GPs have a clear understanding of where to sign-post or refer individuals in order that they receive the most appropriate treatment. GPs who saw patients more frequently who used drugs and who were involved in shared care seemed to be more aware of the referral processes and options for referrals. In some cases there could be improved communication between drug treatment clinics and GPs which could then allow GPs to decide the best option for the individual and also make a decision about recording the drug use or not.

There are examples of both integration and segregation of care with regards to communication between other services and general practices. The RCGP recommends that integration of care in general practice should be; “Patient-centred, primary care led, delivered by multi-professional teams, where each profession retains their professional autonomy but works across professional and organisational boundaries to deliver the best possible health outcomes.” (Royal College of General Practitioners, 2012). Integration of care can therefore be advantageous, not only for the patient, but also for GPs as patient care can be planned and co-ordinated with patients who have complex needs (Royal College of General Practitioners, 2012). The RCGP also recommends that services can also

be designed to incorporate both services in the community and professionals in general practice to make up a multidisciplinary team (Royal College of General Practitioners, 2012). It is beneficial to have shared care, whether it is within the practice or provided by a designated drug worker from the drug treatment services. The data showed evidence of an effective working relationship between the GP and drug worker, which seemed to benefit patient-centred care (Royal College of General Practitioners, 2014). However, a problem could arise if the drug worker or drug nurse leaves, as it takes time for a new relationship to develop between a GP and drug worker and the post could also become redundant. Shared care is beneficial, however a considerable amount of the communication occurs on the phone or in meetings and it is not always documented and entered into the electronic health records. Recording of management and treatment seems to work in the inner city practice that has developed a protocol together with drug workers. It was not always seen as time efficient, but that could be because GPs have so much other information to record. I provide more detail about this recording template in *section 9.8*.

Templates seem to be very useful and efficient with regards to recording management and treatment of drug use in general practice. Maisey *et al.* reasoned that templates can also help ensure quality assurance with regards to recording in General practice (Maisey *et al*., 2008). Templates do however take time to develop and can require IT support, especially if the Read codes are embedded in the template. A report by the RCGP raised the question of whether or not templates (Read codes embedded in these templates) could be used as evidence that intervention with regards to recovery from drug use is taking place (Harris L and Halliday K, 2013). Using templates could make recording drug use in electronic health records easier and more uniform.

In summary the general practice level indirectly influences how and why GPs record drug use in electronic health records. General practices and other services are commissioned by a higher level, the clinical commissioning groups (CCG)

Clinical commissioning group level

CCGs became responsible for commissioning hospital and community services in their area in April 2013 (NHS Clinical Commissioners, 2015). CCGs decide which services are required in the area and are also responsible for providing these services including drugs and alcohol services (NHS Clinical Commissioners, 2015). General practices are incorporated into the applicable CCG (NHS Clinical Commissioners, 2015). Therefore decisions and services provided by the CCG can indirectly influence GP recording of drug use in electronic health records.

CCGs located in areas where there was an awareness of high drug use seemed to have more registered individuals in general practices who they knew used drugs. As previously mentioned in *section 1.3.8.2*, The Localism Act (2011) influenced a shift of responsibility from central to locally based Public Health bodies (Harris L and Halliday K, 2013). As mentioned previously in *section 1.3.8.2,* treating drug use is not in the General Medical Services (GMS) contract, however general practices in certain areas where the needs of the local population have been identified have a Local Enhanced Service for treating drug use and are financially incentivised for treating individuals who use drugs (Department of Health, 2003; Royal College of General Practitioners, 2008). It was interesting to see from the data in this study that GPs perceived that recording of drug use is limited because the GMS contract does not include drug use and treatment. Drug treatment services in the community are also commissioned by the CCG and local authorities (NHS Commissioning Board, 2012). As mentioned previously, the data highlighted that there are various options and services for GPs to treat or refer to or sign-post the patients to for self-referral.

Midwifery services are provided by the CCG. As mentioned previously in *section 5.8.2.3*, GPs rarely see pregnant women during the gestation period and empirical evidence from my second study (*section 5.7.2.1*) supports this. The treatment of drug use during pregnancy seems to be unanimously transferred to the midwifery services rather than continuing at general practice level. Treatment of drug use is more complicated during pregnancy and could be the reason that treatment takes place outside the general practice (Ford *et al*., 2013). The referral is either directly to the specialist midwife service or to the generic midwife services, which may then be triaged to the specialist service. GPs seem to be detailing medical and health conditions more when referring women to the midwifery services, however as previously mentioned, these details my not be Read coded in the electronic health records. It is however a concern that once a woman has been referred to the midwifery services, the GPs generally do not see her until after the baby is born. The RCGP have made the following recommendations; "the management of pregnancy in all drug users should be multidisciplinary at all times (Ford *et al*., 2013). Good communication between the professionals involved is particularly important". From the data, I would argue that these recommendations are not always being followed in primary care and therefore GPs would be less likely to record in the electronic health records.

It seems that different services are using different recording systems which are not usually linked to the general practice. GPs will only hear about the information if they get a discharge letter, communicate directly with the other services or if the patient tells them the information. As mentioned in the previous section, some of the GP practices recording systems are set up, so that the GP can link into the records of the patient at the treatment centre. The general practices that are using the same electronic systems as the drug treatment services seem to be benefitting from this ongoing communication. As long as the patient consents to their records being shared, the GP has a more accurate picture of the patient's care in other

services. This link of electronic health records could be an effective way of sharing information and to improve the patient centred care. They can then see how much and when the patient was prescribed opioid substitution treatment. This electronic linkage is evidence of a method that works to integrate the care of the patient and facilitate recording in electronic health records. I will discuss later (*in section 9.8)* how this system could potentially be rolled out to other areas in the country.

CCGs indirectly influence GP recording of drug use in electronic health records. CCGs are however affected by policies.

Policy level

QOF is a framework that was implemented together with the new GMS contract in 2004 to for performance management and payment of general practices (Dixon *et al*., 2010). There are currently no QOF indicators for recording drug use in primary care electronic health records. There is also no QOF for the treatment of alcohol misuse in primary care, Lock *et al.* (2009) argued that the inclusion of alcohol misuse treatment should be in both the GMS contract and QOF (Lock *et al*., 2009). The same could be argued for drug use and drug treatment. The Payment-by-Results pilot study (see details in *section 1.3.8.1*) is currently evaluating incentives for delivery of recovery for drugs and alcohol in primary care (Department of Health, 2012). The final results of the pilot study have not been published yet, however both Maisey *et al.* and Dixon *et al.* found that diseases or outcomes incentives by QOF were in fact better recorded (Dixon *et al*., 2010; Maisey *et al*., 2008). Dixon *et al*. also argued the QOF can be a barrier to CCGs commissioning services that are meeting the needs of the local population and this is especially evident in areas which serve populations with complex needs, such as the repercussions of drug use. It therefore follows that if QOF indicators for recording drug use were included, recording of drug use in individuals' electronic health records may improve.

In summary GPs directly influence GP recording of drug use in primary care electronic health records, whilst three other hierarchical levels indirectly impact recording. It is evident that recording of drug use in primary care is a complex issue and affected on many factorial levels.

7.8 Conclusion

My qualitative study presents an understanding of how and why GPs record drug use in general practice. My findings illustrate the complexity of recording. A confluence of factors affect both how GPs acquire information about drug use and the management and treatment of drug use which influence various pathways that can lead to GPs recording drug use. The fact that drug use is still a stigmatized and sensitive issue could influence whether or not GPs follow RCGP guidelines, practice protocols or templates. Additionally the analysis identified and explored four distinct levels which influence GP recording of drug use; GPs directly influence recording while the general practice, CCGs and government policy indirectly influences recording of drug use in an individual's electronic health records. Recording of drug us is complex and varies amongst GPs and, GPs face complex choices when deciding whether or not to record drug use.

7.9 How Does This Chapter Support My Thesis?

I have described and discussed my fourth study which used qualitative methods to explore GP recording of drug use and looked at the impact of contextual, organisational, institutional and policy issues. I used qualitative work to increase knowledge and my understanding of the empirical data in THIN. I found that recording of drug use is a complex issue. The two global themes that lead to recording were how GPs acquired information about drug use and the management and treatment of drug use.

My findings have made it clearer as to why, when, how and who GPs decide to record and if they use Read codes or not. As previously mentioned, the main strength of using a large primary care dataset is that it provides a large amount of data from real life primary care. However, meaning and understanding need to be incorporated into work with large datasets (Pope *et al*., 2014). This has been done by using qualitative methods to help understand the methods, classification and the circumstance for recording (Pope *et al*., 2014).

Together with my first three studies, the fourth study helped to reflect on the advantages and limitations of using THIN as a surveillance and/or research tool for drug use and/or opioid substitution treatment during pregnancy. I will synthesize results from all four studies and discuss this more in Chapter 8.

CHAPTER 8 Integration and synthesis of results

8.1 Content and Structure of Chapter 8

In this chapter, I describe the integration and synthesis of results of the qualitative and quantitative studies.

To help navigate this section, I have divided it into four parts.

1. GP recording of drug use in the general population
2. GP recording of opioid substitution treatment in the general population
3. GP recording of drug use and opioid substitution treatment in and around pregnancy
4. GP recording of Neonatal Abstinence Syndrome

8.2 Integrating and Synthesising the Results of the Qualitative and Quantitative Studies

As previously mentioned, I chose to take a pragmatic approach and used both quantitative and qualitative methods, as one methodological approach could not optimally answer all my research questions. Hammersley reasoned that triangulation of two methods helps achieve more of a comprehensive understanding of an issue (Hammersley, 2005). Mixed methods research is increasingly popular in health care research, particularly in primary care (Woodman *et al.*, 20012, 2013). I used the qualitative findings to help explain the results of the quantitative analysis. A strength of the thesis as a whole was that I was able to continue working on my quantitative analysis whilst I undertook my qualitative work. I could therefore iteratively shape the topic guide to answer some of the questions I had regarding recording and the qualitative study therefore helped to add insight and complemented the three epidemiological studies. I will now discuss how the qualitative findings helped me to gain a clearer understanding of GP recording.

8.2.1 Gaining a clearer understanding of GP recording of drug use in electronic health records.

Results from the first study, where I explored GP recording of drug use and opioid substitution treatment in the general population, raised the question of why there are apparent gaps in recording rates (Chapter 4). As previously mentioned in *section 7.7,* it is important to clarify that THIN only includes recorded information about individuals at the top section of the adapted access to healthcare pyramid of healthcare (Huxley and Goldberg, 1993). *Figure 8:1*.

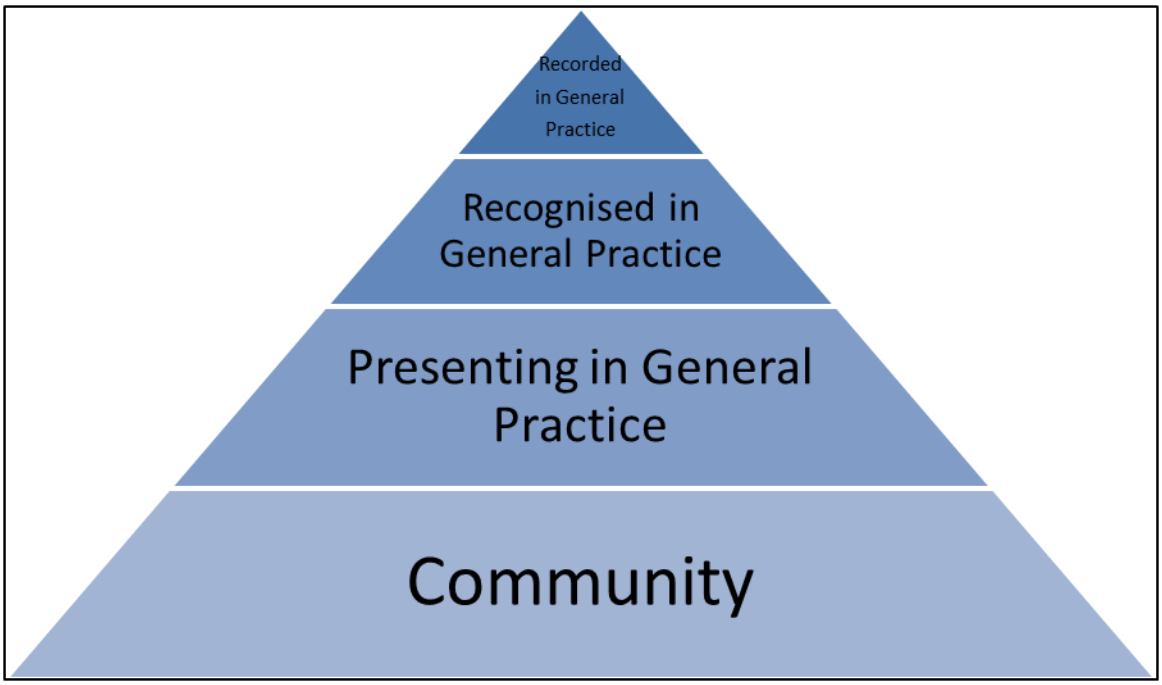


Figure 8:1: Adapted access to healthcare pyramid as describe previously in section 3.4.4.

Individuals who are recorded as using drugs need to be permanently registered with a general practice, consult their GP, disclose their drug use and the GP needs to record the drug use in the electronic health record. The qualitative findings suggest that GPs do not always record information regarding drug use in the electronic health records of all individuals who they know use drugs. GPs seem to record drug use when the drug use is the primary problem and contributing to adverse consequences such as difficulties with relationships, financial and legal problems and imbalance with physical and mental health. It seems therefore that

individuals being captured in THIN are those with more problematic drug use. The shape of the access healthcare model for drug use is similar to the study by Woodman *et al.* where they suggested that the number of children with a maltreatment code in THIN was underestimated compared to the amount of child maltreatment occurring in the community (Woodman *et al.*, 2012). Individuals may also perceive that potential consequences to their disclosure and/or recording of drug use could occur, whereas in a survey, such as The Crime Survey for England and Wales, individuals self-complete the questionnaire and their identity is pseudonomised. Therefore, although the Crime Survey results may be underestimated, it is more likely to capture a larger number of drug users which may resemble a community prevalence of drug use more compared with data from THIN (depicted as the bottom section of the pyramid in *Figure 8:1*). In contrast to other diseases/conditions such as diabetes and cardiovascular disease, there are currently no national guidelines or QOF indicators for recording drug use in electronic health records and therefore it is up to general practices (policy affecting organisational decision) and GPs (individual decision) to decide whether or not they should record drug use or not. The presence of QOF for other chronic disease, may aid in the difference between recording in general practice and community prevalence sections of the healthcare pyramid being less profound.

My qualitative findings brought to light the many different factors that seem to influence whether or not GPs (individual decision) choose to record drug use in the patient's electronic health record. The findings indicated that influences are complex and that individual GPs' perceptions and past patient experience seemed to affect recording, as well as the organisational levels of general practices, Clinical Commissioning Groups and government policies. It was also evident that GPs make the decision to record drug use on a case-by-case basis. Consequently figures relating to drug use in THIN are likely to be underestimated but in contrast, demographic and time-trends in THIN mirror those in the Crime Survey for England and Wales. The qualitative findings suggested that GPs did not always have time

to ask every individual about drug use, and directed their questions to individuals presenting with similar characteristics. These characteristics reflected the demographics of individuals who were most likely to have a recording of drug use in my first study and the Crime Survey for England and Wales, namely; younger males from more deprived areas. The findings also suggested that some patient-groups (e.g. older women from less deprived areas) may be missed because GPs are not asking them about drug use, and this could also contribute to the under-recording in electronic primary care health records.

The timing of recording in the first study showed that a large amount of first recording for drug use occurs within the first two months after the patient registers with a general practice. Previous studies using THIN to evaluate incidence of a condition/disease usually exclude recording during this time-period after registration as these may represent prevalent cases *(explained in section 4.8.9),* but I decided not to as my qualitative findings suggested that the registration period was an opportune time for enquiring about and/or recording drug use. A small number of GPs described how they have included a question about drug use in the patient registration questionnaire and this inclusion could explain why there is this surge of recording during this time. Again, this disclosure is subject to consequences and therefore individuals may not disclose at all.

Results from the first study also revealed that over 500 Read codes are available for GPs to record drug use however GPs were only using half of theses codes. This could partially be explained by the findings from the qualitative interviews (*see section 7.6.5.1.2 for details*). The GP accounts also highlighted that GPs perceived that individuals who used drugs were more likely to be poly-drug users and therefore a generic code would describe the drug use better than using a specific code. GPs also explained that instead of using a Read code for drug use, they used a Read code for the primary problem that the patient presented with

(insomnia, depression) and if they also recorded drug use, it would usually be as free-text. However, in some cases, GPs described that they would use a Read code for drug use if this was the primary problem. Again, this implies that GPs are possibly using Read codes more for problematic drug use (*see section 1.3.2.4 for details*) rather than for recreational drug use in patient's electronic health records. These results concur with the small validation study conducted by Frischer *et al.*, where 92% of individuals with a recording for drug use were being treated for problematic drug use (Frischer *et al.*, 2004)

8.2.2 Gaining a clearer understanding of GP recording of opioid substitution treatment in electronic health records

Results from the first study, where I examined prescriptions of opioid substitution treatment, indicated that the number of people who were given a prescription for opioid substitution treatment in general practice were similar to those reported by the National Treatment Agency (Chapter 4). Choosing to treat drug use with opioid substitution treatment is an organisational decision within the general practice. The general practices that chose to treat were usually financially incentivised by a local enhanced service set up by the Clinical Commissioning Group. Recording of drug use and treatment, including prescriptions were therefore expected in these organisations. However the lack of incentives seemed to affect recording in general practices that did not treat problem drug use. The findings from my qualitative study suggested that regions that were more aware of drug use had more local enhanced services for drug use and often had a practice lead for substance misuse. GPs who had a special interest in drug use seemed to have developed their own templates in order to record drug use and treatment. The practicality of templates seemed to help make recording of drug use and treatment more practical and systematic. One of these templates was linked to Read and prescription codes in the software which made it easier to audit, as recording was essential in order to receive payment from the local enhanced services. GPs who treat drug use also should provide the figures to the National Treatment Agency on a monthly basis. A few of the GPs viewed that more recording of drug use might

take place if there was a QOF indicator for drug use. The question is whether this should be the case and if so would it affect the relationship between GP and patient (*as discussed in section 7.6.2.1*). I will discuss whether or not QOF indications for drug use would be an appropriate method for incentivising and recording drug use in *section 9.8.*

The number of Read codes for opioid substitution treatment was less than prescriptions in the first study. Two reasons for this lower rate could be that firstly GPs described how they seldom use a Read code for a drug prescribed as well as a prescription code, and with almost half (44%) of referrals to drug treatment centres being self-referrals, GPs may not always be aware of individuals who self-refer and are receiving treatment from somewhere else (Public Health England, 2014)., The qualitative interviews suggest that that there seems to be more segregation of care once an individual is seen by another service and GPs perceived that the information is poorly fed back to the GP. There does not appear to be an electronic system in place for communication between most general practices and other services. This could be also an explanation for the low number of Read codes for opioid substitution treatment found in THIN.

