

**Leg ulceration in young people who inject drugs;
causative factors, and how harm may be reduced
- a mixed methods approach.**

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Abstract

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Abstract

The thesis explores chronic leg ulceration experienced by young people who inject drugs (PWID).

The applied health research study, in two phases, used a sequential explanatory mixed methods design. Phase 1 involved a survey of 200 people who injected drugs to investigate the prevalence of skin problems and leg ulceration, together with the identification of risk factors for ulceration.

Phase 2 involved a series of fifteen qualitative semi-structured interviews that explored the results relating to risk factors with a sample of PWID who had experienced leg ulceration, and investigated participants' perceptions of appropriate harm reduction methods.

Main findings

There were three research questions in this study:

1) What is the extent of skin problems and chronic leg ulceration in young people who inject drugs?

The study identified a high prevalence of leg ulceration as 15%. 60% of the sample had experienced a skin problem. Each reported skin complication is clearly defined.

2) What causes chronic leg ulceration in young people who inject drugs?

Leg ulceration experienced by PWID in this study was directly linked to deep vein thrombosis (DVT), as well as injecting in the groin and the leg. DVT was strongly associated with groin and leg injecting. The acceptance amongst injectors of the groin and leg as a site of choice has occurred with a lack of awareness of the long-term consequences of damage to the limb.

3) What are appropriate harm reduction measures in young people who inject drugs?

Harm reduction methods related to the development of leg ulceration have been absent across schools and drug services. Training for healthcare workers which enables them

to identify risk factors should be developed, and harm reduction information related to leg ulceration should be included in drug education within schools, and instigated within drugs services.

This applied health research has led to a number of practice-focused recommendations surrounding clinical care including early detection of venous insufficiency and accessible services to prevent, assess, and treat venous disease in PWID.

The original contribution to knowledge is three-fold:

1. Leg ulcers have been found to be highly prevalent in young people who inject drugs.
2. Ulceration is predominantly caused by venous thrombosis due to injecting in the legs or groin.
3. Harm reduction related to the development of venous disease has lacked impact and effect.

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Chapter 1

Introduction

This chapter provides the foundation for the thesis on leg ulceration in young people who inject drugs. It demonstrates the personal and professional motivation for the study together with an introduction to drug use and leg ulceration. The chapter finishes with an overview of the structure and content of the thesis.

1.1 Personal interest

I have worked as a nurse for almost thirty years, latterly as a ‘tissue viability nurse specialist’ concerned with preventing and managing wounds, with a specific interest in leg ulceration. My interest began when I was running a leg ulcer course and a student submitted an assignment, involving a case study of a drug injector. At that time (1998) there was very little published literature relating to leg ulceration in people who inject drugs (PWID), and I wondered what the aetiological picture was.

Later, when I moved from a full-time practice role to academia, I sought a sessional nursing role to maintain clinical expertise. I was approached to help with the Glasgow ‘Big Issue Foundation’ project (an organisation which works with homeless people), as they had set up a physical health service and had been encountering increasing numbers of drug injectors with large, malodourous, and chronic wounds which they lacked expertise to deal with. I helped set up a wound clinic and found that PWID reported difficulty in accessing suitable care, and they seemed to be provided with simple dressings rather than a more appropriate assessment and management strategy which could achieve quicker healing. My curiosity developed, and it seemed that recommended clinical guidelines for the management of leg ulceration were based on available evidence relating to elderly people and did not necessarily apply to the needs of this ‘new’ younger population of leg ulcer sufferers (Male et al, 2007).

The service that I set up with the Big Issue won the British Journal of Nursing Compression Award in 2002 (Bartlett, 2002; Finnie¹ and Nicolson, 2002a; May, 2002). Subsequently a physical health team was set up by NHS Glasgow and the Big Issue service was absorbed into the NHS service. I continued to work within the NHS team, and also set up a new service within the Harm Reduction Team in NHS Lothian, but my questions surrounding leg ulceration in drug injectors persisted.

Personal observation and anecdotal evidence from colleagues suggested that chronic leg ulceration had become a significant problem in drug injectors (Finnie and Nicolson, 2002b; Goodall, 2010), but the specific causes were unclear. Leg ulceration is traditionally thought to be a disease of old age (Beynon et al, 2010) and where it occurred in younger people (aged under 50) it tended to be in men who were overweight, with a history of DVT and with long bone fracture (MacKenzie et al, 2003). This was not the case for the drug injectors I saw clinically. Most were underweight, and had sustained no fractures, but some had a history of thrombosis. I was puzzled about these chronic painful ulcers and the drug injectors themselves were also unable to explain what caused their ulceration.

1.2 Context

It is estimated that in Scotland alone there are almost 60,000 problem drug users (Information Services Division (ISD), 2011), and of these around 50% may be injecting, and mainly using heroin (ISD, 2012). Problem drug use is defined as ‘the problematic use of opiates (including illicit and prescribed methadone use) and/or the problematic use of benzodiazepines and implies routine and prolonged use as opposed to recreational and occasional drug use’ (ISD, 2014).

PWID are at increased risk from systemic disease, both acute and chronic, including dermatological, cardiac and respiratory diseases, diabetes, and blood-borne viruses as

¹ Alison Coull was formerly known as Alison Finnie

well as localised problems at injecting sites (Cortimiglia-Bish and Brazinsky, 1998; Saunders et al, 2004; McClelland, 2006; Keaney et al, 2011; Nambiar et al, 2014). In one of the earliest retrieved reports, in the period 1938 – 1947, Hussey and Katz cite many medical and surgical complications from injecting including abscesses of the skin, thrombophlebitis, septicaemia, endocarditis, tetanus and malaria (Hussey and Katz, 1950). Subsequently other authors have listed additional conditions of pulmonary embolism, cellulitis, bacteraemia and osteomyelitis (Louria et al, 1967; Holzman and Bishko, 1971; Levine et al, 1986; Thomson and Lynn, 2003).

Health of PWID is regarded as poor. Self-perceived health in a sample of 990 individual Scottish problem drug users was compared with a sample from the UK general population and was found to be consistently worse. Those who injected had worse health than those who did not, and men had significantly better health than women (Neale, 2004a).

Marks et al (2013) investigated the reasons for admission and costs associated with injecting drug use in a London hospital, and found that bacterial and viral infections were largely responsible for the mortality and morbidity of injectors presenting to hospital. They estimated the cost to be £77 million per annum to the NHS.

Health care professionals are increasingly encountering injection-induced skin problems in PWID such as wounds, infections, cellulitis, burns, abscesses and leg ulcers in their practice (Finnie and Nicolson, 2002b; Guild, 2008). Traditionally, skin and wound care is a nursing role and these rising numbers impact directly on the workload of many community, acute and specialist nurses.

1.3 Prevalence of skin problems

Before this study, the incidence and prevalence of skin problems in drug injectors was not known; however, skin disease was known to be a frequent cause of morbidity in the homeless population (Stratigos et al, 1999), many of whom were injectors (Hammersley and Pearl, 1996; Galea and Vlahov, 2002). Identification of the incidence

and prevalence of these problems is challenging, due to the often chaotic nature of a drug injector's life which can be compounded by unemployment, homelessness, and criminal behaviour which may inhibit appropriate access to health care (Taylor and Kearney, 2005).

1.4 Skin breakdown

Skin breakdown may indicate underlying disease processes such as malnutrition, vascular disease, or infective processes (Bellis et al, 2001). Drug injectors have to breach the skin surface in order to achieve drug entry. Numerous skin changes may then occur, such as skin tracks, urticaria, pruritis, abscesses, necrotic changes, burns and other changes associated with venous disease (Pieper, 1996a).

Skin problems may be a result of injecting behaviour, the quality, solvency, and cleanliness of the drug, the equipment, and the environment (Finnie and Nicolson, 2002b). Long-term drug-injecting can result in sclerosis and thrombosis of most superficial veins and if venous access is no longer possible users may resort to skin or muscle 'popping', where injecting occurs directly through the skin surface and the drug is absorbed subcutaneously or from muscle. This approach can be more risky, and may lead to abscess formation and infection (Binswanger et al, 2000; Finnie and Nicolson, 2002b).

It was unclear if there were factors contributing to infective processes such as abscesses becoming chronic ulcers especially in the lower legs as numerous micro-organisms have been identified in wounds of PWID (Tuazon et al, 1974; McGuigan et al, 2002). The physical preparation of heroin by injectors involves heating or boiling with water to dissolve it (Ponton and Scott, 2004). The duration of heating may not eliminate spores or other micro-organisms and it is possible that the heating process may activate spores, enhancing the infective process. In the outbreak of clostridia novyi in Glasgow in 2000, 23 drug users died and skin or muscle popping was strongly associated with disease (McGuigan et al, 2002; Taylor et al, 2005). All cases had soft tissue

inflammation at or near an injection site. It is apparent from the subsequent report that there still is a considerable amount that is unknown about the causative factors, and that skin changes were the initial indicator of fatal disease. Since then there have been other cases of serious systemic disease in PWID – of botulism and anthrax (Powell et al, 2011; Powell, 2011a). All of these initially presented with lesions of the skin which emphasised the importance of wounds to systemic health. The opportunistic factors that lead to skin breakdown in one drug injector and not another but with similar injecting practices are unclear. There are a number of other factors, such as lack of sterility, skin cleansing, injecting technique and adulterants to consider in skin breakdown in this population (Hughes, 2001).

A preliminary search and initial literature review conducted in 2006 and repeated in 2015 revealed a considerable number of publications about drug injecting, infections relating to drug use, and harm reduction methods with PWID. However, there were no empirical studies relating to identification of incidence and prevalence of skin problems and leg ulceration, causal or risk factors, prevention of skin problems, appropriate treatment methods for wounds in PWID or studies relating to improving outcomes for drug injectors with skin problems. There was also a dearth of literature about the short and long-term implications of skin problems for PWID.

1.5 Leg ulceration

Possibly the most significant skin problem in relatively young individuals who are, or have been, drug injectors, is chronic leg ulceration, which impacts on patients' health-related quality of life. Major issues include pain, exudate, social isolation, sleep deficits, depression, and mobility. Costs of treatment are high and there is a considerable burden on both sufferers and society (Franks et al, 2006; Palfreyman, 2008; Shiman et al, 2009). Ulcers can be large open wounds which are associated with greater illness-induced difficulties within the home environment, such as odour and exudate, poorer quality of life and greater psychological distress (Pieper et al, 2000).

Injecting affects the veins causing phlebitis, and clots occur frequently as well as signs of chronic venous insufficiency (CVI) (Pieper and Templin, 2001; Pieper and Templin, 2003).

Many injectors report periods of hospitalisation due to deep vein thrombosis but the causative factors remain unclear, and lasting damage such as post-thrombotic syndrome may result (Pieper and Templin, 2001). It is known that venous disease can lead to ulceration which, in the elderly population, tends to become chronic and recur. The progression of venous disease in young people is unknown, but it is also likely to be long-lasting and costly in terms of managing a long-term condition, pain and suffering (Pieper et al, 1998). It is possible that current young drug injectors may become middle-aged or elderly patients in leg ulcer clinics of the future.

Whilst a number of possibilities contributing to the development of chronic wounds have been outlined, the mechanisms or opportunistic factors that contribute to these skin problems remained unclear. It is puzzling that some wounds become chronic, especially on the legs, and remain long after any drug injecting has ceased (Pieper, 1996a; Finnie and Nicolson, 2002b; Beynon et al, 2010). It is clear that injecting practices vary, and that these could be linked to the development of skin complications. By exploring the current and past history of drug use with drug injectors themselves, patterns may be identified that provide a greater understanding of the causative factors for skin breakdown. If appropriate prevention and treatment methods are to be established, then an understanding of these factors is absolutely crucial.

As drug injecting increases, these problems are only likely to become more common, and investigation before the problem becomes any greater is imperative.

1.6 Objectives

The objectives for this study were therefore:

- To define the range and the extent of skin problems within a representative sample of young drug injectors.
- To determine the extent of chronic leg ulceration in young PWID linked to the above.
- To detail potential causal / risk factors in the development of chronic leg ulceration in young PWID.
- To analyse potential causal / risk factors in the development of chronic leg ulceration in young PWID.
- To identify appropriate harm reduction measures relevant to service delivery and treatment in Scotland and beyond.

1.7 Overview of thesis

The thesis comprises seven chapters. Following on from the introductory chapter, Chapter 2 contains a review of the literature relating to leg ulceration in PWID, aetiology and related risk factors. It highlights the need for better definition of skin problems, and identifies a significant gap in the literature related to cause and to harm reduction, concluding with three research questions.