8.2.3 Gaining a clearer understanding of GPs recording of drug use and opioid substitution treatment in and around pregnancy in electronic health records

The decrease in recording of drug use and/or opioid substitution treatment in and around pregnancy can be partly explained by findings from the qualitative study (Chapter 5). GPs described how they referred newly pregnant women to the midwifery services and how they may write a large amount of detail in the referral letter. The detail in the referral letter may include information about adverse life-style factors such as smoking and drug use if a woman discloses this information. However GPs did not always record this information as a Read code in the electronic health records.

Additionally, pregnant woman did not appear to consult GPs through most of their pregnancy. This was particularly the case if a woman was using drugs as GPs described how they would usually refer her to a specialist midwifery service which usually takes care of a woman's antenatal and other medical care. During pregnancy, the midwifery services provide pregnant women with hand-held antenatal notes which the women retain throughout their pregnancy (Perinatal Institute, 2015). Information about drug use may be in the hand-held notes and/or the maternity computer system rather than in a centralised recording system and consequently the discharge summary may not include some information from these notes. Once the baby has been delivered, the hand-held notes, antenatal summaries (usually completed by the midwife between 8-10 weeks of the pregnancy) and intrapartum notes, are retained and stored in the hospital archives (Perinatal Institute, 2015). The GP receives two summaries; a birth summary after hospital discharge and a discharge summary upon transfer of the mother and baby to the primary care team (Perinatal Institute, 2015). The writing of these summaries is overseen by the community midwife and should be sent to the GP when they see a woman six weeks after her baby is delivered (Perinatal Institute, 2015). GPs described how these summaries were usually scanned in the electronic health records, however if there were problems occurring during the perinatal period, GPs sometimes used either Read codes or free-text to record these issues in the electronic health records.

Another key finding from the second study was that there was a decrease in opioid substitution treatment prescriptions during pregnancy and then a subsequent significant increase after pregnancy. A possible explanation for this was described by GP accounts where they would usually refer women who were receiving opioid substitution treatment to either the midwifery services or directly to the specialist midwifery services, which would take over their treatment. GPs reiterated that communication between the specialist midwifery services and themselves was

lacking during the antenatal period, consequently the quantitative study, using THIN, showed little recording of Read codes for opioid substitution treatment during pregnancy. However, with regards to the increase in prescriptions for opioid substitution treatment, women may have disclosed their drug use to the midwives during pregnancy. Once the baby is delivered, care is usually transferred back to the GP and the discharge summary may notify GPs to start prescribing opioid substitution treatment. Prescriptions would then be recorded in a woman's electronic health records and contribute to the data in THIN.

8.2.4 Gaining a clearer understanding of GP recording of neonatal abstinence syndrome

In the third study where I examined an indirect measure of drug use (opioids, benzodiazepine, barbiturates), approximately a third of the recording of NAS in the hospital setting was recorded in electronic health records in primary care (Chapter 6). The qualitative accounts described how they would record drug use in the electronic health records if a child was involved. However, this did not seem to be the case with NAS and can potentially be explained by the two opposing opinions from GP accounts regarding recording of NAS in electronic health records. The first view was that NAS was a medical issue which was treated in the hospital and as there were no known long term affects GPs decided not to record it as a Read code. The contrasting view was that NAS was both a medical and a social issue and it was important for identifying children who were potentially at risk for both medical and social problems. There are currently no guidelines for recording NAS in the electronic health records, GPs appeared to make individual decisions based on their view about the long term outcomes of NAS. Additionally NAS is an indirect measure of only a few specific drugs. I will expand on the clinical implications of recording NAS in the electronic health records in *section 9.8.*

I have now integrated my quantitative and qualitative results which demonstrate that methodological triangulation helped to strengthen the evidence of my

quantitative work and helped to uncover the missing pieces of the jigsaw puzzle by creating a clearer picture and comprehension of recording drug use in electronic health records. I will now discuss the interpretation in context with other studies.

8.3 How Does This Chapter Support My Thesis?

Together with my first three studies, the fourth study helped to reflect on the advantages and limitations of using THIN as a surveillance and/or research tool for drug use and/or opioid substitution treatment during pregnancy. I have described how the qualitative study has incorporate meaning and understanding into the studies using THIN. I will now discuss the contribution my thesis has made to knowledge and improved method, overarching strengths and limitations, justification for using the CSEW, what I support the argument of the thesis, clinical and research implications and the overall conclusion of the thesis in Chapter 9.

CHAPTER 9 Discussion

9.1 Content and Structure of Chapter 9

In this final chapter, I will firstly present an overview of the thesis and summary of the findings. I will then present the following:

1) Illustrate how the thesis brings new knowledge and/or improves method.
2) Discuss the value of the Offending Crime and Justice Survey as a measure of drug use in the population.
3) Describe the overarching strengths and limitations of the thesis
4) Discuss what I have learnt during the thesis and what I might have done differently
5) Discuss if THIN is sufficient to address the hypothesis concerning drug use during pregnancy or the consequences of NAS?
6) Consider both the clinical and research implications of the thesis
7) Present the conclusions of the thesis

9.2 Overview of the PhD thesis

There are few studies in England and Wales to date, that estimate the burden of drug use and opioid substitution treatment during pregnancy. Pregnancy usually triggers women to visit their general practitioner (GP) which may provide an opportunity for drug use to be raised and recorded. A 2010 survey found GPs are the first healthcare professionals that 77% of women see when they first find out they are pregnant and 45% of antenatal appointments occur in general practice (Redshaw and Heikkila, 2010). I therefore hypothesized that examining electronic health records may be an appropriate method to gain an understanding of the burden of drug use and opioid substitution treatment during pregnancy.

Misuse of drugs is a public health problem which can lead to poor health outcomes and drug use during pregnancy could also potentially harm the unborn baby. Drug use is more common in men, however misuse of drugs has increased in women over the past 30 years (HM Government, 2013). Two thirds of women who enter

treatment for drug use are mothers with only approximately half having custody of their children (National Treatment Agency for Substance Misuse, 2010). Furthermore, it is estimated that between 2-5% of children in England and Wales are living with a parent with drug and/or alcohol problems (HM Government, 2013). One of the main reasons for the lack of studies conducted during pregnancy may be the complexity of accurately obtaining information about drug use due to the stigma which may be intensified during pregnancy. However, women who use drugs may be more willing to seek help from health professionals during pregnancy for a number of reasons (for example: they may be concerned that the drugs may have an adverse impact on their unborn child).

In the UK, all women have an opportunity to be registered with a GP and receive free antenatal care (National Institute for Clinical Excellence, 2010b). Women are recommended to visit either their GP or midwife once they know they are pregnant (National Institute for Clinical Excellence, 2010b). The antenatal care is usually transferred to the midwifery service, and transferred back to the GP when a woman visits her GP six weeks after the birth of her baby (National Institute for Clinical Excellence, 2010b). Depending on the situation, women may still consult their GP for other medical care during their pregnancy (National Institute for Clinical Excellence, 2010b). If a woman chooses to consult her GP at the beginning of her pregnancy and/or after giving birth, these timely appointments lend themselves as opportunity for a GP to enquire about drug use together with other health related behaviours. If a woman discloses that she uses drugs, the GP is in a better position to offer long term support for both mother and child. GPs may also record information regarding drug use during and after pregnancy as a Read code in a woman's electronic health record. Therefore, data from electronic health records could be viewed as an approach to monitoring women who use drugs and/or are prescribed opioid substitution treatment.

I decided to conduct a database cohort study in order to evaluate if primary care data could be utilised as a source of surveillance and research in relation to drug use and opioid substitution treatment, specifically during and 36 months either side of pregnancy. However, in order to understand recording of drug use and/or opioid substitution treatment in women who were pregnant, I first had to examine the recording of drug use and/or opioid substitution treatment in the general population registered in general practice. Previous studies had used the GPRD database to explore trends of problematic drug use and opioid substitution treatment up until 2005, however there were no recent studies from primary care in England and Wales and no studies included recreational drug use (Cornish *et al*., 2010; Frischer *et al*., 2000, 2001, 2004, 2005, 2009). Annual reports are produced from the following national surveys: The Crime Survey for England and Wales, The National Treatment Drug Monitoring System and The Welsh National Database for Substance Misuse (Office for National Statistics, 2015a; Public Health England, 2015; Welsh Government, 2015). These reports make it possible to externally compare drug use and opioid substitution treatment recorded in primary care data.

In summary, GP recording trends for the general population were in keeping with national surveys, but with lower rates. Recording was relatively low in and around pregnancy. GP recording of NAS was similar to hospital data, however rates were lower. Finally, qualitative interview analysis identified that influences on recording drug use were complex and related to pressures at the individual as well as organisational (general practices, Clinical Commissioning Groups) and governmental levels in the shape of government policies.

In the next section I explain how my work builds on previous studies of drug use and demonstrate how the different studies introduce new knowledge and improve methods.

9.3 How the thesis brings new knowledge and/or improves method.

Study 1: GP recording of drug use and opioid substitution treatment in the general population

The thesis contributes to the field of knowledge by providing both empirical and qualitative evidence to an area where there are is limited evidence. The studies by Frischer *et al* and Cornish *et al* examined problematic drug use and opioid substitution treatment respectively using GPRD up until 2005 (Cornish et al., 2010; Frischer et al., 2001, 2000, Frisher et al., 2009, 2004) . My first study was exploratory and contributed new knowledge by including further analysis of data between 1994 and 2012 and therefore time-trends for the later years could be used to compare with other data sources. Furthermore, future longitudinal studies examining individuals with a record in primary care for drug use, will have a longer follow-up period. Additionally, Read code lists for problematic drug use and opioid substitution treatment had been previously developed by Frischer *et al* and Cornish *et al* in GPRD. For this PhD, I updated these lists and also sought to include recreational drug use when examining recording. The reason I decided to include recreational drug use was that the previous studies examining drug use during pregnancy included recreational drugs and I intended to compare my results from THIN with these studies (Farkas et al., 1995; Fergusson et al., 2002; R A Sherwood et al., 1999). However, I later learned from my quantitative and qualitative studies that recreational drug use was poorly recorded in primary care and confirmed that primary care electronic health records are more appropriate for investigations of problematic drug use. Additionally, I decided to include dependence for prescription drugs as this seems to be an emerging problem in high-income countries (Giraudon et al., 2013; Mehdi, 2012; Stannard, 2013). I felt it was important to include 'dependence for prescription drugs' when examining problematic drug use in electronic health records. Indeed, I found that benzodiazepine dependence was one of the most frequently used Read code (10.9%) for drug use in the electronic health records. Furthermore, I explored whether GPs may be recording drug use as free-text and I found an extra 0.03%

(n=520) individuals had a free-text comment relating to drug-use, but no relevant Read and/or prescription code. GPs may also be recording the primary problem (e.g. depression) rather than drug use and/or they may not be recording it at all. Furthermore, my qualitative study also suggested that many of GPs are using free-text rather than Read codes for recording drug use. Future studies could potentially examine free-text in more detail.

While previous work has been unable to examine regional differences in detail, I was able to examine both England and Wales and analysed the data according to the English Strategic Health Authorities. The findings confirmed that most of the recordings for both drug use and opioid substitution treatment occurred in the North East of England and Read codes for opioid substitution treatment occurred most frequently in the North West of England. These regional results concur with results from more problematic drug use data, namely; mortality rates related to drug misuse from England and Wales, where the highest rates were found in the North East and North West of England (69.3 and 61.9 per 1 million population respectively), and the prevalence of opioid and crack use was highest in the North East (9.89 per 1,000 person years) and North West (9.99 per 1000 person years) of England (Hay et al., 2013; Office for National Statistics, 2015b)

I contributed to new knowledge regarding how much of the recording of opioid substitution treatment is being reported to the National Treatment Agency (NTA) by including all possible prescriptions for opioid substitution treatment according to guidelines and comparing these with figures with reports from the NTA. The results were similar and although it is not mandatory for GPs to report prescribing to the NTA, my findings suggest that they are in fact doing it consistently.

Cornish *et al.* examined individuals who had been prescribed opioid substitution treatment in GPRD between 1990 to 2005 (Cornish et al., 2010). They however, did not include all possible treatment available for GPs to prescribe. I therefore decided to include all possible treatments available for GPs to prescribe from the NICE and RCGP guidelines (Ford et al., 2013; National Institute for Clinical Excellence, 2010a). I also examined the dose for each drug to ensure that they were being prescribed as part of a detoxification programme. I therefore contributed to improved methods by including these other prescribed drugs in the drug code list I developed.

Additionally, the Read and drug code lists I have developed have contributed to improved methods as drug use is a potential confounding factor in various epidemiological studies. A study examining the association between smoking and schizophrenia using THIN, is currently being conducted at UCL. The authors have asked to use the Read and drug code lists to include as a confounder (R Jones 2016, personal communication (email), 9th September). Future studies can also use my Read and drug code lists to identify individuals with a recording for drug use and include this in their analysis.

Study 2: GP recording of drug use and opioid substitution treatment in and around pregnancy

The second study is the first to examine recording of drug use and/or opioid substitution treatment in and around pregnancy in electronic health records. The results from the second study echo the pattern of findings of the 2010 national survey of women's experience of maternity care, where more (77%) women consulted their GP when they were first pregnant, but less (45%) went to their GP for subsequent antenatal appointments (Redshaw and Heikkila , 2010). The survey was sent to 10,000 randomly selected women who were 16 years and older and had given birth in England between October and November 2009. Non-

response bias may have influenced the results as the response rate was relatively low (51.2%). Women with the following characteristics were more likely to respond: older, married, living in the least deprived area, born in the United Kingdom and therefore findings within these demographic factors may be overestimated. This survey was repeated in 2014, and the response rate had decreased to 48% with women with the same characteristics being more likely to respond. The proportion of women seeing their GP for antenatal appointments, had decreased to 15% (Redshaw and Henderson, 2014). The authors attributed the lower response rate to increasing number of surveys being sent out and increasing time pressures, especially with a new baby.

The findings from my second study were comparable to those from the pilot questionnaire study in Glasgow and Sheffield maternity units where 1% of women had used drugs during pregnancy (Advisory Council on the Misuse of Drugs, 2011). The majority (92%) of maternity units reported that pregnant women were routinely assessed for both alcohol and drug use during pregnancy. However, different health professionals and different methods were used to routinely assess including biological testing, information gathered by clinical observation and self-disclosure or information from a third party. Additionally, both Sheffield and Glasgow are in the top 10% of most deprived areas in England and Scotland respectively (UK online centres, 2014). Alcohol, smoking and drug use are usually higher in deprived areas and therefore health professionals in these areas may be more aware than in maternity units located in less deprived areas. A strength of my study was that I included English Strategic Health Authorities and Wales in the analysis and found that as with the general population, the recording rates for drug use and opioid substitution treatment was highest for the North East and North West of England. As previously mentioned this concurs with results regarding regional problem drug use and contributes to knowledge about regional service requirements.

Results from my study and the pilot questionnaire study suggest that there was under-recording of drug use in primary care. This is strengthened by the fact that the results of drug use in the two biological, cross-sectional London studies were higher in pregnant women (Farkas *et al*., 1995; Sherwood *et al*., 1999). The first biological study was conducted in a hospital located in East London in 1994 (Farkas *et al*., 1995). Testing of 1,000 urine samples of women attending their 12 week antenatal appointments found that 10% tested positive for drug use, 8.5% positive for cannabis, 1.4% positive for opiates and 1.1% positive for cocaine (Farkas *et al*., 1995). The second study was conducted in South London (1994-1995) and found that urine of 15.6% (126/807) women tested positive for drug use during pregnancy (Sherwood *et al*., 1999). Since my initial literature review, another study examining drug use in pregnancy was published in 2014 (David *et al*., 2014). The results from this study agreed strongly with the studies by Farkas *et al.* and Sherwood *et al.,* although they conducted their studies in three sites (London, Bristol and Birmingham) rather than restricting to London (Farkas *et al*., 1995; Sherwood *et al*., 1999). David *et al.* analysed hair samples of pregnant women and their findings suggested that 14.9% (77/517) of women used drugs during pregnancy (David *et al*., 2014). In these three studies, the identity of women was anonymous and therefore positive findings of drug use would not have potential adverse consequences from the mother's perspective as would disclosure to health professionals. Additionally, biological measures are more accurate than self-reporting (David *et al*., 2014; Farkas *et al*., 1995; Sherwood *et al*., 1999). The biological studies were able to test for recreational drug use, however my findings suggest that recreational drug use is not being captured in electronic health records which could also explain the comparatively lower results. Furthermore, Ferguson *et al*. analysed data from the ASLPAC study (Fergusson *et al*., 2002). The self-reported questionnaire included questions on cannabis and other illicit drugs (Fergusson *et al*., 2002). Consent was required and identities of women were not anonymised which could explain why their findings were lower compared to the three biological studies. In contrast, the findings from Ferguson *et al.* were higher than the pilot study by the Advisory Council on the Misuse of drugs and my

study (6.5% compared with 1%). This could be due to the fact that disclosure of drug use remained confidential and therefore would not have adverse consequences (e.g. the baby being taken away from the mother).

All five of these studies had relatively small sample sizes and covered three or less areas of the UK. In contrast my study had a larger sample size and included the following maternal characteristics: age, deprivation and regional variation. Although the findings suggested that little recording occurs during pregnancy, drug use recorded before pregnancy and opioid substitution treatment recorded after pregnancy can be used as a proxy for drug use and opioid substitution treatment in pregnancy in future studies based on primary care data. I have included a study protocol in section 9.7.2. in order to examine if an independent association exists between drug use during pregnancy and adverse birth outcomes. As with the general population, drug use and opioid substitution during pregnancy could be a potential confounder in future studies. Studies by Petersen *et al* used the Read and drug code lists I had developed, to control for drug use in and around pregnancy (Petersen et al., 2016a, 2014) and doctoral work included drug use (from the Read code lists I developed) as a confounder for parental depression during pregnancy and the first year postpartum (Wijlaars, 2014). Future studies can also use my findings to include these variables as potential confounders in their analysis.