Chapter 3 explores the philosophical approach and the potential methods that could be used to answer the research questions. It identifies a sequential explanatory mixed methods study and justifies this as the best approach for this applied health research. A quantitative survey of 200 current and past injectors to identify the extent of the problem and the potential risk factors is outlined (Phase 1), followed by a qualitative approach of interviews conducted with people who have injected drugs and have experienced leg ulceration (Phase 2). The statistical analysis is described together with framework analysis for the second phase.

The results of the survey are presented in Chapter 4 with the identification of the prevalence of skin problems and leg ulceration in the sample as well as the potential risk and aetiological factors which were further explored in Phase 2.

The Phase 2 findings in Chapter 5 detail the analysis and emergent themes from interviews with drug injectors who have had leg ulceration.

The synthesis of the two phases is presented in Chapter 6 together with a discussion of the results, including limitations and reflections on the study. The penultimate chapter identifies the answers to each research question and links this to literature that emerged during the course of the study.

Finally, Chapter 7 presents the conclusion to the thesis with recommendations for future research and practice.

1.8 Terminology

The term commonly used for drug injectors at the beginning of the study was ‘intravenous drug user’ (IVDU) however, the current nomenclature is now ‘people who inject drugs’ (PWID). Where appropriate, the new term has been applied within the thesis. A glossary of terms and abbreviations is provided in Appendix 1.

1.9 Early dissemination of results – publications from this study.

The work presented in this thesis has led to two publications:

Coull, A.F. Atherton, I. Taylor, A. and Watterson, A.E. (2014) Prevalence of skin problems and leg ulceration in a sample of young injecting drug users. *Harm Reduction Journal* 11:22 DOI: 10.1186/1477-7517-11-22

Coull, A. (2015) The role of intravenous drug use in venous leg ulceration. *British Journal of Nursing* 24: S17

Chapter summary

The purpose of this study is to identify the prevalence of leg ulceration in a sample of young PWID, and then explore the risk factors that might lead to leg ulceration.

Following that, harm reduction methods which may prevent leg ulceration in the first place will be identified which also inform practice and policy.

Chapter 2

Literature Review

Introduction

This chapter informs the study by exploring the literature related to the research objectives outlined in Chapter 1. It seeks to find evidence relating to the prevalence of leg ulceration in people who inject drugs (PWID); to discover potential aetiology and risk factors, as well as key contextual factors of substances and the environment which may contribute to ulceration together with any specific harm reduction literature related to reducing or preventing skin breakdown. The review identifies gaps in knowledge that led to the development of research questions.

2.1 Literature search

The literature was searched widely at the commencement of the study in March 2006, with the intention of undertaking a systematic review. Initial searching around the topic produced frustratingly little relevant literature, and no specific empirical work, so a gap in the evidence was quickly confirmed.

The initial searches were then widened using broader subject headings (Table 1). No papers were found that provided a prevalence of leg ulceration in PWID. There was literature on injecting risk and potential causative factors and some related to injecting harms however, this did not link directly to leg ulceration or venous disease, and no empirical studies were found. This made a meaningful systematic review impossible (Bambra, 2011).

<p>Databases searched:</p> <p>Pubmed / Medline; Cinahl; Health Source</p>
<p>Hand searching of non-indexed sources:</p> <p>Phlebology journal; Wounds UK journal; Leg Ulcer Forum journal; EWMA conferences; Exchange Supplies resources; Lifeline resources; ISD sources</p>
<p>Authors searched:</p> <p>Butcher, Darke, Del Giudice, Frischer, Goldberg, Hay, Hope, Hunt, McKegane, Neale, Pieper, Rhodes, Robertson, Scott, Strang, Taylor, Whittaker</p>
<p>Terms searched: words and categories within titles, abstracts, key words and phrases:</p> <p>leg ulcer*, inject*, 'skin', 'skin disease*', 'substance use and related disorders', 'substance abuse', 'intravenous drug use', 'drug injecting', 'arterial occlusion', 'infection', 'bacterial infection*', 'vascular complications', 'varicose veins', 'vasculitis', 'vein insufficiency', 'phlebitis', 'embolism and thrombosis', 'wound care', 'wounds and injuries', 'harm reduction'</p>
<p>Years searched 1953 – 2015; all available languages</p>
<p>Results: empirical studies</p> <p>Prevalence of leg ulceration in PWID : 0</p> <p>Risk factors for leg ulceration in PWID : 0</p> <p>Harm reduction for leg ulceration : 0</p>

Table 1 Literature search strategy

More tangential literature was reviewed which provided small amounts of information around drug use and injecting. Many of the publications were overviews or case studies. Some paper titles were misleading; for example the paper title 'Extremity complications of drug abuse' (Ritland and Butterfield, 1973) was expected to provide good information relating to ulcers on the extremities, but these were only listed as 'skin ulcers' and as a vascular complication but with no further detail. Although useful in understanding patterns of drug misuse and developing ideas behind risk and harm reduction, the papers lacked scientific detail.

Throughout the study various electronic sources, were searched, monitored and followed up for topical evidence and a focussed search, using terms directly related to

emerging results, was repeated in 2012 and 2015. More recently, from the 1990's onwards, there were more robust empirical studies mostly related to blood-borne viruses and not related to skin breakdown and leg ulceration.

The lack of empirical studies meant systematic literature reviews including rapid review, realist, meta-analysis or meta-synthesis methodologies were impossible (Pawson et al, 2005; Cronin et al, 2008). Instead a narrative review of the literature was conducted drawing widely on the published literature to provide background to injecting practices and to link these to potential causes of skin breakdown.

2.2 Context of drug injecting

A global problem

Illicit drug use reached a peak over the last five years and has remained stable at between 3.5 – 7% of the adult population using an illicit drug in the last year. Around 27 million people worldwide are classed as problem drug users with dependence and drug-use disorders (UNODC, 2014). Problem drug use is defined as 'problematic use of opiates (including illicit and prescribed methadone use) and/or the illicit use of benzodiazepines and implies routine and prolonged use as opposed to recreational and occasional drug use' (ISD, 2014).

The predominant substances used are opiates, but other psychoactive drugs are also misused (UNODC, 2014). Drug use exists in both developed and under-developed countries, is a significant cause of death across the world, and many countries spend vast amounts of government money attempting to reduce drug problems (Reuter, 2006; UNODC, 2014). In Europe it appears that supply reduction dominates spending, prevention activities receive a small share, and law enforcement accounts for more than 50% of budget totals (Ballotta and Bergeron, 2006). Large numbers of drug users are imprisoned worldwide, some may continue to use drugs whilst incarcerated and there is an increased risk of mortality from overdose after release (Strang et al, 2006; Farrell and Marsden, 2007; Hecht et al, 2014).

Scotland

In Scotland alone it is estimated that there are almost 60,000 problem drug users (ISD, 2011), and of these around 50% may be injecting (ISD, 2012). Edinburgh and Glasgow are Scotland's largest cities and contain the majority of the country's drug injectors.

Glasgow

In Glasgow, the drug injecting epidemic began in the early 1980's (Frischer et al, 1997), and in 1983 the prevalence in Glasgow of problem drug users was thought to be around 5000 (Haw, 1985). By 1989, the number of PWID was estimated to have risen to 9424 (Frischer et al, 1991).

From 1990 onwards heroin became more widely available in Glasgow, and injectors started using heroin in preference to previous drugs such as buprenorphine and benzodiazepines (Hammersley et al, 1995).

In 1992, Makower et al reported that PWID attending Accident and Emergency (A & E) at Glasgow Royal Infirmary were becoming a significant part of workload and described the characteristics of attendees (Makower et al, 1992). The average age of the drug injector admitted to A & E was 24.2 years. Mean age at first injection was 18.3 years, with a mean duration of habit of 5.7 years. The three most commonly used drugs were buprenorphine, heroin and temazepam, although there was widespread mixing of drugs. Sites of the most recent injection were upper limb, and lower limb - groin and feet. The drug-related reasons for presentation included abscesses, some of which were in the lower limb, cellulitis, deep venous thrombosis, phlebitis, and 'vascular'. Only 65% were known 'registered addicts', which suggested there were many more drug injectors who were unknown to authorities.

Glasgow now has the highest rate of problematic drug use in Scotland, with prevalence rates remaining consistent in the last five years, and thought to be around 13,900 individuals (ISD, 2011) including the largest number of injectors in Scotland (ISD, 2012) with proportionately three times as many males as females (King et al, 2013).

Many believe this estimate to be conservative, citing the additional hidden presence of heroin users throughout the UK (Shewan et al, 1998; Taylor and Kearney, 2005).

2.3 Social and physical factors associated with drug injecting

Injection drug use is most common in disadvantaged communities (Macleod et al, 2013) and is strongly associated with social and material deprivation (Baumann et al, 2007; Macleod et al, 2010). Drug users are more likely to have fewer educational qualifications, lower rates of employment, poorer physical health, and housing difficulties as well as more behavioural, psychological and psychiatric problems than non-users (Pieper, 1996b; Strang et al, 2006). Problematic drug use is also associated with psychological ill-health, and social factors such as unemployment, criminal activity, and relationship difficulties (McClelland, 2006; Nambiar et al, 2014).

The health of a drug user is bound to their social environment (Galea and Vlahov, 2002) and social networks with friends and partners are influential in drug using behaviour (Lakon et al, 2006). Many PWID have been imprisoned (Gill et al, 1995; Taylor et al, 2013) where injecting equipment is not readily available and sharing of equipment is more likely to occur resulting in increasingly risky behaviour (Long et al, 2004).

Homelessness

The extent of homelessness amongst drug users is extremely high. For some, drug use precipitates homelessness and for others drug use is an escape from the harsh reality of being without a home (Neale, 2001).

In 2000, Fountain et al (2003) surveyed 389 homeless people in London, and 63% of respondents reported that their drug or alcohol use was one of the reasons they became homeless. Substance use increased with the length of time the person was homeless. Kemp et al (2006) identified that the risk factors for homelessness are similar to the risk factors for problematic drug use. It is likely that trauma precedes homelessness, and

that the use of both drugs and alcohol and criminal activity increases following homelessness (Martijn and Sharpe, 2006).

Homeless people tend to be involved in riskier injecting practices and homelessness may have a direct impact on health outcomes (Lowry, 1990; Keaney et al, 2011). However, it may be difficult to distinguish between ill-health caused by homelessness, or caused by drug use in homeless drug users. There is evidence that homeless drug users exhibit higher levels of life-threatening behaviours such as high-risk injecting practices and suicide attempts (Greene and Ringwalt, 1996; Reid and Klee, 1999; Galea and Vlahov, 2002; Davidson et al, 2002; Rowe, 2005). A study conducted in Ottawa, Canada found that homelessness is the strongest predictor of public injecting which obviously reduces privacy, but also impacts on safety (Navarro and Leonard, 2004). It is more difficult to maintain cleanliness, injecting would require to be swift and undetected, and there may be less opportunity to collect and store clean injecting equipment. All of these factors may contribute to skin breakdown.

Initiation into drug use

In Scotland, early and damaging drug using behaviour tends to occur in the late teenage and early twenty years, followed by attempts to quit drug use in the late twenties and early thirties. In the late thirties or early forties there may be some success in stopping using; however it is not unusual to find drug users in their 50's or 60's who have remained intermittently dependent for decades (Robertson et al, 1994; Mustasa, 2001).

A number of international studies report earlier initiation with some commencing injecting as young as 12 years of age. Drug injecting can be evident from a young age and is not a problem restricted to a particular age group (Chiang et al, 1990; Fuller et al, 2002; Dolan and Niven, 2005; Day et al, 2005; Abelson et al, 2006).

Although drug use may start early for some individuals there is also evidence that drug users are becoming older and a substantial number of drug users are now aged over 40 years (Beynon et al, 2010). It would appear that drug users are living longer, and using

for longer, thus increasing opportunities to acquire drug-related problems such as skin disease which may be exacerbated by age-related changes. Long-term users of illegal drugs may be biologically much older than their chronological age therefore diseases more common in old age such as leg ulceration may appear much earlier (Beynon et al, 2010; Roe et al, 2010; Palfreyman and Fenwick 2011).

2.4 The Injecting Process

2.5 Substances

This sub-section describes the many substances that may be injected and might affect ulceration. The extent of their use within Scotland is described although no evidence directly links causation to ulceration.

Heroin

The most commonly injected illicit substance in Scotland is thought to be heroin (diamorphine), a potent opioid that acts on receptors throughout the body. Heroin in the UK tends to be brown and is usually sourced from Afghanistan, the world's biggest producer of opium (Brett et al, 2004; Zerell et al, 2005; Robertson and Richardson, 2007; UNODC, 2014). Heroin can be highly impure and is commonly manufactured and prepared on the ground and contamination during production can have major implications for health (Tuazon et al, 1974; Zerell et al, 2005).