Study 3: GP recording of neonatal abstinence syndrome

The third study contributes to both new knowledge and improved methods as it is the first study to examine recording of NAS in primary care and also provides a birth prevalence for NAS in England using HES. The HES study was based on and used similar methods to the studies conducted by O'Donnell et al and Patrick et al.(O'Donnell et al., 2009; Patrick et al., 2012) Since my initial literature review, a study by Jones *et al.* was published which examined recording trends of NAS in

Welsh births (Jones *et al*., 2013). They found that rates of recorded NAS increased from 0.28 to 1.6 live births between 1999 and 2011 (Jones *et al*., 2013). Additionally, Turner *et al.,* published a study in 2015 which showed a 15-fold increase of recorded NAS between 1999 and 2011 in Ontario, Canada (0.28 to 4.29 per 1000 live births) (Turner *et al.,* 2015). Recorded NAS rates in England have remained relatively stable in recent years compared with Wales, Scotland, the USA and Ontario, Canada (Jones *et al*., 2013; National Statistics Scotland, 2012; O'Donnell *et al*., 2009; Patrick *et al*., 2012; Turner *et al*., 2015). As with all the studies, the findings are reliant on identification, recording and correct coding of NAS in the hospital data. Furthermore, work is being conducted at the institute for child health to link the babies recorded with NAS that I identified in HES with family courts data (Professor R Gilbert and Dr L Wijlaars, 2016, personal communication (face to face conversation), 9th November).

NAS is less well recorded in primary care than in hospital settings. This may suggest that NAS is a transient issue, but it may potentially be a marker for maternal drug use. Future studies could examine the risk of having a recording for both NAS and child maltreatment and compare the birth prevalence of NAS in England and other countries. Again, NAS could also be a potential confounder and therefore my findings could help future research include NAS in analysis.

Study 4: Factors affecting recording of drug use – a qualitative study

My qualitative study is the first to provide new knowledge and a deeper understanding of the factors that influence GP recording of drug use. My work can help future researchers when designing studies using primary care data, especially if it includes sensitive and stigmatised issues similar to drug use.

Finally, as well as developing Read and drug code lists for future research, I have also developed different cohorts using THIN and HES which could be used for future research examining problem drug use, drug use during and around pregnancy and infants who have been recorded with NAS:

1) Individuals who are recorded as using drugs or prescribed with opioid substitution treatment (registered with a general practice in England and Wales).

2) Women who are pregnant and have a code for drug use and/or prescription for opioid substitution treatment (registered with a general practice in England and Wales).
3) Infants with a recording for NAS in both THIN (registered with a general practice in England) and HES (in England).

I will now discuss the Crime Survey for England and Wales (CSEW) and the offending Crime and Justice Survey and justify why I used the CSEW to compare my results to.

9.4 The value of the Offending Crime and Justice Survey as a measure of drug use in the population.

In Chapter 4, I compared the results from THIN with the Crime Survey for England and Wales (CSEW). The main reasons for using the CSEW were that it has been used both nationally and internationally to compare recreational drug use, it has a relatively large sample size (n=46,031), appropriate stratification, relatively high response rate (75%) and the survey includes weightings in the analysis to adjust for non-responders (Lynn and Elliot, 2000; Office for National Statistics, 2015a). However, the CSEW also has several limitations which include underestimation of drug use as it provide trends of drug use rather than an absolute count, potential sampling bias, sampling error and underrepresents individuals from younger age-groups (16-24) (Lynn and Elliot, 2000; Tipping et al., 2010). The survey has tried

to compensate for this by randomly selecting and interviewing more than one person aged 16-24 per household and thereby also increasing the sample size of this age-group, however the response rate for the age-group is still relatively lower (68%) (Tipping et al., 2010)

The Offending Crime and Justice Survey (OCJS) is an alternative survey which could be used together with the CSEW as it was developed and implemented with the aim of obtaining a more accurate prevalence of both offending and drug use in England and Wales, specifically amongst younger age-groups (10-25 years). The OCJS was a panel study that was commissioned by the Home Office and conducted by the British Market Research Bureau Social Research and the National Centre for Social Research (NatCen) between 2003 and 2006 (Home office, 2008). The rotating panel design allows some of the previous year's sample to be re-interviewed as well as adding new people in the next wave (Home office, 2008). Approximately 10,000 interviews were conducted each year, with half the sample being in the 10-25 age-group (Home office, 2008). The response rate was relatively high; 82% from the original panel sample and 69% for the fresh sample (Matthews et al., 2006). The survey also allows a more detailed analysis of criminal behaviour (including drug use) than the CSEW, as it focuses on the relevant contextual data (Hales et al., 2009). Similar to the CSEW, the OCJS has a separate self-completion section for sensitive topics (which include drug use) to help improve privacy and confidentiality and uses Computer Assisted Self-Interviewing (CASI) to complete these questions (Office for National Statistics, 2015a). CASI is also very useful for individuals with literacy problems, which may be more in the case of the OCJS due to inclusion of younger age-groups (Hales et al., 2009). The OCJS includes questions about the use of specific drugs and if they have been used in the last month, last year or in their lifetime (Office for National Statistics, 2015a). The types of drugs and timing of drug use is similar in both surveys. However, the OCJS also includes the following additional questions: "if the individual used alcohol and drugs together", "if they used more than one

drug at a time", "if they had missed usual commitments such as school or work because of drug use", "if they had committed a crime in order to obtain money for drugs", "if anyone had found out about their drug use", "if they had been in contact with the Crime and Justice System due to drug use", "whether or not they had looked for help regarding their drug use" and "the age the person started and last age they used drugs" Questions from both the CSEW and OCJS can be found in the respective user guides (Home Office, 2006; Office for National Statistics, 2015c)

As with the CSEW, the OCJS also has several limitations. Firstly, the OCJS omits serious offences such as homicide and sexual offences which the authors suggested would not have too much impact on drug use estimates (Hales et al., 2009). I agree with the authors that these crimes are unlikely to have a major impact on drug use estimates, although many crimes are often related to drug use (Social Unit, 2002; Stewart, 2008). Secondly, both surveys have been criticised for having sampling bias by excluding certain groups of people, including those in hostels, the homeless, prisoners, students living in university halls of residents, individuals living in very remote locations (Lynn and Elliot, 2000). These groups have zero probability of selection and the estimates of drug use are therefore likely to be underestimated. However, access to individuals from some of these groups may be unfeasible for any survey as the individual may have a relatively more chaotic lifestyle or no fixed address. Thirdly, non-response bias exists in both surveys, as with the CSEW, younger people and individuals who have more chaotic lives may be more difficult to interview and/or refuse to participate in the OCJS (Hales et al., 2009).

Fourthly, as with most surveys, response bias frequently occurs. However, a self-completion section for answering sensitive questions (including illicit drug use) has been included to help reduce response bias. Particularly in the OCJS, younger

participants may not understand the questions and some participants may not disclose this drug use even though they are assured of anonymity and confidentiality (PRCI, 2007; Wilson et al., 2006). The context of the surveys may also impact on how honestly the participants report. In the CSEW, interview questions on being a victim of crime precede the self-completion questions on drug use whilst questions on criminal behaviour precede the drug use questions in the OCJS. Qualitative interviews were conducted on the accuracy of answering questions in the CSEW (n=35) (White and Lewis, 1998). Most people reported that they were honest when questions about crime were asked, however in the self-completed questionnaire, they often underestimated drug use (White and Lewis, 1998). Factors that encouraged more accurate reporting were good sense of rapport with the interview and how confidential they perceived the information to be (White and Lewis, 1998).

The two main reasons most surveys underestimate drug use is that firstly individuals with problematic drug use may not be living in private households and if they are, they may be more reluctant to participate. Secondly, the accuracy of the information depends on the understanding of questions, recalling events accurately and willingness to provide accurate and honest answers. There are no absolute accurate estimates to compare drug use to. However, if the underestimation remains constant, the trend of the data may be informative even if the actual prevalence may be underestimated.

Although both surveys have their limitations, there is no gold standard for measuring drug use as neither surveys can obtain the actual prevalence. However these surveys offer the best information that is available on drug use and Hickman *et al* suggested that findings from both the OCJS and CSEW are comparable (Hickman et al., 2007). I decided to use the CSEW as it has previously been used both nationally and internationally (European Monitoring Centre for Drugs and Drug

Addiction, 2013; Frisher et al., 2009). In addition, the OCJS was only conducted between 2003 and 2006 and my analysis covered the years between 1994 and 2012. On further reflection however, the two surveys could be used concurrently as the OCJS could strengthen the weaknesses of the CSEW namely, that it focuses on the younger age-groups and asks more detailed questions about drug use.

9.5 Overarching Strengths and Limitations

The strengths and limitations of the thesis rely on the strengths and limitations of using the different databases and qualitative methods; THIN, HES and qualitative interview methods.

9.5.1 Strengths and limitations of using THIN

The main strength of using THIN is that it includes a large amount of data from real life patient-GP consultations in primary care and results can be generalisable to the UK population (*see section 3.4.2 for details*). Individuals who are permanently registered with a general practice can be analysed longitudinally as they are assigned a unique identity number (ID) within the general practice. Frischer *et al.* noted that the main advantages of using a primary care database (GPRD) for monitoring drug use was that it contained recorded Read codes for drug use, time trends of drug misuse, associated co-morbidities and prescribing (Frischer *et al.*, 2001, 2000; Frischer *et al.*, 2009). It is also mandatory for GPs to record all prescriptions in electronic health records, subsequently if an individual was receiving a prescription for opioid substitution treatment from their GP, it would be captured in THIN. It can be difficult to differentiate between individuals who were being treated for drug dependence with opioid substitution treatment and for chronic pain medication. However, I applied strict inclusion criteria when examining the dosage of drug being prescribed and time between prescriptions (BMJ group, 2013; Cornish *et al.*, 2010; Royal College of General Practitioners, 2011; Strang *et al.*, 2010).

The findings from both the quantitative and qualitative studies suggest that individuals who are on the more severe spectrum of dependency and/or addiction are more likely to be recorded in primary care records. The advantage of this is that primary care records have higher specificity with regards to individuals who use drugs and therefore those who are recorded as using drugs are likely to be true positives.

Another strength of using THIN is that in order to receive free antenatal care, women in the UK are encouraged to register with a GP and therefore consultations may be recorded in their electronic health records (Maternity Action, 2011; NHS Choices, 2014). The study by Dhalwani *et al.* suggests that recording of smoking (a different harmful health behaviour) in general practice was comparable to national surveys in the general population and also in early pregnancy; however there seems to be a large amount of under-recording in the later stages and after pregnancy (Dhalwani *et al.*, 2014). I could therefore use THIN to examine recording in and around pregnancy as the database provides access to information about women during their pregnancy, which is often a challenging period to conduct other research. Read codes that are used to identify infants with NAS are specific and there is little risk of false positive recording of NAS. Additionally, I could identify babies who were linked to mothers if they were registered with the same general practice. Furthermore, THIN has previously been used to study relatively rare exposures effectively and I could therefore justify using THIN to explore recording of drug use and/or opioid substitution treatment, especially during pregnancy.

There were several limitations to using THIN. Firstly, THIN only includes information about individuals who are permanently registered with a general practice and have been in contact with their GP. This may be an issue with

regards to problematic drug users who may have a more chaotic lifestyle and may be more transient.

Secondly, disclosure of drug use may have more to do with the consequences and therefore a self-selected group may be disclosing drug use to their GP. Fewer individuals become problem drug users compared with those taking drugs recreationally (Public Health England, 2015) and my findings suggest that GPs seem to record problematic drug use more in electronic health records. Recording may be picking up the effects of drug use rather than the actual drug use, unless the individual is wanting to stop using drugs and then this may either be recorded as a Read code or in the free- text. The disadvantage is that we are only seeing the tip of the iceberg with regards to drug use and the full effect of drug use is not being captured in primary care electronic records. Individuals that have a record of drug use or indications that they receive opioid substitution treatment could be included as a confounding factor in longitudinal analysis, but it should be emphasised that the adjustment may only account for the more severe dependency. My findings also agree with de Lusignan *et al.* whereby GPs may also be aware that the patient-doctor relationship could be compromised if the patient is coded as a drug user and therefore decide not to record the drug use (de Lusignan *et al.*, 2003). Therefore, examination of THIN reveals the minimum estimate of people who use drugs and not a community estimate or prevalence of drug use in society. The closest community prevalence (bottom section of pyramid in *Figure 8:1*) of drug use is estimated by the annual Crime Survey for England and Wales which is conducted in approximately 375,000 households (Office for National Statistics, 2015a). The confidential survey includes a self-complete section on drug use and therefore individuals may be more inclined to disclose both their problematic and recreational drug use than if they were seeing their GP.

Thirdly, there are to date no large validation studies for recording drug use if the person is not receiving treatment in secondary care and no validation studies for recreational drug use. This was also acknowledged in earlier studies by Frischer *et al.* who examined drug misuse recorded in GPRD (Frischer *et al.*, 2001, 2000). Frischer *et al.* did however conduct a small validation study for recording problem drug use in primary care databases in a later study (Frischer *et al.*, 2004). They looked at a random sample and found that 92% of this sample of patients being treated for substance misuse in secondary care also had a diagnosis of substance misuse by their GP (Frischer *et al.*, 2004). In contrast, a systematic review by Kahn *et al.* presents the various validation studies that have been conducted for recorded diagnoses primary care databases (Khan *et al.*, 2010). Diagnoses with a high positive predictive values and high sensitivity include those for psychosis, COPD and current smoking (Lewis and Brensinger, 2004; Nazareth *et al.*, 1993; Soriano *et al.*, 2001). Within the scope of the PhD there was insufficient time to conduct further validation study.

Fourthly, the majority of Read codes that are available for GPs to use were generic and not specific for a particular drug. Frischer *et al.* acknowledged the numbers of individuals with Read codes for specific drugs were too low to analyse (Frischer *et al*., 2005). This could be because poly-drug use is common amongst drug users (Leri et al., 2003). Symptoms are more obvious with opiate drug users whilst symptoms of other drugs are not as obvious and could be missed.

Fifthly, my results reflect that recording rates were higher for more socially deprived groups. This may be because there are more people using drugs amongst the socially deprived groups, but it could also be masking the fact that drug users with less social deprivation could be seeking help elsewhere (e.g. private health care) or denying the problem and avoiding the stigma associated with drug use (United Kingdom Drug Policy Commission, 2010). THIN does not

capture individuals who use private health care, unless a discharge letter has been sent to GPs, but again, the information may not be captured as a Read code. I therefore could not examine individuals using private care when I used THIN. Electronic primary care records may also not include individuals from groups where drug prevalence is known to be relatively high, which include prisoners, the homeless and students (*see section 3.4.4 for details*).

Sixthly, GPs may not be aware that an individual is receiving a prescription elsewhere and not record it as a Read code in the individual's electronic health record. The National Treatment Agency only clarified where an individual received treatment from and the type of treatment they received (psychological vs pharmaceutical) from April 2012. It was not possible to compare the number of those with prescriptions in THIN to the total number from the National Treatment Agency Monitoring System (Public Health England, 2013a). I could therefore only compare the previous years' prescriptions with those in 2012. Furthermore, the Welsh Substance Misuse Database does not categorise the settings and I could therefore not compare the results for opioid substitution treatment capture in THIN in Welsh general practices. Additionally due to the strict inclusion criteria that I applied with regards to opioid substitution treatment, I would have excluded individuals who were being treated with diamorphine (Strang *et al.*, 2010)

The final limitation of using THIN to examine recording of drug use during pregnancy is that even though women are encouraged to register with a GP when they are pregnant, some women who use drugs may choose to self-refer to either the midwifery or drug treatment services and therefore they will not be captured in THIN. (National Institute for Clinical Excellence, 2010b; National Treatment Agency for Substance Misuse, 2010). Pregnancy may be a critical point for seeking help and in this case disclosure and recording in electronic health records may increase. However, due to the increased stigma and fear of the child being

taken away, disclosure may decrease and there is little chance for recording occurring (Advisory Council on the Misuse of Drugs, 2011; United Kingdom Drug Policy Commission, 2010). As with the study by Dhalwani *et al.*, they suggested that women who are pregnant may not disclose their smoking status due to the social stigma attached to the behaviour (Dhalwani *et al.*, 2014).

Following referral to the midwifery service, information regarding drug use and/or opioid substitution treatment is not recorded in a centralised recording system, and unless this information is included in the discharge summary, the GP may not know. Additionally if the information regarding drug use is in the discharge summary, the GP may scan the summary and not include the information about drug use as a Read code. The information about drug use during pregnancy would not be captured in THIN.

In contrast if prescriptions for opioid substitution treatment need to be given, these would be recorded in the electronic health records and captured in THIN, however this would be for the period after pregnancy. As with the study by Dhalwani *et al.*, it was also challenging to determine the timing of recording of drug use in the THIN database. GPs may have used a Read code to record drug use before the woman was pregnant and may not have re-recorded this with a Read code at the beginning of pregnancy, additionally GPs may have only recorded drug use after pregnancy when they became aware of the drug use. Therefore, in order to try and include these women, I examined all recordings for drug use and/or opioid substitution treatment 36 months either side of and during pregnancy and not just the first recording.

It was evident that using THIN in a cohort study design for examining drug use and/opioid substitution treatment encompasses both strengths and limitations. An

alternative to using THIN could be an anonymous and confidential questionnaire conducted in various general practices each attender at a general practice could be asked about drug use. (This is depicted in the third section in the health care pyramid *Figure 8:1*). This study design may give less of an under-estimate of drug use as no consequences would result from disclosure and the questionnaire may capture both recreational and problem drug users. However recruitment and collection of data would be time-consuming and costly, the study would have a smaller sample size and may be less representative of the general UK population compared with using THIN.