Heroin has high lipid solubility and enters the brain rapidly. It is a depressant that produces a euphoric effect, 'a high' of relaxation, calm, freedom from worry and freedom from pain. After the euphoric period, the person enters a rebound phase marked by irritability, despair, anxiety, decreased sedation, and increased pain. Tolerance to the euphoria develops rapidly, which tends to result in the user steadily increasing the amount of drug used to achieve the same effect (Pieper, 1996b). Users may start by snorting or smoking heroin but the increased tolerance also escalates use and subsequent cost, and individuals will often start injecting smaller and cheaper

amounts once their smoking threshold becomes financially unsustainable (Devey, 2010). Once injecting commences the protective layer of the skin is breached and damage occurs.

Adulteration and dilution

Illicitly prepared and supplied drugs, especially heroin, may be adulterated with chemicals such as quinine, paracetamol and caffeine which may have a similar, complementary or potentiating effect, and diluted with a variety of generally inert materials such as dextrose or lactose or talc substances which are added to create bulk and maximise profit (Kirchenbaum and Midenberg, 1982; Coomber, 1997a; Coomber, 1997b; Passaro et al, 1998; Buttner et al, 2000; Brett et al, 2004). It is unclear at any time what exactly illicit drugs comprise (Matzner, 1973). Much rumour and controversy surrounds the topic of adulteration and the lay perception is that illicit drugs are adulterated with dangerous substances such as brick dust and rat poison though this appears to be a myth (Coomber, 1997c). However, the adulterants and the lack of purity within heroin is a cause for concern and may be implicated in infection, venous damage and skin breakdown. Unusual skin lesions may also occur due to the variations in additives (Dunne and Johnson, 1972).

Some small scale studies have shown that foreign body elements of the inoculum were responsible for soft tissue infection with crushed tablets and cocoa powder cited as problematic (Fullarton, 1983). Talcum powder and starch have been known to embolise distally (Al Zahrani, 1997), and dextrose solutions have caused thrombophlebitis (Kirchenbaum and Midenberg, 1982; Fellner and Ledesma, 1990).

Quinine was initially added to heroin in the 1930's because of its anti-malarial properties as malaria was common in injectors who often shared needles. Quinine became widely used in the 1940's as its bitter taste was similar to that of the taste of heroin, preventing the purchaser from tasting the apparent strength of the drug (Kirchenbaum and Midenberg, 1982). Quinine may be used for its 'rush' – a feeling of

accelerated and enhanced euphoria (Dunne and Johnson, 1972; Gursel et al, 1978), which may result from peripheral vasodilation (Kirchenbaum and Midenberg, 1982) but it is a known sclerosing agent used in the treatment of varicose veins, which works by irritating the vascular endothelium leading to thrombosis (Kirchenbaum and Midenberg, 1982). When injected into the skin it can cause cellulitis, often followed by bacterial abscesses and leading to ulceration (Fellner and Ledesma, 1990 Anonymous, 1997). Quinine also possesses acidic bactericidal properties which may render a wound transiently aseptic, and presumably would also damage the skin cells essential for healing.

Knowledge of the cutting agents is important because they may contribute significantly to the disease process. However, injectors may be unaware what their injection truly comprises which creates a difficulty in the identification of these as causative factors in skin breakdown.

Use of acidifier

A laboratory study undertaken by Scott et al (2000) demonstrated that the addition of an acidifier to impure brown heroin is necessary to create an injectable solution, and this is common practice in Scotland. Scott's study found that the diamorphine content of the heroin she studied was only 56%. Different purities will require different amounts of acidifier. Acidifier (citric acid or vitamin C) is commercially available in single-use 100mg sachets distributed free by injecting equipment providers (IEP) in Scotland. Injectors also report using unsterile traditional options such as lemon juice or vinegar which can cause problems such as fungal infection in the eye (Albini et al, 2007).

Adding acidifier to injections may cause tissue and muscle damage, scarring, and reduced blood flow which would favour the growth of anaerobic bacteria such as clostridia at, or in, the injection site especially if injected intramuscularly or subcutaneously (Brett et al 2004; Taylor et al, 2005). It is possible that injectors may

use too much, causing acidic damage, such as burns, or sclerosis of the veins (Williams and Southern, 2005).

Acidifiers are not used in countries such as the US and Australia where the street heroin is in a soluble form (Maliphant and Scott, 2005; Coull and Pieper, 2006) and this makes international comparisons around injecting harm difficult, as different solutions are injected.

Cocaine

The use of cocaine has become progressively more widespread. It acts as a stimulant and produces an intense high, or euphoria, largely due to enhanced stimulation of the dopaminergic system, which lasts only a few minutes and the after-effects are depression and a craving for more (Pieper, 1996b; van Beek et al, 2001). Due to its short half-life it is typically injected more frequently and frenetically than heroin and higher doses can cause severe behavioural alterations (van Beek et al, 2001).

Cocaine has a potent vaso-constrictive and local anaesthetic effect (Buttner et al, 2003; Ducasse et al, 2004). All routes of administration of cocaine are associated with ischaemia, atherosclerosis and infarction of various organs including the heart and the brain, and although intravenous use is most commonly implicated, the causative mechanism is unclear (Myers et al, 1991; Tolat et al, 2000; Erwin et al, 2004).

Vascular damage in cocaine users has been reported, in single case studies, with users suffering from arteritis, thrombophlebitis, atherosclerosis, vasculitis and occlusions, although adulterants may be implicated. In cocaine these tend to be more water-soluble, and less toxic than those in heroin, and therefore less problematic for vein walls (Karch and Billingham, 1995; Chen et al, 1996; Hofbauer et al, 1999; Mockel et al, 1999; Gertner and Hamlar, 2002).

Alkalinisation and extraction produces a heat-stable pure form of cocaine called 'crack'. When heated the crystals make a popping sound, and crack is usually smoked

but may also be injected when mixed with acid and may be more harmful than injecting cocaine (Pieper, 1996b; Lankenau et al, 2004; McKee, 2005).

In a large study of 212 cocaine users in Sydney, Australia, both injectors and non-injectors and infrequent and irregular users identified serious physical and psychological symptoms. Amongst non-injectors the most common physical problems were nasal bleeding and ulceration, chronic sinus / nasal congestion, and heart palpitations. Amongst injectors the most common symptoms were worse - severe weight loss, palpitations and chronic insomnia. Of eighteen physical symptoms recorded (for both injectors and non-injectors), two related to skin, 'facial sores' and 'abscesses at injecting sites'. There were no reports of chronic ulceration; however, the skin symptoms may not have been explored in enough detail (Kaye and Darke, 2004).

Van Beek et al (2001) also report thrombosed veins, abscesses, and skin picking and 'coke sores' caused by compulsive scratching and picking. These areas can become infected leading to sepsis. Whilst they report a number of physical and psychological issues with cocaine injecting, these authors do not discuss the issues associated with cocaine's anaesthetic effect. If a missed hit (injecting into the subcutaneous tissues usually in error) occurs it would normally cause pain, but not with cocaine which numbs the injecting area. Because of this effect, injecting cocaine tends to cause more problems because of the absent natural warning of the pain response.

Benzodiazepines

Oral benzodiazepines (such as diazepam and temazepam) are often prescribed to drug users but intravenous use also occurs. A study of 208 drug users in Britain identified 186 participants who had used benzodiazepines, and of these, 103 had injected them (Strang et al, 1994). Different preparations of capsules, tablets, and syrup, all designed for oral consumption, had been injected and were commonly mixed with other drugs such as heroin or buprenorphine because of the additional pleasurable sensations and

emotional feelings produced (Forsyth et al, 1993; Strang et al, 1994; Dwyer et al, 2009).

Gel-filled (rather than liquid) capsules of temazepam caused particular vascular problems, as it was toxic to vessels and appeared to cause endothelial damage and swelling (Wilce, 2004) probably due to the wax content that solidified once injected (Forsyth et al, 1993). These were painful to inject and known to cause thrombosis of the vein (Halliday et al, 1986; Dwyer et al, 2009). Manufacturers changed to producing solid-fill capsules. However, these were also used for injecting and caused even greater morbidity (Strang et al, 1994).

It is unknown whether injecting temazepam causes any long-term effects on the skin or venous system, but it is likely to be of importance, particularly in long-term injectors.

Buprenorphine

Buprenorphine is a synthetic opiate, usually taken sublingually as an analgesic. In the early 1990's there was a change in trend in Glasgow from injecting heroin to injecting buprenorphine (Anonymous, 1993). As a controlled drug, its availability was reduced and subsequently Glasgow doctors entered a voluntary prescription ban in 1993 in order to attempt to reduce supply (Forsyth et al, 1993). It continued to be used illicitly with tablets being crushed and injected, which caused significant harm to the skin (Del Giudice et al, 2005; Jenkinson et al, 2005). It was reintroduced in 2006 as an alternative substitute prescription to methadone.

Amphetamines

Amphetamines can be snorted, injected or smoked, and using results in an intense euphoria. Synthetic amphetamine is a known potent vasoconstrictor (Ducasse et al, 2004) and injecting can result in severe infections and abscesses at injection sites (Rawson and Condon, 2007). Amphetamine users sometimes experience a feeling as if something is crawling under their skin; this can lead to scratching and skin picking, and

the vaso-constrictive effects can reduce subsequent healing (Sim et al, 2004; Rawson and Condon, 2007). Amphetamines are thought to have only a limited presence in Scotland.

Methadone

Oral methadone, in syrup form, is prescribed as a substitute for heroin and commonly with other medications such as antidepressants like benzodiazepines (Holt, 2007), but it is not unusual for both prescribed methadone and illicit heroin to be taken concurrently (Seymour et al, 2003; Bloor et al, 2008). Whilst injecting methadone is unreported in the Scottish literature, methadone injecting has been reported in Australia (Darke et al, 1996) where it was found that long-term injecting of methadone 'for injection' caused the tissues in the arms and upper thighs to become 'woody', with loss of contours, fat and muscle atrophy, and numerous deep punched out ulcers (Farrant et al, 2005).

Whilst opiate substitute prescribing is controversial (McKeganey et al, 2006; Bloor et al, 2008) studies have indicated that the receipt of prescribed oral methadone is associated with a significantly lower risk of illness and this may be due to the reduced likelihood of injecting (Taylor et al, 2005).

Cannabis

Cannabis is usually smoked to produce a 'high'. It is a known vasoconstrictor which can lead to distal arterial lesions or occlusions with venous thrombosis and therefore its role in skin disease is worth exploring (Ducasse et al, 2004; Hall, 2015).

In summary, different substances are injected in Scotland and it is unclear which if any drug, or what combinations, may contribute most significantly to tissue damage.

2.6 Injecting technique and preparation of injections

This section describes the techniques and preparation of injections that may contribute to skin breakdown although no empirical studies were found directly linking techniques to ulceration.

Preparation of heroin

Heroin needs to be prepared before injecting and the materials required are usually a spoon or cooker (a container used for mixing and heating), needle and syringe, tourniquet, acidifier, water, a filter, and a heat source such as a lighter or matches. The process is rarely sterile, and equipment may be reused many times (Scott, 2008).

Brown heroin is mixed with the acidifier that will dissolve the heroin. The combination is diluted with water or another liquid and heated, often in a spoon or foil, until it dissolves. The water may be tap water, sterile water, bottled water, saliva, from a sink or even a toilet (Joseph et al, 1973; Ponton and Scott, 2004). The resulting fluid is then drawn up in a syringe, usually filtered to eliminate impurities in the solution, and injected (Taylor et al, 2004a). Filters are available as part of Injecting Equipment Provision (IEP). This is a recent development (Scott 2005; Scottish Government, 2010), but filters may also be home-made using cotton wool, cigarette filters or other fabrics. Fibres may be drawn into the syringe and injected causing multiple microscopic foreign bodies (Joseph et al, 1973; Khanna and Drehmer, 2001).

In 1988, 50% of Edinburgh's drug injectors had Human Immunodeficiency Virus (HIV) infection (Robertson et al, 1994) and common practice involved initially washing out the heroin from the syringe by repeatedly drawing back and injecting the users own blood and secondly, washing the heavily bloodied equipment in a communal receptacle (Brette and Nelles, 1988). Early papers such as the overview of injecting and infection-related behaviour written by Hughes (2001) describe risky practice related to lack of sterile (new) equipment, including cleaning of equipment, hiding of tools, and different methods of sharing. Sharing equipment is known to be heavily implicated in

the spread of blood-borne viruses and has been actively discouraged following a number of good quality studies (Hughes, 2001; Taylor et al 2001; Scottish Government, 2010). Many of these practices are now less common in Scotland but they may have been part of a drug using career for those that have been injecting for a long time, possibly as paraphernalia were not freely available (Thiede et al, 2007; Scott, 2008; Strike et al 2010; University of the West of Scotland, Health Protection Scotland, University of Strathclyde and the West of Scotland Specialist Virology Centre, 2012).