Despite its limitations, THIN is possibly the most suitable database to use to examine GP recording of problematic drug use and opioid substitution treatment at present. However, because women are not regularly in contact with their GP during pregnancy, it may be more appropriate for researchers to use drug use one year before pregnancy and/or 6 months after and infants recorded with NAS as proxies for drug use during pregnancy. I will discuss how other studies have used this approach when controlling for drug use in their studies in section 9.6 (Petersen et al., 2016a)

9.5.2 Strengths and limitations of using the Hospital Episode Statistics database

The main strengths of using HES is that it has developed into a key resource for monitoring health outcomes and assisting in epidemiological research (*mentioned in detail in section 3.5.3*) (Morleo *et al*., 2011; Murray *et al*., 2013; Royal College of Obstetricians and Gynaecologists, 2014). The database is an extensive electronic resource which is cost-effective, and can compare outcomes between hospitals and trusts (Health and Social Care Information Centre, 2012; Morleo *et al.*, 2011). The unique HESID, allows longitudinal analysis of each individual patient. HES includes approximately 96% of births in England and it was therefore ideal for examining the recording of NAS to obtain an estimated prevalence of NAS in

England (Birthplace in England Collaborative Group *et al*., 2011). Individuals are also given specific ICD-10 diagnostic codes for syndromes like NAS and I could therefore identify babies who had been diagnosed with NAS.

As with THIN, the main limitation of using HES was that it was not intended for research purposes, but rather designed primarily for costing in secondary care (Health and Social Care Information Centre, 2012). The variation in recording is likely to reflect partly whether trusts have specialist services or protocols for dealing with drug misuse in pregnancy which in turn impinges on recognition, diagnosis, recording, and coding (O'Grady *et al.,* 2009). Variation is also likely to be related to geographical area and to local protocols (O'Grady *et al*., 2009). Hospital staff do not routinely check and test for NAS, unless they are aware that the mother has used drugs and/or has been treated with opioid substitution treatment during pregnancy (Dr K Johnson 2013, personal communication (face to face conversation), 19th November). There may then be infants with NAS that are undiagnosed or discharged too early and not recorded for NAS in secondary care and therefore will definitely not be recorded in primary care. There are no national standards for coding and therefore the quality of data coded and sent to HES is of varying quality (Knight *et al*., 2013b). Consequently, the quality of baby data is still relatively poor, especially with regards to missing data and the index of multiple deprivation (IMD). I therefore could not look at IMD in the second part of my third study as 75% of IMD was missing in the baby records. Using HES can also lead to systematic error, either because of incorrect recognition of NAS or recording by the doctor and/or coding by the hospital coder. The mother and baby identities were not linked in HES and I could therefore not obtain information regarding the mother (e.g. type of drug used) as it may not be in the baby record. As with THIN, HES is not a flawless database, however, it is the most appropriate database to examine the prevalence of NAS in English births at present.

9.5.3 Strengths and limitations of qualitative interview methods

Finally, the main strength of the qualitative study design was that it gave perspective about GP recording of drug use using GP accounts describing when and why they did not record drug use in electronic health records. The interviews provided an insight into some of the reasons why GPs did not follow RCGP and practice guidelines on recording for drug use.

Another strength of my qualitative study was that I was able to recruit and interview GPs with and without a special interest in drug use, but also with various demographic factors. I recruited and interviewed GPs from a geographical spread which allowed me to gain an understanding of different perspectives and practices in different regional areas. Males and females, who were in various stages of their careers-from a GP trainee to GPs with over 15 years' experience- were recruited. Both GPs who were leads in substance misuse and GPs who did not see individuals who used drugs regularly in their practice were interviewed. This allowed me to explore if there were similarities and differences in recording practices of GPs with more and GPs with less interest in drug use. All the GPs had and described examples of individuals who used drugs, whether they treated them for their drug use or not. There was consistency of themes between the interviews, but there were also contrasts of opinions and descriptions of recording action between individuals, which allowed me to compare and contrast the data during analysis. My sample size was relatively small, but in order to gain a deeper qualitative understanding it was important to keep it small. With all qualitative studies the relatively small sample size makes it difficult to generalize to a wider population. However, I have described my research context and assumptions thoroughly to improve transferability and to allow someone to conduct a similar study.

The qualitative findings of my study offers an insight into GPs accounts of their perspectives and what they have done under certain circumstances. In some cases GPs referred back to the electronic records to ascertain exactly how they had recorded in the electronic health records, but this was not always the case. These are also the views and perspectives of GPs alone, and this study lacks opinions from other health professionals, including practice nurses and drug workers. The voice of individuals who use drugs and come to see GPs about their drug use is also not included in my study. I will discuss how future research could include recruitment of health professionals and patients in *section 9.8.2*.

My qualitative interviews were influenced and shaped by myself, as I was working on my own most of the time. I tried to improve this by having regular meetings with my supervisors to discuss my interviews, transcripts, coding structure and developing themes. I also organised and executed a data-clinic where other qualitative researchers could interpret and comment on one of my transcripts.

Finally, not all of the GPs I interviewed used the same software for patient management (Vision) that is used in general practices which contribute data to THIN. Some GPs used EMIS and others used System One. The different type of software might have an impact on how data is recorded, but I did not examine this in further detail.

I would argue that interviews were the most appropriate method to use to help answer the research questions given/within the time available within my PHD. Now that I have discussed the strengths and limitations of using the two databases and qualitative interview methods in the thesis I will now discuss how the evidence from all four studies has helped to answer the research questions of the thesis.

9.6 What I have learnt during the thesis and what I may have done differently

From my first study, I learnt that GPs are recording drug use in the electronic health records. However, my qualitative study suggests that individuals who use drugs do not always disclose this to their GP. Disclosure seems more likely to occur when the drug user's behaviour causes harm and functional impairment and consequently more problematic drug use seems to be recorded. Furthermore, recording of drug use will only be captured when a GP ultimately makes a clinical decision to record or not when an individual discloses information. Recording may therefore be picking up the effects of drug use rather than the actual drug use, unless the individual is wanting to stop using drugs and then this may either be recorded as a Read code or in the free- text. Therefore on reflection, electronic primary care records may be best suited for studies that involve problematic drug use.

I also learnt from my research that GPs were using a variety of Read codes to record drug use, but that most of them were generic. I therefore could not do sub-analysis on different recorded drug types. The qualitative work supports the fact that GPs are often using generic codes as an individual may be using more than one drug, but GPs do not always spend time looking for specific Read codes and often record the type of drug in the free-text rather than as a Read code. A lot of information about the type of drug used is therefore not captured for analysis in THIN. I was however surprised that a tenth of recorded Read codes were specifically for individuals who were dependent on the prescription drug benzodiazepine and 7% for individuals dependent on cannabis. This again seems to be coding for individuals with a dependency problem relating to drug use and therefore is included in the definition of problematic drug use. Depending on the research question for future studies that involve dependence on prescription drugs could also be included as my research indicates that this seems to be an emerging problem.

Before working with THIN, I was unaware that primary care electronic health records would not capture those in temporary accommodation (e.g. the homeless, ex-prisoners) or those in prison. This unfortunately is a limitation of using THIN and other primary care databases as prevalence of drug use in those groups could potentially be high. I also learnt that the demographics (age, gender and deprivation) for individuals recorded with a Read code and/or opioid substitution treatment were similar to other national surveys and surveillance databases which indicates that individuals with similar demographics are being identified and recorded in primary care. The qualitative study suggested that GPs are focusing on asking certain individuals with these characteristics and therefore other individuals without these characteristics could in fact be missed and consequently recording of these individuals is not captured in primary care. The studies support the fact that drug-use in THIN is underestimated and future research needs to acknowledge that THIN is only capturing the tip of the ice-berg with regards to drug-use in the community.

I also found that more recording was occurring in regions that are known to have a higher prevalence of problematic drug use, namely North East, North West and South East regions of England. These regions may have more local enhanced services for drug use which the qualitative findings suggest may initiate the development of protocols for recording drug use. I did not expect to find that London had one of the lowest rates, but this could be because individuals may be accessing community drug clinics rather than going to their GPs. Additionally, the lower rates could also be an indication of the higher transient population in London and therefore individuals may not be captured in THIN as they are not permanently registered with a general practice for a certain amount of time. I would recommend that future studies also include both region and deprivation as confounders.

Furthermore, I learnt that although it was not mandatory for GPs to report individuals who were receiving opioid substitution treatment in general practice to the National Drug Treatment Monitoring System (NDTMS), results from my first study indicated good comparability between THIN and the NDTMS. These findings suggest that GPs are being compliant with regards to reporting and this was also supported by findings in the qualitative study when interviewing GPs who treated opioid substitution treatment in general practice. These GPs may have templates set up which aid reporting to the NDTMS because they have a local enhanced service which financially incentivises their recording.

As previously mentioned, findings from my second study revealed that very little recording of drug use occurred during pregnancy. However, drug-use was recorded significantly more before pregnancy and opioid substitution treatment was recorded significantly more after pregnancy. This is one of the key findings of the thesis which is supported by the qualitative study which illustrated that GPs routinely referred pregnant women to midwifery services and are often referred straight to the specialist service if they were known to use drugs. The qualitative findings also highlighted that although some women may still see their GP for other issues during pregnancy, women who were cared for by the specialist midwifery services would usually be seen by the assigned GP in the specialist service. Women who use drugs were considered high risk pregnancies and managed differently. The increase in opioid substitution treatment after pregnancy indicated that some women's care was transferred back to the GP. Again it seems that THIN is capturing more problematic drug use than recreational drug use in and around pregnancy. This could be another explanation for why the rates were lower than previous biological and survey studies. GPs may have used a Read code to record drug use before the woman was pregnant and may not have re-recorded this with a Read code at the beginning of pregnancy. Additionally, GPs may have only recorded drug use after pregnancy when they became aware of the drug use. Therefore, in order to try and include these women, I examined all recordings for

drug use and/or opioid substitution treatment 36 months either side of, and during pregnancy and not just the first recording. I was also able to perform a sensitivity analysis in THIN with regards to the stability of the pregnant population and I found that women who may be more transient with regards to GP registration had similar drug-use results compared with women who were registered for longer period of time.

Despite its limitations, THIN is possibly a suitable database to use to examine GP recording of problem drug use and opioid substitution treatment at the present time and future research could include recording of drug use before and after pregnancy as a proxy for drug use during pregnancy. This has been done recently by Petersen *et al.* who argued that alcohol, illicit drug use and smoking are not recorded regularly in electronic health records (Petersen et al., 2016a). They therefore used a sensitive rather than specific approach to capture women who used illicit drugs by including women if they had at least one recording of drug use and or opioid substitution treatment up to three years before the start of pregnancy (Petersen et al., 2016a).

Furthermore, in my third study, I learnt that GPs were recording a third of infants diagnosed with NAS in the electronic health records of the infant rather than the mother. It would have been valuable to have linked mother-baby records within HES to obtain more information about which drugs the mother used at the time of delivery. Unfortunately, due to time constraints, this was not possible during my PhD, however current work is taking place to link mothers and babies in HES which could be used in future research studies (Harron et al., 2015). As mentioned previously, it would have also been useful to have linked HES and THIN data, but this link had not occurred whilst I was conducting my analysis. Once the linking has been completed future research can use this to ascertain which infants

diagnosed with NAS are being recorded in primary care and also longitudinally analyse these infants using both their primary care and hospital records.

If I had the chance to repeat my research, I may have done the qualitative work before the quantitative studies. However, I was under the assumption that drug-use would be well recorded in primary care and it was only after conducting my quantitative studies that I realised that I needed to include a qualitative study in order to answer the question that arose during conducting the quantitative work. There is no pre-defined order within mixed methods research as the order usually depends on which questions need to be answered and which is the best method to answer them.

9.7 Is THIN sufficient to address the hypothesis concerning drug use during pregnancy or the consequences of NAS?

There are various approaches I could have used to address the hypothesis concerning drug use during pregnancy or the consequences of NAS. Several birth cohort studies have been designed and developed to examine pregnant women and their children longitudinally. These include the Avon Longitudinal Study of Parents and Children (ALSPAC), the Southampton Women's Survey, the Born in Bradford Cohort Study and the Millennium Cohort Study (Boyd et al., 2012; Connelly and Platt, 2014; Fraser et al., 2012; Inskip et al., 2006; Wright et al., 2012). All cohort studies recruited women between a specific time period; ALSPAC (1991-1992, n=13,761 women and 13,876 pregnancies), Southampton (1998-2002, n=12,500), Born in Bradford (2007-2010, n=13,500) and Millennium (2000-2001, n=19,000). All cohorts have a relatively large sample size which is essential as the occurrence of both outcomes is relatively low. Previous studies have shown that drug use time-trends vary in the UK and therefore a limitation of obtaining information from cohort studies during pregnancy is that the information would be obtained during a specific time period and may not be representative of

other time periods. Additionally, the first three of these cohort studies recruited women locally and is therefore only representative of that particular area and not of the rest of the UK population. In contrast, the Millennium Cohort Study recruited a UK national representative of women and children. Only the ALSPAC and Born in Bradford studies included questions on drug use during pregnancy, however these were limited to marijuana and ecstasy. Furthermore, none of these cohort studies ask specific questions about NAS in the birth questionnaires. A potential way of examining drug use during pregnancy is if more detailed questions on drug use and NAS are included in the questionnaires. A limitation of questionnaires in cohort studies such as these is that a high risk of recall bias exists, if the questions are asked retrospectively. Alternatively the children of mothers in the original cohorts have started or may have children of their own and questions could be included in these prospective questionnaires. In order to add any additional questions to my qualitative study, I would have required additional design work, development, ethics board submissions, piloting and implementation, all of which were not achievable within the funding and time constraints of my PhD.

As it was not feasible to use the existing cohort studies, I explored electronic health records. THIN may not be sufficient to address problematic drug use during pregnancy and NAS on its own, however it may provide the best option as it is cost-effective, representative of the population in England and Wales over a long time period. Hence my study focused on the extended time-period between 1994 and 2012. The findings from both my quantitative (studies 2 and 3) and qualitative (study 4) studies support the use of examining drug use and opioid substitution treatment before and after pregnancy but not during pregnancy. As with studies by Petersen *et al*, if information regarding drug-use is captured outside pregnancy (3 years before and 6 months after), I have made the assumption that the individual would also be using drugs during pregnancy (Petersen et al., 2016b, 2016c). The qualitative findings have given further justification for using the recording on either side of pregnancy as GPs do not usually see women during pregnancy, but if they

know that a women uses drugs, they will refer her to the specialist midwifery services and continue her care after delivery.

Additionally, it would have been ideal to link the electronic health records with the maternity health records, but unfortunately at present most of the maternity notes are kept in hard copy. University College London Hospital does retain some information from maternity notes electronically, however these records have not yet been de-identified and therefore permission to access them was not possible during my PhD (Professor R Gilbert, 2015: personal communication (face-to-face) 1st August). Pilot studies are currently evaluating the transfer of maternity records electronically in Shrewsbury and Telford and Bradford (details in section 9.7.1.) If the results from these pilot studies are positive, future studies could link the electronic health records from primary care with the maternity records and researchers would then have a clearer picture of a woman's pregnancy journey.

Furthermore, since June 2015, the Information Standards Notice (which mandates the national collection of data) requires maternity service providers to collect data locally and submit the data centrally (NHS Digital, 2012). Approximately two thirds of the providers are currently providing data (Harron et al., 2016). A recent report conducted by the Family Nurse Partnership (FNP) in 2015 justified that using both population-based linkage from the FNP and administrative data from other services would provide evidence for monitoring and evaluating maternal and child health (Harron et al., 2016). These services include maternity data and CPRD and therefore future studies could use the linkage to obtain a closer community estimate of drug use during pregnancy.

Finally, with regards to NAS, the findings from my third quantitative and qualitative (study 4) studies support the fact that around a third of diagnosed NAS is being recorded in primary care electronic health records. The linkage of THIN and HES

would have benefited the thesis and shed more light onto which particular infants were diagnosed and recorded with NAS in the primary care records. Since conducting my analysis, the two databases have been linked as previously mentioned on page 313. Therefore future studies could use the linked data to expand the results from the second and third studies (drug use during pregnancy and NAS).

I have discussed if THIN sufficient to address the hypothesis concerning drug use during pregnancy or the consequences of NAS and I will now discuss the implications the findings have on policy, clinical practice and research.

9.8 Implications for Policy, Practice and Research

9.8.1 Implications for policy and practice

General practitioners may be reticent to manage drug dependency in primary care but still play an integral role in the management of patients' physical health and people who use drugs often have poor physical health (National Institute for Clinical Excellence, 2007b). Presently the General Medical Service contract does not have specific QOF indicators for substance misuse. QOF indicators may not be the most suitable method for incentivising recording of drug use in general practice. However the proposed local incentive schemes could include recording of drug use and may be more appropriate, especially in areas where a high amount of drug use is recognized (NHS England, 2015). Local incentive indicators could be introduced to help GPs identify and refer on to other services or treat this vulnerable group of people. However recording of drug use should still be discussed with the individual as the qualitative findings suggest that there is a risk that the GP-patient relationship could be compromised if the GP is obliged to record drug use in the electronic health records.

The RCGP have developed a certified course in the management of drug misuse which can go some way towards helping GPs to manage and treat patients with drug use problems (Royal College of General Practitioners, 2015a). The topic of recording drug use in electronic health records is not included in the modules, but my qualitative findings suggest that the topic of recording could be included in the curriculum (Professor C Ford, 2015: personal communication (email) 8th December 2015). The scope to develop clear care pathways for those identified in general practice and then treated either in the practice or referred to an appropriate community drug clinic needs careful consideration. It is possible that not all GPs would wish to engage with people who use drugs leading to a disparity in the provision of care (United Kingdom Drug Policy Commission, 2012). Nevertheless, appropriate identification of people who use drugs by GPs and appropriate management or referral can go some way in ensuring clarity in the management of this group of people.

Findings from the second study show the minimum estimate of drug use during pregnancy in primary care (Chapter 5). Women who use drugs, often have a myriad of other social and medical problems which can lead to complex lives, social disadvantages and vulnerability (Advisory Council on the Misuse of Drugs, 2011). Drug use may or may not be detected and/or recorded in and around pregnancy (Rayns *et al*., 2013). However, my qualitative findings suggest that it is not recorded because women are referred to maternity services during pregnancy and do not always see their GPs during this time. Additionally, the Saving Mothers' Lives report (2007) highlighted the fact that woman using drugs did not always look for early antenatal support and often missed subsequent antenatal appointments (Royal College of Obstetricians and Gynaecologists, 2010). However, pregnancy is a critical time to engage and support women who use drugs and GPs may be the first point of contact and a gateway to appropriate services (Rayns *et al*., 2013). The first appointment between a woman and GP once she learns that she is pregnant may be an opportune time for the GP to ask about drug use, together

with asking about other adverse health behaviours such as smoking (Dhalwani *et al*., 2014).

Various recommendations have been made with regards to the care pathway for pregnant women who use drugs. NICE recommends that the first point of antenatal contact with a health professional should include guidance on smoking cessation, the consequences of recreational drug use and alcohol during pregnancy (National Institute for Clinical Excellence, 2010b). Whilst, the Department of Health advises GPs to refer pregnant women who use drugs directly to specialist midwife services (Department of Health, 1999). In addition, the saving mother's report also recommends that when GPs refer pregnant women who use drugs to the midwife services, they should include information such as psychiatric history and alcohol and drug use in the referral form (Centre for Maternal and Child Enquiries, 2011). If this information is included in the referral form, it could also potentially be recorded as a Read code in the electronic health records. Presently, maternity services and general practice are segregated and communication via phone calls, emails and faxes may not be recorded electronically. Referral and discharge letters may only be scanned and may miss out some information (Centre for Maternal and Child Enquiries, 2011). Electronically recorded maternity notes may help with communication and loss of information and some trusts have already started introducing paperless maternity services. Shrewsbury and Telford Hospital NHS Trust have piloted using an electronic system to replace hand-held maternity notes for antenatal consultations and are rolling out the programme to include postnatal notes (System C Connected Care, 2013). Similarly, Bradford Teaching Hospital NHS Foundation Trust is piloting replacing hand-held maternity notes with an electronic recording system from February 2015 (Bradford Teaching Hospitals NHS Trust, 2015). A centralized or improved integration of recording systems between maternity services and GPs may be model of healthcare that could be implemented (Centre for Maternal and Child Enquiries, 2011).

Women who use drugs and alcohol during pregnancy need support as they are vulnerable and have a higher risk of suicide, especially if there is a chance that their baby will be taken away (Advisory Council on the Misuse of Drugs, 2011). This support could be offered by a GP, especially if a trusting and therapeutic relationship has developed between the woman and GP. However, once a woman has been referred to the antenatal or specialist midwife service she has very little contact with her GP. A model of shared care, incorporating more GP appointments together with midwife appointments has been developed and implemented for all low-risk pregnant women in the London borough of Tower Hamlets (Smith *et al.*, 2010). This model could potentially be rolled out to ensure that all pregnant women, including those who use drugs, receive more continuous care and support during and after pregnancy. Recording of drug use as a Read code in the electronic health records at the initial consultation may be helpful to GPs during subsequent consultations.

The findings from my third study (Chapter 6) suggest that the rates of NAS in secondary care seem to be stable in England, however rising rates in Scotland, Wales, the USA and Ontario and the increased use of opioid analgesics highlight the need for national NAS surveillance and for monitoring the source of opioids used (Jones *et al*., 2013, National Statistics Scotland, 2012; O'Donnell *et al.*, 2009; Patrick *et al.*, 2012; Tolia *et al.*, 2015). Additionally, children who have been recorded with NAS are more likely to suffer from child maltreatment and hospital readmission later (O'Donnell *et al*., 2009; Uebel *et al*., 2015b). The identification, management and provision of a high standard of care for children whose parents use drugs is not always the focus (Advisory Council on the Misuse of Drugs, 2011). Given the high cost and serious consequences for mother and baby of opioid use in pregnancy, policy makers should consider extending surveillance through linkage with administrative data (primary and secondary care) to guide pre- and post-natal health and social care provision and improve outcomes for both mother and child (Bagley *et al*., 2014).

The qualitative study suggested that many factors influence how GPs ask and record drug use in electronic health records (Chapter 7). There did not seem to be a uniform way of asking about drug use, however GPs used their experience to develop ways of asking patients about a sensitive issue. As mentioned previously, the RCGP offers a certified course in the management of drug misuse and GPs who had completed the course found that it helped them with their confidence in enquiring about, managing and treating patients with problematic drug use (Roberts, 2005; Royal College of General Practitioners, 2015a).

My findings also suggested that there seem to be redundant Read codes for drug use, therefore Read codes for drug use could be revised and only relevant and utilised codes kept. Particular general practices with relatively more registered patients who used drugs have developed special templates for recording drug use and treatment. The templates are linked with specific Read codes in the patient's electronic health records. General practices using these templates found them easy to use and helped with systematic recording and auditing recording of drug use. The templates could potentially be rolled out to other CCGs to ensure more uniform and systematic recording of drug use in electronic health records. Additionally, recording systems between services and general practices are linked in a CCG located in Yorkshire and Humberside (Leeds & York Foundation Trust, 2015). If a patient gives consent, GPs can monitor and acquire a clearer picture of a patient's management and treatment in other drug treatment services (Leeds & York Foundation Trust, 2015). The linkage of services using Read codes could also potentially be rolled out nationally.

Finally, it was evident from my findings that people who use drugs (both problem and recreational drug users) are consulting with their GP. Recording drug use with Read codes in electronic health records may be challenging as the recording is

permanent and may impact on the trust between GPs and patients. HIV is an example of a sensitive and stigmatised disease, where information regarding diagnoses is confidential (Madge *et al.*, 2011). However in order to understand the size of the problem, clinicians and laboratories voluntarily report anonymised information to the Health Protection Agency (Public Health England, from April, 2013) (Madge *et al*., 2011). Between 1968-1997, it was mandatory for doctors to notify the Home Office of any confirmed and suspect addicts (Corkery, 2002). Notified individuals were then recorded in the Home Office Addicts Index (details in section 1.3.8). I would argue that in order to understand the burden of drug use, especially during pregnancy, a similar reporting system to Public Health England could be introduced. However, unlike the Home Office Addicts Index, the identity of individuals would be pseudonymised to reduce double counting of individuals.

9.8.2 Implications for research

Various research implications have arisen from the thesis. Firstly, templates for recording drug use could be rolled out nationally and evaluated using qualitative research methods. Additionally, if linked communication between services (using Read codes) is rolled out and implemented, evaluation of these linked systems would be necessary in order to assess the value and cost-effectiveness of the linking services. GPs are only using half the available Read codes for recording drug use in electronic health records. My qualitative findings suggested that there were too many unnecessary Read codes for recording drug use and that it was often time-consuming to try and find the most appropriate Read code to use. A qualitative study is therefore needed to understand which Read codes are the most useful and need to be kept with regards to drug use.

THIN could potentially be used as a research tool to examine outcomes of individuals who are recorded as using drugs. There was little known about how recreational drug use (in young people) impacts long term outcomes and potential

complications and studies are needed (McCambridge and Strang, 2004). Furthermore, following on work conducted by Cornish *et al.*, individuals who have been prescribed with opioid substitution treatment in general practice could be followed up longitudinally and relative health outcomes and adherence to opioid substitution treatment could be explored (Cornish *et al.*, 2010).

This would be particularly relevant during pregnancy, especially if babies were linked to mothers in THIN, so that other outcomes could be examined. It may also be appropriate when researching drug use during pregnancy using electronic health records to include women who have at least one recording of drug use up to 3 years before the start of pregnancy (Petersen et al., 2016a). I have included a potential analysis plan at the end of this section to examine drug use during pregnancy and adverse birth outcomes.

At the time of doing my analysis, I did not have access to linked HES and THIN data. It would be valuable to examine infants who are recorded with NAS in HES and follow them up longitudinally in both THIN and HES to examine long term outcomes and also hospital admissions.

Finally, based on the results of my qualitative study, I have only looked at GP accounts and therefore an in-depth qualitative study is needed to explore other health professionals such as practice nurses' and drug workers' narratives as well as patients' perspectives and experiences when accessing general practice for drug use. As mentioned previously, an ethnographic study could also be conducted to gain a clearer understanding of recording practices in the context of which they occur.

Analysis Plan: History of drug use and risk of adverse birth outcomes

Background:

There is evidence that certain adverse and poor birth outcomes occur due to drug use during pregnancy. Madgula *et al* conducted a systematic review on this subject and their findings concluded that opioid use during pregnancy caused neonatal abstinence syndrome (Madgula et al., 2011a). However, the causal effects of drug use on other birth outcomes was inconclusive as studies contributing to the systematic review had small sample sizes, used different methods and were conducted in different settings (Summary of studies in Appendix 13) (Madgula et al., 2011a). The Health Improvement Network (THIN) contains both mother and baby electronic health records that have previously been linked and used to examine the associations between prescribed medicines in pregnancy on specific adverse birth outcomes (Ban et al., 2014, 2012, Petersen et al., 2016a, 2016b, 2016c). THIN can therefore be used to examine whether drug use either side of and during pregnancy is associated with specific birth outcomes.

Aims:

To determine if history of drug use is associated with the following adverse birth outcomes; congenital heart anomalies, major congenital malformations, and poor birth outcomes (low birthweight, preterm birth and caesarean section).

Hypothesis:

Women who use drugs or opioid substitution treatment around and during pregnancy will be more likely to give birth to infants with adverse and/or poor birth outcomes.

Data Source:

Data from the large primary care database, THIN will be used. THIN provides anonymised information from individual's electronic health records which include clinical signs and symptoms and prescriptions. Longitudinal analysis can be conducted on individuals who are permanently registered with a general practice and THIN represents approximately 6% of the UK population.

Study population:

For this study I will use a linked mother-child cohort which includes records for the time period between 1st January 1995 and 31st December 2012. Mother and infants have been linked within THIN based on family identifier codes, delivery month (mother) and birth month (infant). I will include mothers who have been permanently registered with a general practice for at least 36 months before during and 36 months after pregnancy as this represents a relatively stable cohort. I will have two cohorts, those women who have a record of drug use in the 36 months before or during pregnancy (Cohort A) and those who have no record in this period or at any time before (Cohort B).

Exposures:

Women will be defined as having a history of drug use if they have had at least one recording for drug use and/or opioid substitution treatment 36 months before, during or 6 months after pregnancy. Some women have more than one pregnancy, for these women I will select a random pregnancy. This is to ensure that the pregnancies in the sample were independent of each other (Kirkwood and Sterne, 2003).

Outcome measures:

I will examine the following adverse and poor birth outcomes as these are often examined in studies of prescribed medication.

Adverse birth outcomes (EUROCAT, 2016; Madgula et al., 2011a; World Health Organisation, 2010)

- Congenital heart anomalies
- Major congenital malformations

Poor birth outcomes (Madgula et al., 2011a; World Health Organisation, 2010)

- low birthweight (<2500g)
- preterm birth (<37 weeks)
- caesarean section

All outcome measures will be binary (yes/no).

Potential confounding variables:

I will include the following variables based on previous studies examining drug use during pregnancy and adverse birth outcomes and the information that can be obtained from the woman's electronic health records; calendar year of delivery, age of mother at time of delivery, pre-pregnancy BMI (obtained from maternal height and weight up to a year before pregnancy), parity, smoking status, history of problem alcohol use, pre-existing medical conditions (depression, epilepsy, psychosis, hypertension and diabetes), pre-existing prescriptions (antidepressants, anxiolytics, hypnotics, anticonvulsant mood stabilisers and lithium) (BMJ group, 2013; E Day and George, 2005; Fergusson et al., 2002; Madgula et al., 2011b; Petersen et al., 2016a, 2016b, 2016c).

Maternal age will be categorized into the following six categories; <19, 20-24, 25-29, 30-34, 35-39 and >=40 years old. I will obtain pre-gestation height and weight from the additional health records in THIN. I will then calculate the pre-gestational

BMI (kg/m^2) and group into four categories; underweight (<18.5), normal weight (18.51-24.9), overweight (25-29.9) and obese (>30).

I will use the same Read codes as Petersen *et al* to obtain smoking status and history of alcohol problems from the additional health records in THIN and transform into binary variables (yes/no) (Petersen et al., 2016b). As with drug use, smoking and alcohol are not recorded on a regular bases, so I will include any recording thirty six months before and during pregnancy (Petersen et al., 2016b). In order to examine the parity of women, I will sum their total number of pregnancies and use it as a continuous variable.

In order to examine the social deprivation status and the region, I will use information about quintiles of the Townsend deprivation scores and region (strategic health authority (SHA)) (Health and Social Care Information Centre, 2013a; Townsend, 1987) which is available in THIN at individual level.

Analyses:

1. Tabulate characteristics and of women and birth outcomes in cohorts A (women who had a history of drug use) and cohort B (women who had no history of drug use)
2. Ascertain if there is potential confounding by examining if there is an association between the exposure and confounder and an association between the confounder and the outcome. (Kirkwood and Sterne, 2003).
3. I will estimate the absolute risks and 95% confidence intervals as well as the risk difference for each of the outcomes.
4. Perform Poisson regressions to estimate the relative risk ratios and 95% confidence intervals using cohort B as the reference cohort. I will carry out hypothesis testing using likelihood test and Akaike information criterion to

select the model of best fit (Akaike, 1974; Kirkwood and Sterne, 2003; Zucchini, 2000)

All data will be analysed using STATA (version 14) statistical software (Stata Corp LP, College Station, Texas).

Limitations:

Drug use during pregnancy may be underestimated in electronic health records and that is why I have chosen to examine the effect associated with a history of drug use by including records three years prior to the pregnancy. It is possible that some of the women in this cohort may not be using drugs during pregnancy. If that is the case my estimates may be diluted towards the null. It is possible that the risk of adverse pregnancy outcomes may differ between different drugs, but most of the Read codes are generic and the numbers of women recorded with specific Read codes are too small for stratified analysis. Some women would have received parts of their care outside primary care, including women who are treated for opioid substitution treatment in community drug clinics. Some of these women may not have any information about this treatment in their primary care records and therefore the number of women prescribed opioid substitution treatment during pregnancy may be underestimated. In terms of the outcomes it is likely that some information from the hospital discharge letters may not be entered as a Read code in the mother's or baby's records. However if the diagnosis is more complicated such as congenital heart anomaly, it is likely to be entered as a Read code in the primary care records. Women who have experienced domestic violence may be underestimated as they may be re-housed and transferred to another GP practice and therefore not be captured in THIN.

9.9 Overall Conclusions

The thesis has made a considerable contribution to the broader landscape of knowledge and improved method, by generating a clearer picture and deeper understanding of GP recording of drug use and opioid substitution treatment in general practice using a mixed methods approach. My quantitative studies highlighted epidemiological recording trends were similar to national survey reports and other studies, but recorded at lower rates. The qualitative findings demonstrate the complexities and challenges GPs face when making decisions on whether or not to record in the patient's electronic health records. If GPs choose to record drug use, they often use free-text rather than Read codes, or they may record for the primary problem rather than a Read code for drug use. In contrast, recording of prescriptions for opioid substitution treatment is mandatory. If an individual was however prescribed opioid substitution treatment from a drug treatment service, it was not always recorded as a Read code in the electronic health records. General practice is the cornerstone of primary care and possibly ideal for identification and management of individuals who are problematic drug users. A confluence of factors affects both how GPs acquire information and how they manage and treat problematic drug use which in turn influences GPs decision to record drug use.

Primary care databases can assist in monitoring trends of drug use in the general population, however those individuals who are recorded in the electronic health records are more likely to be problematic drug users. Primary Care electronic health records could potentially be a useful tool to assess the level of burden of drug use during pregnancy by looking at recording of drug use either side of pregnancy as a proxy. Recording guidelines should be revised and questions about drug use could be asked routinely together with questions about smoking and alcohol. Recording guidelines regarding NAS could also be revised, as this is an indirect measure of drug use during pregnancy. The current antenatal care

model lends itself to two opportune times where GPs could ask about drug use: the first consultation after the start of pregnancy, and the 6 week appointment after delivery. GPs could then discuss together with the pregnant woman about recording drug use in electronic health records.

Information regarding drug use may be in hand-held maternity notes, but this information either does not always get reported back to the GP or the GP is aware of the information but decides not to enter the information as a Read code in the electronic health record. Improved integration of maternity and primary care recording systems could improve communication and pass on relevant medical, lifestyle and social information, which may include drug use.

In conclusion, the evidence from my thesis supports the use of THIN as a suitable tool for monitoring trends but not rates of problematic drug use in the general population. Additionally, THIN could potentially be used as a tool to monitor the impact of drug use during pregnancy. The thesis also supports the use of THIN as a research tool to identify drug use and to monitor those individuals who have been recorded with drug use longitudinally in the general population and in and around pregnancy.