Injecting equipment

Reusing blunt and dirty equipment may have implications for skin breakdown and infection. Current recommendations are that IEPs should provide as many needles as an individual client requires, and supply, free of charge, acidifiers, cookers, filters, water for injections and pre-injection swabs in order that injectors may use a sterile needle and injecting paraphernalia for every injection (Scottish Government, 2010; Preston and Derricott, 2013). Using the shortest needle reduces the assault on the vascular system, but it is also important to use the right needle for the size of vein (Maliphant and Scott, 2005).

Filters

Filtering the injection is important as particulate matter including oral drug suspensions or tablets crushed, dissolved, and injected may contain micro-particles which act as emboli and cause phlebitis and soft tissue infection which can create blockages in peripheral veins leading to occlusion, necrosis, vasculitis and skin breakdown (Al Zahrani, 1997; Brust, 1997; Khanna and Drehmer, 2001; Ponton and Scott, 2004; Del Giudice et al, 2005; Darke et al, 2015).

Learning to inject

Most PWID are taught to inject by another injector which can perpetuate unsafe practices. In a study examining initiation into injecting heroin in Sydney, Australia,

Day et al (2005) found that the majority of study participants (63%) were taught to inject by a friend, family member, or partner. Only a few study participants (10%) were self-taught. Initiating others into injecting was also associated with sharing of equipment. Women appear to be more vulnerable to initiation by male partners (Simmons et al, 2012). Injecting others can be relatively common practice, and may be done because of problems with technique, or an awkward site such as the neck, and might be performed for a fee of money or drugs (Cherry et al, 2009).

Injecting sites

The forearms are often the first site for injecting into due to easy visibility and access. In a detailed Australian survey on injecting sites, Darke et al (2001) reported that 94% of injectors start in the cubital fossa. Other sites used in order of popularity were: forearm (71%), hand (53%), upper arm (20%), foot (19%), leg (18%), neck (10%), groin (6%), fingers (6%), and toes (3%). A smaller percentage had injected in the clavicle, breast, shoulder and penis. The mean number of injection sites used in the preceding six months was two. There was marked progression in the use of different sites and whilst the starting point was the cubital fossa, the forearm was next used for a median of two years after commencing injecting, the upper arm after 3.5 years, and the hand after 4 years. Injections in the neck, foot, and leg occurred after six years of injecting. Injection in the groin, toes and fingers occurred, on average, after a decade of injecting. The unusual longevity of use of certain sites may be due to the purity of heroin used in Australia (Maliphant and Scott, 2005).

Women have more difficulty accessing superficial veins as they are smaller and less visible and it is more likely for the vein to be missed (Spijkerman et al, 1996; Derricott et al, 1999; Andresz et al, 2006). It is unclear whether women have more skin problems than men.

As injectors become older and veins collapse, riskier sites may be selected such as breast, tongue, feet, femoral, axillary, jugular and penile veins. These are areas where veins may be smaller and more easily damaged, and also may be in more bacteria-laden

sites such as the groin and feet, or close to vital structures such as in the neck, where complications such as an abscess could cause compression (Bennett et al, 1973; Finelli and Taylor, 1977; Barg et al, 1986; Cunningham and Persky, 1989; Cooper, 1990; Haverkos and Lange, 1990; Maggi et al, 1995; Bergstein and Baker, 1995; Butcher, 2000; Biller and Murr, 2004).

It is unclear whether the injecting site is important in the development of skin breakdown.

Skin and muscle popping

As veins become more difficult to locate, drugs may be injected subcutaneously or intramuscularly known as ‘popping’ (Binswanger et al, 2000). Once venous access fails, popping may occur typically in the legs and buttocks (Formica and Perazella, 1998; Forshaw and Power, 2001) but also in the foot and ankle (Pirozzi et al, 2014). The proximity to deeper structures such as bones and tendons can make popping in such areas very risky. With popping there is usually erythema, swelling and induration at the injection site. This may be transient, form abscesses, spread via lymphatics or tissue planes, or heal, producing hyper-pigmented macules or circumscribed retracted scars (Hirsch, 1972).

Popping is a major risk for serious infection (Pieper, 1996b; Forshaw and Power, 2001; Murphy et al, 2001; Taylor et al, 2005). It is likely that deposition of unsterile and foreign material in extravascular spaces, such as muscle, provides a focus for infection, as it creates more favourable conditions for the growth of anaerobes, causing deeper wounds and potential for systemic illness not seen when injecting into the venous system (Graham et al, 1999; Brett et al, 2005).

Injecting into wounds

Wounds may also be used as injecting sites which may contribute to non-healing (Reed and Jefferson, 2003; Williams and Southern, 2005; Thakor and Wijenaike, 2009). One single case report of an unusual non-healing ulcer of the forearm in a 32 year old drug

user was attributed to injecting heroin in the wound. This was described as a ‘shooter’s patch’ and was painful, with vascular edges. Microbial cultures were positive for staphylococcus aureus, pseudomonas aeruginosa and other skin bacteria, and radiography revealed bony changes consistent with osteomyelitis. Unfortunately this case was lost to follow-up, so it is unclear how and if healing took place (Tice, 2002).

Other authors have also described ‘shooter’s patches’ following skin popping, and the ulcerated tissue is used as a portal for continued injecting (Lyer et al, 2011; Phillips et al, 2013). It would be interesting to investigate how common wound injecting is, as this would affect a desire for healing.

Femoral

Femoral or groin injecting is becoming more common (Rhodes et al, 2006a). Drug injectors may choose to use the femoral site as it is easily hidden and a reliable site for speedy and convenient injecting especially for those that inject in public (Ti et al, 2014). Sinuses may develop from repeated injections at the same site creating a permanent and readily accessible route from the skin to the underlying vein, on one or both sides, that can be used for many years (Chiang et al, 1990; Jensen and Gregersen, 1991; Devey 2010).

However, it is a risky site with many reported problems. Thickened scar tissue at the groin site causes difficulty with injecting such as needle breakage and a requirement to use longer thicker needles. Swellings or aneurysms can occur in the groin area, and there is a risk of inadvertent arterial injection, DVT, venous insufficiency, infection and pain (Gan et al, 2000).