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APPENDICES

Appendix 1

Table 1: Change of definition from DSM IV to DSM V (American Psychiatric Association, 2013b)

Change	DSM IV	DSM V
1	The section was divided into two sections: *'Substance abuse'* *'Substance dependence'*	The two sections have been incorporated and re-labelled: *'Substance use disorder'*
2	The statement; *'Frequent legal problems (e.g. arrests, disorderly conduct) for substance abuse'* was removed from DSM V-	The statement; *'Craving, or a strong desire or urge to use the substance'* was added to DSM V
3	The threshold for diagnosis of *'substance abuse'* was at least one criteria and the threshold for diagnosis *'substance dependence'* was at least three criteria	The threshold for diagnosis of *'substance use disorder'* is at least 2 criteria
4		*'Cannabis withdrawal'* has been added
5		*The severity of substance use disorder is based upon the number of criteria* *2-3=mild disorder* *4-5=moderate disorder* *>6=severe disorder*
6		*'Early remission*' is defined as at least 3 but less than 12 months
7		*'Sustained remission'* is defined as remission for at least 12 months
8		New specifiers include *'in a controlled environment'* and *'on maintenance therapy'*

Appendix 2

Table 2: Breakdown of cost of opioid substitution treatment in the United Kingdom (Joint Formulary Committee, 2013)

Opioid substitution treatment	Recommended dose	Dose breakdown	Cost per day (Prices based on BNF version 66)
Methadone hydrochloride oral solution	60-120mg	*liquid* 1mg/ml (can be more concentrated but under special circumstances) *Injectable* 10mg (1ml) ampoules 35mg (3.5ml) 50mg (5m, 2ml or 1ml) ***Tablets not licensed for opioid substitution treatment but are used***	1mg/mL, net price 100mL=1.27 60-120mL needed =£0.76-£1.52 per day
Buprenorphine (licensed in 1999 for opioid dependence) Subutex ®**(only formula until 2008)**	12-32mg	0.4mg, 2mg, 8mg sublingual tablets	0.4mg 7 tablets =£1.60 £6.99-£18.44 2mg 7 tablets=£2.79 £2.34-£6.24 8mg 7 tables=£5.58 £1.19-£3.16o
Buprenorphine/naloxone – Suboxone ®**(licenced in 2007)** Scottish Medicines consortium has advised that this should be used in those where methadone is		2mg/0.5mg, 8mg/2mg sublingual tablets	Suboxone: £25.40 per 28 tablets. Need 6-16 tablets per day £5.44-£14.51 per day

Opioid substitution treatment	Recommended dose	Dose breakdown	Cost per day (Prices based on BNF version 66)
unsuitable			
Lofexidine hydrochloride Managing symptoms of opioid withdrawal 7-10 day duration if no opioid use (longer may be required	2.4 (max dose at a time is 800µg)	200mg tablets	12 tablets =£12.38
Naltrexone hydrochloride To prevent relapse in previously opioid dependent patient (should be opioid free for 7-10 days)	50mg	50mg tablets daily, but can spread out through week	£0.81 per day
Dihydrocodeine (not licenced for opiod dependence but is used in General practice)	480-1800mg	60mg, 90mg, 120mg tablets	£0.75-£2.83 £0.77-£3.09 £0.79-£2.97
Diamorphine used in a small group who do not respond to other treatment. Needs specialist advice and license by GP	Dependent on patient	Injectable	

Appendix 3

I used the following terms for the literature search (Chapter 1):

- **Study design-**Quantitative:

  “epidemiological monitoring”, “medical audit”

- **Study design-**Qualitative

  “interviews” “focus groups”

- **Setting:**

  “primary care”, “general practice”, “general practitioner”, “primary medical care”, “primary care databases”

- **Drug use**

  “substance abuse”, “drug misuse”, “drug dependence”, “drug abuse”, “illicit drug”, drug dependence”, “problematic drug use”, “methadone”, “buprenorphine” “opioid substitution treatment”

- **Information processing**

  “recording”, ”medical record”,

- **Timing**

  “pregnancy”, “peri-natal”, “ante-natal”, “post-natal”

Appendix 4

Table 3: Structure of Read codes (Chisholm, 1990)

Structure of Read code	Description
0	Occupations
1	History and symptoms
2	Examination and signs
3	Diagnostic procedures
4	Laboratory procedures
5	Radiology and physics in medicine
6	Preventative procedures
7	Operations, procedures and sites
8	Other therapeutic procedures
9	Administration
A	Infectious and parasitic diseases
B	Neoplasms
C	Endocrine, nutrition, metabolic and immunity disorders
D	Diseases of blood and blood forming organs
E	Mental disorders
F	Nervous system and sense organ diseases
G	Circulatory system diseases
H	Respiratory system diseases
J	Digestive system diseases
K	Genitourinary system diseases
L	Complications of pregnancy, childbirth and the puerperium
M	Skin and subcutaneous tissue diseases

Structure of Read code	Description
N	Musculoskeletal and connective tissue diseases
P	Congenital anomalies
Q	Perinatal conditions
R	[D] Symptoms, signs and ill-defined conditions
S	Injury and poisoning
T	Causes of injury and poisoning
U	[x] External causes of morbidity and mortality
Z	Unspecified conditions

Appendix 5

Read codes for drug use in THIN

Read code	Description
1P62.00	Abnormal craving for drugs
13r0.00	Abstinent from drug misuse
13r1.00	Abstinent from drug misuse in normal environment
13r2.00	Abstinent from drug misuse in protected environment
13r3.00	Abstinent from drug misuse on maintenance replacement
13r4.00	Abstinent from drug misuse when receiving blocking therapy
T85y.00	Accid. poisoning by other drugs acting on nervous system OS
T842000	Accidental poisoning by amphetamine
T841000	Accidental poisoning by cannabis derivatives
T852000	Accidental poisoning by cocaine
T801.00	Accidental poisoning by methadone
1V22.00	Age at starting drug misuse
1V0D.00	Am spent per day on drug habit
Z1Q6312	Amphetamine maintenance prescribing
Z1Q6311	Amphetamine maintenance scripting
E244.00	Amphetamine or other psychostimulant dependence
E244z00	Amphetamine or psychostimulant dependence NOS
E244300	Amphetamine or psychostimulant dependence in remission
E244100	Amphetamine or psychostimulant dependence, continuous
E244200	Amphetamine or psychostimulant dependence, episodic
E244000	Amphetamine or psychostimulant dependence, unspecified
SL97011	Amphetamine poisoning
E241.13	Benzodiazepine dependence
8BAo.00	Benzodiazepine dependence detoxification
1V62.00	Buying drugs
ZR3Z.11	CAAP - Cocaine abuse assessment profile
E243300	Cannabis dependence in remission
E243100	Cannabis dependence, continuous
E243200	Cannabis dependence, episodic
E243000	Cannabis dependence, unspecified
E243z00	Cannabis drug dependence NOS
SL96000	Cannabis poisoning
E243.00	Cannabis type drug dependence
SM23z00	Chlorinated hydrocarbon solvent causing toxic effect NOS
ZR3Z.00	Cocaine abuse assessment profile
E242300	Cocaine dependence in remission
E242100	Cocaine dependence, continuous
E242200	Cocaine dependence, episodic
E242000	Cocaine dependence, unspecified
E242z00	Cocaine drug dependence NOS
SL85000	Cocaine poisoning
E242.00	Cocaine type drug dependence
E249z00	Combined drug dependence, excluding opioid, NOS
E249100	Combined drug dependence, excluding opioid, continuous
E249200	Combined drug dependence, excluding opioid, episodic
E249300	Combined drug dependence, excluding opioid, in remission

E249000	Combined drug dependence, excluding opioid, unspecified
E249.00	Combined drug dependence, excluding opioids
E248.00	Combined opioid with other drug dependence
E248z00	Combined opioid with other drug dependence NOS
E248300	Combined opioid with other drug dependence in remission
E248100	Combined opioid with other drug dependence, continuous
E248200	Combined opioid with other drug dependence, episodic
E248000	Combined opioid with other drug dependence, unspecified
1P31.00	Compulsive drug taking
1P30.00	Compulsive uncontrollable drug taking
13cC.00	Continuous use of drugs
1P60.00	Craves for drugs
1P6..00	Craving for drugs
13c7.00	Current drug user
13cK.00	Current non recreational drug user
ZRBK.11	DAST - Drug abuse screening test
1V60.00	Dealing with drugs
9NdN.00	Declined consent for notification of drug misuse
G801E00	Deep vein thrombosis of leg related to intravenous drug use
7P22000	Delivery of rehabilitation for drug addiction
Z192.00	Dependent drug detoxification
8BA9.00	Detoxification dependence drug
Z1Q6300	Dexamphetamine maintenance
E241.14	Diazepam dependence
1V34.00	Does not inject drugs
1TF..00	Does not use heroin on top of substitution therapy
Z1Q6100	Dose equivalent drug substitution
8AA..00	Drug abuse monitoring
1V0C.00	Drug addict
9G2..11	Drug addict notific admin
9G21.00	Drug addict notific to CMO
9G23.00	Drug addict re-notif to CMO
9G22.00	Drug addict re-notific due
9G24.00	Drug addict-notify local SMR22
E24..11	Drug addiction
9G2Z.00	Drug addiction notif NOS
9G2..00	Drug addiction notification
E24..00	Drug dependence
L183000	Drug dependence - unspec whether during pregnancy/puerperium
E24z.00	Drug dependence NOS
L183100	Drug dependence during pregnancy - baby delivered
L183300	Drug dependence during pregnancy - baby not yet delivered
L183z00	Drug dependence during pregnancy/childbirth/puerperium NOS
8BAX.00	Drug dependence home detoxification
8I2N.00	Drug dependence home detoxification contraindicated
L183.00	Drug dependence in pregnancy, childbirth and the puerperium
L183400	Drug dependence in puerperium - baby previously delivered
L183200	Drug dependence in the puerperium - baby delivered
8BAW.00	Drug dependence self detoxification
8B23.13	Drug dependence therapy

8680.00	Drug desensitisation therapy
Z192114	Drug detoxification
8FB0.00	Drug detoxification programme completed
1V37.00	Drug inject equipment hygiene
1V3..00	Drug injection behaviour
4Q1..00	Drug level
9k52.00	Drug misus trt prim care - ESA
9k50.00	Drug misuse - enhanced service completed
9k5..00	Drug misuse - enhanced services administration
9kS..11	Drug misuse assessment declined
9kS..00	Drug misuse assessment declined - enhanced services administ
1V...00	Drug misuse behaviour
9k52.11	Drug misuse treatment in primary care
SL...12	Drug poisoning
1V44.00	Drug priority ov finance oblig
1V42.00	Drug priority ov social obligs
1V43.00	Drug priority over family
E02..00	Drug psychoses
E02z.00	Drug psychosis NOS
8FB..00	Drug rehabilitation
Z1Q6.11	Drug substitution
13cG.00	Drug tolerance
13c..00	Drug user
Z192100	Drug withdrawal regime
E020.00	Drug withdrawal syndrome
E02y000	Drug-induced delirium
E02y100	Drug-induced dementia
E02y300	Drug-induced depressive state
E021100	Drug-induced hallucinosis
E021z00	Drug-induced paranoia or hallucinatory state NOS
E021.00	Drug-induced paranoia or hallucinatory states
E021000	Drug-induced paranoid state
E02y400	Drug-induced personality disorder
1V6..00	Drug-relat offending behaviour
1V53.00	Drug-related rituals
44q9.00	Drugs of abuse screening test
68U0.00	Drugs of abuse urine screening
E24A.00	Ecstasy type drug dependence
1P63.00	Excessive craving for drugs
146C.00	Failed heroin detoxification
L255.00	Foetus with drug damage
L255100	Foetus with drug damage - delivered
L255z00	Foetus with drug damage NOS
L255000	Foetus with drug damage unspecified
L255200	Foetus with drug damage with antenatal problem
Q007C00	Foetus/neonate affected-plac./breast transfer addictive drug
4I3e.00	Fluid sample amphetamine level
1V54.00	Follows drug-related rituals
1V2..00	Frequency of drug misuse
1T4..00	H/O amphetamine misuse

1T8..00	H/O cannabis misuse
1T5..00	H/O cocaine misuse
1T6..00	H/O crack cocaine misuse
1T40.00	H/O daily amphetamine misuse
1T80.00	H/O daily cannabis misuse
1T50.00	H/O daily cocaine misuse
1T60.00	H/O daily crack cocaine misuse
1T70.00	H/O daily hallucinogen misuse
1T00.00	H/O daily heroin misuse
1T10.00	H/O daily methadone misuse
1T90.00	H/O daily solvent misuse
1T7..00	H/O hallucinogen misuse
1T0..00	H/O heroin misuse
1T42.00	H/O infrequent amphetamine misuse
1T82.00	H/O infrequent cannabis misuse
1T52.00	H/O infrequent cocaine misuse
1T62.00	H/O infrequent crack cocaine misuse
1T72.00	H/O infrequent hallucinogen misuse
1T03.00	H/O infrequent heroin misuse
1T12.00	H/O infrequent methadone misuse
1T92.00	H/O infrequent solvent misuse
1T1..00	H/O methadone misuse
1T9..00	H/O solvent misuse
1T41.00	H/O weekly amphetamine misuse
1T81.00	H/O weekly cannabis misuse
1T51.00	H/O weekly cocaine misuse
1T61.00	H/O weekly crack cocaine misuse
1T71.00	H/O weekly hallucinogen misuse
1T01.00	H/O weekly heroin misuse
1T11.00	H/O weekly methadone misuse
1T91.00	H/O weekly solvent misuse
146F.00	H/O: drug abuse
1463.00	H/O: drug dependency
146E.00	H/O: recreational drug use
E245.00	Hallucinogen dependence
E245z00	Hallucinogen dependence NOS
E245300	Hallucinogen dependence in remission
E245100	Hallucinogen dependence, continuous
E245200	Hallucinogen dependence, episodic
E245000	Hallucinogen dependence, unspecified
13cL.00	Has never injected drugs
1V25.00	Has never misused drugs
13cN.00	Has never shared drug injection equipment
1V51.00	Has routine of drug activities
E243.11	Hashish dependence
1V0E.00	Health prob sec to drug misuse
E243.12	Hemp dependence
E240.11	Heroin dependence
Z1Q6214	Heroin maintenance
1V65.00	Heroin misuse

SL50100	Heroin poisoning
1V64.00	Illicit drug use
13c0.00	Injecting drug user
1V31.00	Injects drugs intramuscularly
1V30.00	Injects drugs subcutaneously
13c3.00	Intramuscular drug user
13c4.00	Intranasal drug user
13c1.00	Intravenous drug user
1P64.00	Irresistible craving for drugs
SL83000	Ketamine poisoning
E241.15	Librium dependence
67H3.00	Lifestyle advice regarding drug misuse
1V01.00	Long-term drug misuser
Z1Q6211	Low threshold methadone prescribing
E245.12	Lysergic acid diethylamide dependence
63C6.00	Maternal drug abuse
63C6.11	Maternal drug misuse
E245.13	Mescaline dependence
E240.12	Methadone dependence
SL50200	Methadone poisoning
Z1Q6212	Methadone therapy
E25z.00	Misuse of drugs NOS
E259400	Misuse of prescription only drugs
1V26.00	Misused drugs in past
1V0..00	Misuses drugs
13cB.00	Misuses drugs orally
1V04.00	Misuses drugs rectally
1V03.00	Misuses drugs sublingually
1V05.00	Misuses drugs vaginally
SL76.00	Mixed sedative poisoning NEC
Q485000	Neonat withdrawal symptom from mat use of drug of addiction
Q484.00	Newborn drug reaction and intoxication
Q484z00	Newborn drug reaction or intoxication NOS
Q485.00	Newborn drug withdrawal syndrome
1P61.00	No craving for drugs
46Q1.00	No drug found in urine
1V40.00	No priority to drug activities
1V50.00	No routine of drug activities
9OhB.00	Non-steroidal anti-inflammatory drug risk assessmnt completd
E25..00	Nondependent abuse of drugs
E257.00	Nondependent amphetamine or other psychostimulant abuse
E257z00	Nondependent amphetamine or psychostimulant abuse NOS
E257200	Nondependent amphetamine or psychostimulant abuse, episodic
E257300	Nondependent amphetamine/psychostimulant abuse in remission
E257100	Nondependent amphetamine/psychostimulant abuse, continuous
E257000	Nondependent amphetamine/psychostimulant abuse, unspecified
E258.00	Nondependent antidepressant type drug abuse
E258z00	Nondependent antidepressant type drug abuse NOS
E258300	Nondependent antidepressant type drug abuse in remission
E258100	Nondependent antidepressant type drug abuse, continuous

E258200	Nondependent antidepressant type drug abuse, episodic
E258000	Nondependent antidepressant type drug abuse, unspecified
E252.00	Nondependent cannabis abuse
E252z00	Nondependent cannabis abuse NOS
E252300	Nondependent cannabis abuse in remission
E252100	Nondependent cannabis abuse, continuous
E252200	Nondependent cannabis abuse, episodic
E252000	Nondependent cannabis abuse, unspecified
E256.00	Nondependent cocaine abuse
E256z00	Nondependent cocaine abuse NOS
E256300	Nondependent cocaine abuse in remission
E256100	Nondependent cocaine abuse, continuous
E256200	Nondependent cocaine abuse, episodic
E256000	Nondependent cocaine abuse, unspecified
E259.00	Nondependent mixed drug abuse
E259z00	Nondependent mixed drug abuse NOS
E259300	Nondependent mixed drug abuse in remission
E259100	Nondependent mixed drug abuse, continuous
E259200	Nondependent mixed drug abuse, episodic
E259000	Nondependent mixed drug abuse, unspecified
E25y.00	Nondependent other drug abuse
E25yz00	Nondependent other drug abuse NOS
E25y300	Nondependent other drug abuse in remission
E25y100	Nondependent other drug abuse, continuous
E25y200	Nondependent other drug abuse, episodic
E25y000	Nondependent other drug abuse, unspecified
1V55.00	Not follow drug-relate rituals
1V3A.00	Not share drug inject equipmen
1V07.00	Notified addict
222P.00	O/E - evidence of cessation of drugs
222N.00	O/E - signs of drug withdrawal
1V00.00	Occasional drug user
E240z00	Opioid drug dependence NOS
E240.00	Opioid type drug dependence
4I74.00	Oral fluid cocaine level
4I7..00	Oral fluid drug of abuse level
4I75.00	Oral fluid methadone level
SM23.00	Other chlorinated hydrocarbon solvent causing toxic effect
E02y.00	Other drug psychoses
E02yz00	Other drug psychoses NOS
SM2y.00	Other solvents causing toxic effect
SM2yz00	Other solvents causing toxic effect NOS
E247.00	Other specified drug dependence
E247z00	Other specified drug dependence NOS
E247300	Other specified drug dependence in remission
E247100	Other specified drug dependence, continuous
E247200	Other specified drug dependence, episodic
E247000	Other specified drug dependence, unspecified
E022.00	Pathological drug intoxication
Q431100	Perinatal jaundice from maternal transmission drug or toxin

13cH.00	Persistent substance misuse
9k53.11	Pharmacy attended for drug misuse
9k53.00	Pharmacy attended for drug misuse - enhanced services admin
1V02.00	Poly-drug misuser
1V63.00	Possession of drugs
L183.11	Pregnancy and drug dependence
13cF.00	Preoccupied with substance misuse
1T43.00	Previous history of amphetamine misuse
1T83.00	Previous history of cannabis misuse
1T53.00	Previous history of cocaine misuse
1T63.00	Previous history of crack cocaine misuse
1T73.00	Previous history of hallucinogen misuse
1T02.00	Previous history of heroin misuse
1T13.00	Previous history of methadone misuse
1T93.00	Previous history of solvent misuse
13cJ.00	Previously injecting drug user
1V4..00	Priority of drug activity
1V41.00	Priority to drug activities
13cE.00	Prolonged high dose use of cannabis
13c8.00	Reduced drugs misuse
8HHe.00	Referral to community drug and alcohol team
8HHL.00	Referral to community drug dependency team
8H7x.00	Referral to drug abuse counsellor
8HHd.00	Referral to drug treatment centre
8Hl5.00	Referral to drugs therapist
8Hl6.00	Referral to drugs worker
9N6b.00	Referred by drug non-statutory service
9N6a.00	Referred by drug statutory service
1V5..00	Routine drug-related activity
9K4..00	SMR25a drug misuse initial assessment form
9K5..00	SMR25b drug misuse follow up assessment form
1V52.00	Same drug routine every day
E254.13	Sedative abuse
E241.16	Sedative dependence
9N0Z.00	Seen in drug rehabilitation centre
1V61.00	Selling drugs
44vB.00	Serum dexamphetamine level
9k51.11	Shared care drug misuse treatment
9k51.00	Shared care drug misuse treatment - enhanced services admin
1V35.00	Shares drug equipment
1V38.00	Sharing drug inject equipment
13c9.11	Skin pops drugs
SL7z.11	Sleeping drug poisoning
13cA.00	Smokes drugs
1V08.00	Smokes drugs in cigarette form
1V09.00	Smokes drugs through a pipe
1V0B.00	Sniffs drugs
SM2z.00	Solvents causing toxic effect NOS
13c9.00	Subcutaneous drug user
13cM.00	Substance misuse

13c6.00	Substance misuse decreased
13c5.00	Substance misuse increased
9HC6.00	Substance misuse treatment declined
9BZ..00	Supply of drugs payment NOS
9B...00	Supply of drugs payment admin
1J11.00	Suspected abuse hard drugs
1J10.00	Suspected abuse soft drugs
1J1..00	Suspected drug abuse
1JP..00	Suspected drug overdose
1V1..00	Time devotd drug rel activties
1V23.00	Time since stopped drug misuse
1V10.00	Time spent obtaining drugs
1V12.00	Time spent recover from drugs
1V11.00	Time spent taking drugs
1V24.00	Total time drugs misused
9NN1.00	Under care of community drug team
46QO.00	Urine 3,4-methylenedioxyethamphetamine level
46QA.00	Urine cocaine
46QH.00	Urine cocaine metabolite screen
44qP.00	Urine drug metabolite screening test
46Qu.00	Urine ketamine level
46Qa.00	Urine methylamphetamine level
46Qx.00	Urine norbuprenorphine level
1V06.00	Uses drug paraphernalia
1TE..00	Uses heroin on top of substitution therapy
E241.17	Valium dependence
Q485100	Withdrawal symptoms from therapeutic use of drugs in newborn
R10B000	[D]Finding of cocaine in blood
R10B400	[D]Finding of opiate drug in blood
R10B.00	[D]Findings of drugs & oth subs not norm found in blood
ZV6D700	[V]Drug abuse counselling and surveillance
ZV57B00	[V]Drug rehabilitation
ZV11500	[V]Personal history of drug abuse by injection
U608312	[X] Adverse reaction to cocaine
U606312	[X] Adverse reaction to cocaine
U608212	[X] Adverse reaction to ketamine
U609612	[X] Adverse reaction to marijuana
U1A5600	[X]Acc pois/expos narcotic drug indust/construct area
U1AA600	[X]Acc pois/expos org solvent,halogen hydrocarb,indust area
U1ADz00	[X]Acc poison by and exposure to amphetamine - unspec places
U1AD400	[X]Acc poison exposure to amphetamine - street/highway
U1A5200	[X]Acc poison/expos narcotic drug school/pub admin area
U1AA200	[X]Acc poison/expos org solvent,halogen hydrocarb, school
U1AA400	[X]Acc poison/expos org solvent,halogen hydrocarb,in highway
U1AA700	[X]Acc poison/expos org solvent,halogen hydrocarb,on farm
U1AA100	[X]Acc poison/expos org solvent,halogen hydrocarb,res instit
U1AA300	[X]Acc poison/expos org solvent,halogen hydrocarb,sport area
U1AA500	[X]Acc poison/expos org solvent,halogen hydrocarb,trade area
U1AD300	[X]Acc poison/expos to amphetamine - sport/athletic area
U1AD600	[X]Acc poison/exposure to amphetamine - indus/construct area

U1AD100	[X]Acc poison/exposure to amphetamine - resident institut
U1AD500	[X]Acc poison/exposure to amphetamine - trade/service area
U1AD700	[X]Acc poisoning by and exposure to amphetamine - farm
U1A5300	[X]Accid pois/expos narcotic drug in sport/athletic area
U1A5y00	[X]Accid pois/expos to narcotic drug other spec place
U1A5400	[X]Accid poison/expos narcotic drug in street/highway
U1A5500	[X]Accid poison/expos narcotic drug trade/service area
U1AA000	[X]Accid poison/expos organ solvent,halogen hydrocarb, home
U1A5100	[X]Accid poison/expos to narcotic drug at res institut
U1A5z00	[X]Accid poison/expos to narcotic drug unspecif place
U1AA.00	[X]Accid poison/exposure to organ solvent,halogen hydrocarb
U1A5000	[X]Accident poison/exposure to narcotic drug at home
U1A5700	[X]Accident poison/exposure to narcotic drug on farm
U1AD000	[X]Accident poisoning by and exposure to amphetamine - home
U1A5.00	[X]Accident poisoning/exposure to narcotic drug
U1AA.11	[X]Accidental poisoning from glue solvent
Eu12211	[X]Drug addiction - cannabis
Eu14211	[X]Drug addiction - cocaine
Eu16211	[X]Drug addiction - hallucinogen
Eu11211	[X]Drug addiction - opioids
Eu18211	[X]Drug addiction - solvent
Eu19211	[X]Drug addiction NOS
Eu15211	[X]Drug addiction-other stimul
Ryu8600	[X]Finding of other drugs of addictive potential in blood
Eu11212	[X]Heroin addiction
U205600	[X]Int self pois narcotic drug indust/construct area
U20A600	[X]Int self pois org solvent,halogen hydrocarb,indust area
U205300	[X]Int self poison narcotic drug in sport/athletic area
U205y00	[X]Int self poison narcotic drug other spec place
U205200	[X]Int self poison narcotic drug school/pub admin area
U20A200	[X]Int self poison org solvent,halogen hydrocarb, school
U20A400	[X]Int self poison org solvent,halogen hydrocarb,in highway
U20A700	[X]Int self poison org solvent,halogen hydrocarb,on farm
U20A100	[X]Int self poison org solvent,halogen hydrocarb,res instit
U20A300	[X]Int self poison org solvent,halogen hydrocarb,sport area
U20A500	[X]Int self poison org solvent,halogen hydrocarb,trade area
U205000	[X]Int self poison/exposure to narcotic drug at home
U205700	[X]Int self poison/exposure to narcotic drug on farm
U205400	[X]Intent self pois narcotic drug in street/highway
U205500	[X]Intent self pois narcotic drug trade/service area
U20A000	[X]Intent self pois organ solvent,halogen hydrocarb, home
U205100	[X]Intent self poison narcotic drug at res institut
U205z00	[X]Intent self poison narcotic drug unspecif place
U205.00	[X]Intent self poison/exposure to narcotic drug
U20A.00	[X]Intentional self poison organ solvent,halogen hydrocarb
Eu12400	[X]Men & beh dis due cannabinds: withdrwl state wth delirium
Eu14700	[X]Men & beh dis due cocaine: resid & late-onset psychot dis
Eu16400	[X]Men & beh dis due hallucngns: withdrwl state wth delirium
Eu18400	[X]Men & beh dis vol solvents: withdrawal state wth delirium
Eu14400	[X]Men & behav dis due cocaine: withdrawl state wth delirium

Eu14y00	[X]Men & behav dis due to use cocaine: oth men & behav dis
Eu19.00	[X]Men & behav disorder multiple drug use/psychoactive subst
Eu1A700	[X]Men beh dis due crack cocaine: resid late-onset psych dis
Eu1A600	[X]Men behav disorders due crack cocaine: amnesic syndrome
Eu12y00	[X]Men/behav dis due to use cannabinoids: oth men/behav disd
Eu16y00	[X]Men/behav dis due to use hallucinogens: oth men/behav dis
Eu18y00	[X]Men/behav dis due to use vol solvents: oth men/behav disd
Eu14z00	[X]Ment & behav dis due use cocaine: unsp ment & behav dis
Eu1Az00	[X]Ment behav dis due crack cocaine: unsp ment and behav dis
Eu1A400	[X]Ment behav dis due crack cocaine: withdraw state delirium
Eu1A000	[X]Ment behav dis due use crack cocaine: acute intoxication
Eu1Ay00	[X]Ment behav disord due crack cocaine: other ment behav dis
Eu19z00	[X]Ment/beh dis multi drug use/oth psy sbs unsp mnt/beh dis
Eu12z00	[X]Ment/behav dis due use cannabinoids: unsp ment/behav disd
Eu16z00	[X]Ment/behav dis due use hallucinogens: unsp ment/behav dis
Eu18z00	[X]Ment/behav dis due use vol solvents: unsp ment/behav dis
Eu19500	[X]Ment/behav dis mlti drug use/oth psyc sbs: psychotc dis
Eu16000	[X]Mental & behav dis due hallucinogens: acute intoxicatn
Eu12500	[X]Mental & behav dis due to cannabinoids: psychotic disordr
Eu16500	[X]Mental & behav dis due to hallucinogens: psychotic disord
Eu14000	[X]Mental & behav dis due to use cocaine: acute intoxication
Eu14500	[X]Mental & behav dis due to use cocaine: psychotic disorder
Eu18500	[X]Mental & behav dis due to vol solvents: psychotic disordr
Eu18000	[X]Mental & behav dis due vol solvents: acute intoxication
Eu18.00	[X]Mental & behav disorders due to use of volatile solvents
Eu12300	[X]Mental and behav dis due cannabinoids: withdrawal state
Eu16300	[X]Mental and behav dis due hallucinogens: withdrawal state
Eu16200	[X]Mental and behav dis due to hallucinogens: dependence syn
Eu12600	[X]Mental and behav dis due to use cannabinoids: amnesic syn
Eu14600	[X]Mental and behav dis due to use cocaine: amnesic syndrome
Eu14200	[X]Mental and behav dis due to use cocaine: dependence syndr
Eu14300	[X]Mental and behav dis due to use cocaine: withdrawal state
Eu16100	[X]Mental and behav dis due to use hallucinogens: harmfl use
Eu14100	[X]Mental and behav dis due to use of cocaine: harmful use
Eu18600	[X]Mental and behav dis due to use vol solvents: amnesic syn
Eu18200	[X]Mental and behav dis due to vol solvents: dependence synd
Eu16600	[X]Mental and behav dis due use hallucinogens: amnesic syndr
Eu18300	[X]Mental and behav dis due vol solvents: withdrawal state
Eu18100	[X]Mental and behav dis due volatile solvents: harmful use
Eu16.00	[X]Mental and behavioural disorders due to use hallucinogens
Eu14.00	[X]Mental and behavioural disorders due to use of cocaine
Eu1A.00	[X]Mental and behavioural disorders due use of crack cocaine
Eu1A500	[X]Mental behav disord due crack cocaine: psychotic disorder
Eu1A300	[X]Mental behav disord due crack cocaine: withdrawal state
Eu1A200	[X]Mental behav disorders due use crack cocaine: depend synd
Eu1A100	[X]Mental behav disorders due use crack cocaine: harmful use
Eu12700	[X]Mnt/bh dis due cannabinds: resid & late-onset psychot dis
Eu16700	[X]Mnt/bh dis due hallucngns: resid & late-onset psychot dis
U205.11	[X]Overdose - heroin
U405300	[X]Pois/exp ?intent narcotic drug in sport/athletic area

U405200	[X]Pois/exp ?intent narcotic drug school/pub admin area
U40A200	[X]Pois/exp ?intent org solvent,halogen hydrocarb, school
U40A400	[X]Pois/exp ?intent org solvent,halogen hydrocarb,in highway
U40A700	[X]Pois/exp ?intent org solvent,halogen hydrocarb,on farm
U40A100	[X]Pois/exp ?intent org solvent,halogen hydrocarb,res instit
U40A300	[X]Pois/exp ?intent org solvent,halogen hydrocarb,sport area
U40A500	[X]Pois/exp ?intent org solvent,halogen hydrocarb,trade area
U405y00	[X]Pois/exp ?intent to narcotic drug other spec place
U405400	[X]Pois/expos ?intent narcotic drug in street/highway
U405600	[X]Pois/expos ?intent narcotic drug indust/construct area
U405500	[X]Pois/expos ?intent narcotic drug trade/service area
U40A000	[X]Pois/expos ?intent organ solvent,halogen hydrocarb, home
U405100	[X]Pois/expos ?intent to narcotic drug at res institut
U405z00	[X]Pois/expos ?intent to narcotic drug unspecif place
U40A.00	[X]Pois/exposure,?intent,to organ solvent,halogen hydrocarb
U405000	[X]Poison/exposure ?intent, to narcotic drug at home
U405700	[X]Poison/exposure ?intent, to narcotic drug on farm
U405.00	[X]Poisoning/exposure, ? intent, to narcotic drug
Eu16711	[X]Post hallucinogen perception disorder
U20A.11	[X]Self poisoning from glue solvent
SyuG100	[X]Toxic effect of other organic solvents

Appendix 6

Prescriptions for Opioid Substitution treatment

Drug code	Name of drug
85255998	BUPRENORPHINE HCl + NALOXONE HCl sublingual tab 2mg + 500micrograms
85261998	BUPRENORPHINE HCl + NALOXONE HCl sublingual tab 2mg + 500micrograms
85254998	BUPRENORPHINE HCl + NALOXONE HCl sublingual tab 8mg + 2mg
85257998	BUPRENORPHINE HCl + NALOXONE HCl sublingual tab 8mg + 2mg
99070997	BUPRENORPHINE HCl sublingual tab 200micrograms
95933998	BUPRENORPHINE HCl sublingual tab 200micrograms
98782998	BUPRENORPHINE HCl sublingual tab 2mg
92359990	BUPRENORPHINE HCl sublingual tab 2mg
92593990	BUPRENORPHINE HCl sublingual tab 2mg
92616990	BUPRENORPHINE HCl sublingual tab 2mg
88476997	BUPRENORPHINE HCl sublingual tab 2mg
99070996	BUPRENORPHINE HCl sublingual tab 400micrograms
92617990	BUPRENORPHINE HCl sublingual tab 400micrograms
92594990	BUPRENORPHINE HCl sublingual tab 400micrograms
88476998	BUPRENORPHINE HCl sublingual tab 400micrograms
92360990	BUPRENORPHINE HCl sublingual tab 400micrograms
95933996	BUPRENORPHINE HCl sublingual tab 400micrograms
92615990	BUPRENORPHINE HCl sublingual tab 8mg
92592990	BUPRENORPHINE HCl sublingual tab 8mg
98782997	BUPRENORPHINE HCl sublingual tab 8mg
88476996	BUPRENORPHINE HCl sublingual tab 8mg
92358990	BUPRENORPHINE HCl sublingual tab 8mg
96377996	DIHYDROCODEINE mr tab 120mg
96375996	DIHYDROCODEINE mr tab 120mg
96377998	DIHYDROCODEINE mr tab 60mg
96375998	DIHYDROCODEINE mr tab 60mg
96377997	DIHYDROCODEINE mr tab 90mg
96375997	DIHYDROCODEINE mr tab 90mg
97863998	LOFEXIDINE tabs 0.2mg
97831998	LOFEXIDINE tabs 0.2mg
97730992	METHADONE 100 MG SUP
96327992	METHADONE 15 MG SUP
97733992	METHADONE 20 MG SUP
97731992	METHADONE 25 MG SUP
96328992	METHADONE 30 MG SUP
97732992	METHADONE 40 MG SUP
97734992	METHADONE 5 MG/ML INJ
96709992	METHADONE 50 MG SUP
96497990	METHADONE COLOURANT FOR mix liq
92008998	METHADONE COLOURANT FOR mix liq
90004998	METHADONE DILUENT liq
90005998	METHADONE DILUENT liq
98733990	METHADONE HCl pwdr
98321990	METHADONE HCl pwdr
98303990	METHADONE HCl pwdr
98714990	METHADONE HCl pwdr

98768990	METHADONE HCl pwdr
84024998	METHADONE caps
90157998	METHADONE conc oral soln sf 10mg/ml
90195998	METHADONE conc oral soln sf 10mg/ml
90157997	METHADONE conc oral soln sf 20mg/ml
90195997	METHADONE conc oral soln sf 20mg/ml
84021998	METHADONE impregnatd cigarette
84022998	METHADONE inj
93260990	METHADONE inj 10mg/1ml
85569998	METHADONE inj 10mg/1ml
85578998	METHADONE inj 10mg/1ml
93264990	METHADONE inj 10mg/1ml
93256990	METHADONE inj 10mg/1ml
93252990	METHADONE inj 10mg/1ml
85573998	METHADONE inj 10mg/1ml
99765990	METHADONE inj 10mg/ml
95878998	METHADONE inj 10mg/ml
92568998	METHADONE inj 10mg/ml
97871990	METHADONE inj 10mg/ml
95879997	METHADONE inj 10mg/ml
95286990	METHADONE inj 10mg/ml
96584990	METHADONE inj 10mg/ml
85572998	METHADONE inj 20mg/2ml
93259990	METHADONE inj 20mg/2ml
93251990	METHADONE inj 20mg/2ml
93263990	METHADONE inj 20mg/2ml
93255990	METHADONE inj 20mg/2ml
85568998	METHADONE inj 20mg/2ml
85577998	METHADONE inj 20mg/2ml
85571998	METHADONE inj 35mg/3.5ml
93254990	METHADONE inj 35mg/3.5ml
93250990	METHADONE inj 35mg/3.5ml
93258990	METHADONE inj 35mg/3.5ml
85567998	METHADONE inj 35mg/3.5ml
85576998	METHADONE inj 35mg/3.5ml
93262990	METHADONE inj 35mg/3.5ml
95879996	METHADONE inj 35mg/ml
87159998	METHADONE inj 50mg/1ml
91544998	METHADONE inj 50mg/1ml
93398990	METHADONE inj 50mg/1ml
87710998	METHADONE inj 50mg/1ml
87160998	METHADONE inj 50mg/2ml
87712998	METHADONE inj 50mg/2ml
87711998	METHADONE inj 50mg/2ml
93397990	METHADONE inj 50mg/2ml
93257990	METHADONE inj 50mg/5ml
93249990	METHADONE inj 50mg/5ml
93261990	METHADONE inj 50mg/5ml
85575998	METHADONE inj 50mg/5ml
85566998	METHADONE inj 50mg/5ml

93253990	METHADONE inj 50mg/5ml
85570998	METHADONE inj 50mg/5ml
98080998	METHADONE linc 2mg/5ml
99512989	METHADONE linc 2mg/5ml
98492990	METHADONE linc 2mg/5ml
84301998	METHADONE oral liq
88038997	METHADONE oral soln 1mg/ml
96882990	METHADONE oral soln 1mg/ml
97685990	METHADONE oral soln 1mg/ml
90944998	METHADONE oral soln 1mg/ml
89287998	METHADONE oral soln 1mg/ml
98491990	METHADONE oral soln 1mg/ml
96915990	METHADONE oral soln 1mg/ml
88045998	METHADONE oral soln 1mg/ml
84426998	METHADONE oral soln 1mg/ml
93503998	METHADONE oral soln 1mg/ml
96635990	METHADONE oral soln 1mg/ml
99512990	METHADONE oral soln 1mg/ml
96619990	METHADONE oral soln 1mg/ml
84424998	METHADONE oral soln 5mg/ml
84425998	METHADONE oral soln 5mg/ml
99512988	METHADONE sf oral soln 1mg/ml
88038998	METHADONE sf oral soln 1mg/ml
95878996	METHADONE sf oral soln 1mg/ml
96811990	METHADONE sf oral soln 1mg/ml
88749998	METHADONE sf oral soln 1mg/ml
93503997	METHADONE sf oral soln 1mg/ml
95049990	METHADONE sf oral soln 1mg/ml
95268990	METHADONE sf oral soln 1mg/ml
96617990	METHADONE sf oral soln 1mg/ml
84023998	METHADONE sup
84025998	METHADONE tabs
95878997	METHADONE tabs 5mg
95879998	METHADONE tabs 5mg
85256998	NALOXONE HCl + BUPRENORPHINE HCl sublingual tab 2mg + 8mg
85258998	NALOXONE HCl + BUPRENORPHINE HCl sublingual tab 500micrograms + 2mg
84724998	NALTREXONE HCl tabs 500 micrograms
94595998	NALTREXONE HCl tabs 50mg
85122998	NALTREXONE HCl tabs 50mg
94594998	NALTREXONE HCl tabs 50mg

Appendix 7

Read codes for Opioid substitution treatment

Read code	Description
13r3.00	Abstinent from drug misuse on maintenance replacement
13r4.00	Abstinent from drug misuse when receiving blocking therapy
1T1..00	H/O methadone misuse
1T10.00	H/O daily methadone misuse
1T11.00	H/O weekly methadone misuse
1T12.00	H/O infrequent methadone misuse
1T13.00	Previous history of methadone misuse
44u1.00	Serum methadone level
44uK.00	Plasma methadone level
44v8.00	Serum buprenorphine level
44v9.00	Plasma buprenorphine level
46QB.00	Urine methadone
46Qf.00	Urine methadone metabolite level
46Qr.00	Urine buprenorphine level
46Qx.00	Urine norbuprenorphine level
4I75.00	Oral fluid methadone level
8B23.00	Drug addiction therapy
8B23.11	Drug addictn therap-methadone
8B23.13	Drug dependence therapy
8B2M.00	Buprenorphine maintenance therapy
8B2N.00	Drug addiction detoxification therapy - methadone
8B2P.00	Drug addiction maintenance therapy - methadone
8B2Q.00	Drug addiction maintenance therapy - buprenorphine
8B2R.00	Drug addiction detoxification therapy - buprenorphine
8BE0.00	Reinduction to methadone maintenance therapy
8BE1.00	Reinduction to buprenorphine maintenance therapy
9k51.00	Shared care drug misuse treatment - enhanced services admin
9k51.11	Shared care drug misuse treatment
9k52.00	Drug misus trt prim care - ESA
9k52.11	Drug misuse treatment in primary care
9k53.00	Pharmacy attended for drug misuse - enhanced services admin
9k53.11	Pharmacy attended for drug misuse
E240.12	Methadone dependence
SL50200	Methadone poisoning
T801.00	Accidental poisoning by methadone
Z192.00	Dependent drug detoxification
Z192100	Drug withdrawal regime
Z192114	Drug detoxification
Z1Q6.11	Drug substitution
Z1Q6100	Dose equivalent drug substitution
Z1Q6200	Methadone maintenance
Z1Q6211	Low threshold methadone prescribing
Z1Q6212	Methadone therapy

Appendix 8.1

Ethics approval from UCL Ethics Committee

UCL RESEARCH ETHICS COMMITTEE
RADUATE SCHOOL OFFICE

Dr Fiona Stevenson

Research Department of Primary Care and Population Health

UCL

4 June 2014

Dear Dr Stevenson

Notification of Ethical Approval Project ID: 5664/001: What factors determine recording of illicit drug use in primary care? A qualitative study

I am pleased to confirm that in my capacity as Chair of the UCL Research Ethics Committee I have approved your project for the duration of the study i.e. **until June 2015.**

Approval is subject to the following conditions:

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

The form identified above can be accessed by logging on to the ethics website homepage: http://www.grad.ucl.ac.uk/ethics/ and clicking on the button marked 'Key Responsibilities of the Researcher Following Approval'.

2. It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. Both non-serious and serious adverse events must be reported.

Reporting Non-Serious Adverse Events

For non-serious adverse events you will need to inform Helen Dougal, Ethics Committee Administrator (ethics@ucl.ac.uk), within ten days of an adverse incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Chair or ViceChair of the Ethics Committee will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

Reporting Serious Adverse Events

The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator immediately the incident occurs. Where the adverse incident is unexpected and serious, the Chair or ViceChair will decide whether the study should be terminated pending the opinion of an independent expert. The adverse event will be considered at the next Committee meeting and a decision will be made on the need to change the information leaflet and/or study protocol.

On completion of the research you must submit a brief report (a maximum of two sides of A4) of your findings/concluding comments to the Committee, which includes in particular issues relating to the ethical implications of the research. With best wishes for the research.

Yours sincerely

Professor John Foreman
Chair of the UCL Research Ethics Committee

Cc: Hilary Davies, Applicant

Professor Irwin Nazareth, Head of Department UCL Research Ethics Committee, c/o The Graduate School, North Cloisters, Wilkins Building University College London Gower Street London WC1E 6BT Tel: +44 (0)20 7679 7844 Fax: +44 (0)20 7679 7043 ethics@ucl.ac.uk www.ucl.ac.uk/gradschool

Appendix 8.2

Approval of amendment to ethics application

Amendment Approval Request Form

1	**Project ID Number:** ~~5644/001~~ 5664/001	**Name and Address of Principal Investigator:** FIONA STEVENSON RESEARCH DEPARTMENT OF PRIMARY CARE AND POPULATION HEALTH UPPER THIRD FLOOR UCL MEDICAL SCHOOL, ROYAL FREE ROWLAND HILL STREET NW3 2PF
2	**Project Title:** What factors determine recording of illicit drug use in primary care: A qualitative study	
3	**Type of Amendment/s (tick as appropriate)** ☐ Research procedure/protocol (including research instruments) ☒ Participant group ☐ Sponsorship/collaborators ☐ Extension to approval needed (extensions are given for one year) ☐ Information Sheet/s ☐ Consent form/s ☐ Other recruitment documents ☐ Principal researcher/medical supervisor* ☒ Other * *Additions to the research team other than the principal researcher, student supervisor and medical supervisor do not need to be submitted as amendments but a complete list should be available upon request.	
4	**Justification** (give the reasons why the amendment/s are needed) 1) Our previous proposal stated that we would be recruiting GPs from the London area. We wish to also include GPs from across England. The reason for this proposed change is that patients attending GP practices in the London area are more transient than in practices across England. We would like to ensure that we include GPs who have been treating patients who use illicit drugs for a prolonged length of time. 2) Our previous proposal stated that we would be giving £20 amazon voucher to each GP who participated in the study. We would like to increase this to £30 as we would like to show our appreciation of their time.	
5	**Details of Amendments** (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation) 1) We have stated in the proposal that we will be recruiting GPs from the London area. We would like to include GPs from across England. This has been changed in the UCL ethics application (attached) in the following sections: a) Section B2, page 5 b) Section B3, page 6 c) Information sheet, page 11 2) Whave previously stated in the proposal that we would be giving the participants £20, this has been changed to £30 in the following sections: a) Section C4, page 8 b) Information sheet, page 11	
6	**Ethical Considerations** (insert details of any ethical issues raised by the proposed amendment/s) N/A	

Declaration (to be signed by the Principal Researcher)

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendments to be implemented.
- For student projects I confirm that my supervisor has approved my proposed modifications.

Signature: [redacted]

Date: 4/6/14

FOR OFFICE USE ONLY:

Amendments to the proposed protocol have been approved by the Research Ethics Committee.

Signature of the REC Chair, Professor John Foreman [redacted]

Date: 17/6/2014

Appendix 9
Information Sheet for participants

Information Sheet:

Title of project: Which factors determine recording of illicit drug use in primary care: A qualitative study

You will be given a copy of this information sheet.

This study has been approved by the UCL Research Ethics Committee (Project ID Number): 5644/100

Name	Hilary Davies
Work Address	Research department of Primary Care and Population Health
	Upper Third Floor
	UCL medical school, Royal Free
	Rowland Hill Street
	NW3 2PF
Contact Details	02077940500 (extension 31033)

We would like to invite you to participate in this research project:.

Details of Study:

Illicit drug use is a public-health problem with serious health impacts (Madgula et al., 2011a). In 2009, between 149 and 271 million people had used an illicit drug globally (United Nations Office on Drugs and Crime, 2014). The United Kingdom (UK) has one of the highest prevalence of illicit drug use in Europe (European Monitoring Centre for Drugs and Drug Addiction, 2013). According to the Crime survey for England and Wales (CSEW), there has been a reduction in reported illicit drug use from 11% in 2001 to 8.2% in 2012/13. Men consistently have higher recording of illicit drug use compared to women, however females of childbearing age contribute to the majority of illicit drug use recorded in females (Office for National Statistics, 2013b). Illicit drug use during pregnancy not only impacts the mother, but also the health of the foetus and developing child (5). Accurately estimating the incidence of illicit drug use in pregnancy is difficult: international estimates range from 3-5%, but these figures mask the complexity of accessing this patient group(Gyarmathy *et al*., 2009; O'Donnell *et al*., 2009; van Gelder *et al.*, 2009).

We recently (2013/14) conducted a quantitative study to further investigate recording by GPs of illicit drug use

in primary care in England and Wales. We used another large primary care database, The Health

Improvement Network (THIN) (9, 10). In order to increase our understanding of primary care recording of illicit drug use, we first examined the whole population and will subsequently focus on females and pregnant women. To date, we identified 33,508 (22 622 males and 10 886 females) with a first recording of illicit drug use and 3412 women who have a recording for one or more pregnancies and at least one recording for illicit drug use. Future work will include examining the timing of the recording in relation to the gestation time of the identified women.

It is evident from our quantitative studies that GPs are recording illicit drug use in the total population and during pregnancy. It is however, still unclear as to why and how GPs record illicit drug use and why they may use specific methods for different patients. The main strength of using a large primary care dataset is that it provides a large amount of data from real life primary care. However, meaning and understanding need to be incorporated into large datasets (12) .This can be done by using qualitative data to help understand the methods, classification and the circumstance for recording (Pope *et al*., 2014).

This qualitative study therefore aims to complement existing data by exploring the factors which determine recording by GPs of illicit drug use in primary care.

We are recruiting GPs from the UK who currently have patients who use illicit drugs (street drugs or any opiate based drugs) in their practice. If you agree to take part in our study, the qualitative interview will take approximately 30 minutes. The interview can take place at your practice and at a time suitable to yourself.

We can send you a final report of the findings after completion of the study. If it would be beneficial to your GP practice, we would be happy to present the findings at a practice meeting.

All data will be collected and stored in accordance with the Data Protection Act 1998. You will be asked keep the identity of the patients that you discuss during the interview anonymous. Your identity and the identity of your practice or health centre will be kept confidential. A pseudonym will be assigned to you and your practice during transcription of the interview. All recordings will be saved on an encrypted audio file (using TrueCrypt software) and subsequently erased from the dictaphone. Once the interviews have been transcribed, they will be saved on an encrypted word file. After completion of the study, the files will be archived and kept on the UCL secure server for 2 years. After this, the files will be sent and archived to UCL's records office (in accordance with UCL policy). The research team will need to apply for access to use these files. No one else will have access to these files.

Please discuss the information above with others if you wish or ask us if there is anything that is not clear or if you would like more information.

It is up to you to decide whether to take part or not; choosing not to take part will not disadvantage you in any way. If you do decide to take part you are still free to withdraw at any time and without giving a reason.

If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will be given a £30 amazon voucher as a gesture of our appreciation for your valuable time.

References:

1. Madgula RM, Groshkova T, Mayet S. Illicit drug use in pregnancy: effects and management. Expert Rev Obstet Gynecol. 2011 Mar;6(2):179–92.

2. European Monitoring Centre for Drugs and Drug Addiction. Information on drugs and drug addiction in Europe [Internet]. [cited 2013 Oct 7]. Available from: http://www.emcdda.europa.eu/

3. Office for National Statistics. Crime Survey for England and Wales, 2013. [Internet]. [cited 2013 Dec 19]. Available from: http://www.ons.gov.uk/ons/dcp171778_318761.pdf

4. Public Health England. National Treatment Agency for Substance Misuse - Homepage [Internet]. [cited 2013 Oct 7]. Available from: http://www.nta.nhs.uk/

5. O'Donnell M, Nassar N, Leonard H, Hagan R, Mathews R, Patterson Y, et al. Increasing prevalence of neonatal withdrawal syndrome: population study of maternal factors and child protection involvement. Pediatrics. 2009 Apr;123(4):e614–621.

6. Gyarmathy VA, Giraudon I, Hedrich D, Montanari L, Guarita B, Wiessing L. Drug use and pregnancy - challenges for public health. Euro Surveill Bull Eur Sur Mal Transm Eur Commun Dis Bull. 2009 Mar 5;14(9):33–6.

7. Guthrie B, Saultz JW, Freeman GK, Haggerty JL. Continuity of care matters. BMJ. 2008 Aug 7;337(aug07 1):a867–a867.

8. Royal College of Obstetricians and Gynaecologists. Pregnancy and complex social factors: A model for service provision for pregnant women with complex social factors [Internet]. 2010. Available from: http://www.nice.org.uk/nicemedia/live/13167/50861/50861.pdf

9. Lis Y, Mann RD. The VAMP Research mulit-purpose database in the U.K. J Clin Epidemiol. 1995;48(3):431–43.

10. Chisholm J. The Read clinical classification. BMJ. 1990 Apr 28;300(6732):1092.

12. Pope C, Halford S, Tinati R, Weal M. What's the big fuss about "big data"? J Health Serv Res Policy. 2014 Apr 1;19(2):67–8.

Appendix 10

Final topic guide

Title of project

What are the factors determining the recording of illicit drug use in primary care: A qualitative study.

Fact Sheet

Name of interviewer:

Name of participant:

Date of interview:

Time of start of interview:

Time of end of interview:

GP Practice or Health Care Centre:

Any other comments:

Interview Schedule:

Section 1: Introduction for participant (5 minutes)

- Confirm consent
- Reconfirm permission from the participant that the interview will be audio recorded
- Record name of participant, interviewer, time, date and place verbally (this information will also be recorded on the fact sheet)
- Explain aims of the study
- Clarify the structure of the interview
- Clarify the participant of the length of the interview (up to 30 minutes)
- Advise participant that there will be an opportunity to approve the transcript
- Confirm that the interview can be stopped at any time and the participant can withdraw at any time without reason and without implication.
- The identity of the participant will be confidential
- The data will be anonymised
- Ask the participant if they want any clarifications before stating the interview.

Section 2: Semi-structured questions:

1) I understand that you see patients who use illicit drugs, in the last month can you think of an example?

   Prompt:
   Would you enter information about their illicit drug use on the system?
   Prompt:
   If yes, how would you do this,
   If no, what are your reasons for not recording?

2) If you use Read codes, which ones would you use?

   Prompt: does your practice have a template

3) If you use freetext, would you also use Read codes?

   Do you find the software easy to use
   Do you find Read codes easy to use
4) Can you think of an example of a patient who has asked you not to record their illicit drug use?

   Prompt:
   If yes, what did you do in this situation?

5) Can you think of an example of a patient who you suspect is using illicit drugs, but does not disclose the information

   Prompt:
   :
   If yes, what did you do in this situation?

6) Do you find that you saw more or fewer patients using illicit drugs in the last 10 years

   Prompt:
   t: treatment more in the community
7) Do you find that you see more patients who use illicit drugs at certain times of the year?

   Prompt:
   :e.g. after big events such as festivals
8) Can you think of a patient who was pregnant and using illicit drugs during her pregnancy?

   Prompt:
   Did you record this patient in the system?
   Prompt:
   If yes, how would you do this?

If no, what are your reasons for not recording?

9) Can you think of an example of a patient who is pregnant, using illicit drugs during pregnancy and who has asked you not to record?

Prompt:
If yes, what did you do in this situation?

10) Can you think of an example of a patient who is pregnant and who you suspect is using illicit drugs, but does not disclose the information

Prompt:
If yes, what did you do in this situation?

11) If a patient has disclosed that she is using illicit drugs during pregnancy, did you refer her to specialized services?

Prompt:
If yes, which services?
If no, what were your reasons?
If no, what were your reasons for not referring?
10) If you know a women has used illicit drugs during pregnancy, do you look for neonatal abstinence syndrome in her discharge records?
Prompt:
If yes, do you record this? How?
If yes, do you record this in the mother or the baby's records? How?

Field notes for interviewer:

Appendix 11

Publications from thesis

1) Davies HR, Nazareth I, Petersen I (2015) Trends of People Using Drugs and Opioid Substitution Treatment Recorded in England and Wales General Practice (1994-2012). *PLoS ONE* 10(4): e0122626. doi:10.1371/journal.pone.0122626

2) Davies HR, Gilbert R, Johnson K, Petersen I, Nazareth I, O'Donnell M, Guttmann G, Gonzalez-Izquierdo A. Neonatal drug withdrawal syndrome: cross-country comparison using hospital administrative data in England, the USA, Western Australia and Ontario, Canada. *Arch Dis Child* Foetal Neonatal Ed 2015;0:F1–F5. doi:10.1136/archdischild-2015-308948