MacKenzie et al (2000) identified femoral injecting as a risk for iliofemoral thrombosis and severe groin infection in a retrospective study of patients admitted to hospital in Aberdeen. Maliphant and Scott (2005) investigated femoral vein injecting using short semi-structured interviews amongst 47 IEP clients who were groin injecting in Bristol, UK. Their small study reported a wide age range, varied length of injecting time in the

groin, and differing times to start groin injecting from time of first injection. One person had used no other site other than the groin, nine people had used one other, and another nine had used two sites. The study was too small to be conclusive, but they noted a possible increased risk of vascular complications, such as DVT, leg ulcers and vascular insufficiency. Ingram and Baxter (1994) describe three PWID who presented with a swollen leg. All were assumed to have DVT, but following Doppler sonography DVT was not confirmed; instead, each case had femoral stenosis thought to be due to the peri-venous fibrosis secondary to repeated injection.

Injectors can find it difficult to use the non-dominant hand (Maliphant and Scott, 2005) and dominance may be significant when choosing which femoral vein to use, rotation between sites, and skill in technique (Aitken et al, 2009).

Groin injecting is viewed as becoming normalised within the UK but harm reduction strategies are piecemeal and provision of information is patchy (Zador, 2007). Miller et al (2008) consider that groin injectors who use this site as a last resort should be taught to inject safely there, whereas others choosing it for convenience should be encouraged to use other sites. Concern has been expressed that in attempting to reduce harm amongst those who femorally inject, service workers are crossing ethical boundaries (Rhodes et al, 2006a) as in fact, this site is never 'safe' to inject in (Zador 2007). Of all the papers sourced, none laid out clearly the risk that a stenosis of the femoral vein creates and the full ramification of groin injecting requires exploration, particularly of the impact on the venous system lower in the leg.

Pseudo (or false) aneurysm

Pseudoaneurysm is a collection of blood contained by a clot that has formed outside a blood vessel following an injury. The collection is attached by a channel to the blood vessel so blood flows within it (NICE, 2004). It is a serious complication of groin injecting and occurs as a result of intra-arterial injection and repeated trauma to the vessel wall with or without infection. It usually presents as a pulsatile mass in the groin and can rupture and bleed easily (Kirchenbaum and Midenberg, 1982; Cheng et al, 1992; Ting and Cheng, 1997; Al Zahrani 1997; Heis et al, 2008).

Johnson et al (1984) state that pseudoaneurysm should be considered in any patient presenting with groin infection after injection and may require surgical repair (Reddy et al, 1986; Millburn and Brittenden, 2006). Lo et al (1990) report amputations in drug injectors caused by femoral pseudoaneurysms resulting in distal embolus, sepsis and thrombosis. The mean age of limb loss was 26 years compared to 57 years in the general population.

Ischaemia caused by damage and surgical repairs could lead to arterial ulceration lower in the leg, and surgical repairs could also damage both the arterial and venous systems, impacting on the limb and precipitating skin breakdown (Welch et al, 1990; Gan et al, 2000; Georgiadis et al, 2005).

Arterial injection

An artery may be hit with a needle accidentally, particularly in the groin, producing what is known as a 'flash', a burning pain or paraesthesia and red flush along the arterial line. Spasm and ischaemia may follow, with swelling and a cold cyanosis. Gangrene may develop later if an injection into the artery occurs (Pieper, 1996b; Del Giudice et al, 2005).

The literature describes, in small case reports, examples of complications following intra-arterial injection such as amputation, vasculitis, penile infection, digital ischaemia and distal micro-emboli. Surgical intervention was often required (Daniel, 1973; Bickley et al, 1988; Cunningham and Persky, 1989; Charney and Stern, 1991; Dodd et al, 1994; Forshaw and Power, 2001; Del Guidance et al, 2005).

This is important as the damage caused to arteries by injection or surgical repair can affect blood supply and impact on healing.

2.7 Drug use and skin problems

Injecting breaches the body's outer protective layer and this section examines the disease processes affecting the skin.

Since Hussey and Katz (1950) initially raised awareness of skin problems in 'narcotic addicts', numerous publications have reported injecting injuries to the skin, as well as soft-tissue infection, but the majority tend to be superficial case reports and may be dated or focus on treatments rather than discussing causative or risk factors (e.g. Biderman and Hiatt, 1987; Butcher, 2000; Acton, 2008; Powell, 2011a; Acquaro, 2012).

In an early study by Weidman and Fellner (1971) 86% of subjects attending a medical clinic for drug injectors had cutaneous adverse effects. Kirchenbaum and Midenberg (1982) reported that abscesses and ulcers (which are not defined) were the most common cutaneous complications at the site of injection. They postulated that they were the result of the use of unsterile needles and syringes as well as the uncontrolled inclusion of adulterants within the drugs.

Darke et al (2001) interviewed injectors about their physical injection sites in Australia, and the majority reported experiencing problems, with females reporting significantly more problems than males. Prominent bruising or scarring, lumps or swelling, were the most common, with difficulty injecting due to vascular scarring. However, the authors make no mention of open wounds nor of chronicity of these problems. This may be due to purer heroin which may cause fewer skin problems.

Roxburgh et al (2005) also found women reporting more skin problems than men, which may indicate a higher likelihood of vascular damage in females.

Skin and soft-tissue infection

Skin and soft-tissue infections are significant problems in drug injectors. Hope et al (2008) estimated that over 30,000 PWID seek health care for injection site infections in England each year with at least 18,500 requiring admission to hospital.

Many papers and reports about drug injectors refer to 'soft tissue infection'.

Fullarton (1983) described soft-tissue infections in PWID in Glasgow as types of abscess or cellulitis, none of which are defined, but microbiology and treatment is described in detail. Dunlop and Steedman (1985) in Edinburgh also reported PWID presenting with an open wound, cellulitis or abscess but these were not defined. Takahashi et al (2003) estimated that the prevalence of soft tissue infections (by case note review), abscesses, cellulitis and infected ulceration in PWID is between 21% and 32%, but again definition of infection was missing. Stone et al (1990) reviewed all case records of attendees in the A & E Department in Glasgow Royal Infirmary during 1986. Of these 0.6% (n = 488) had documentary evidence of intravenous drug use. Clinical examination revealed signs of soft tissue sepsis in 31% of these (n = 150) in varying sites of the body, and this was defined as 'either abscess or cellulitis' but these were not explained.

Marks et al (2013) agreed that skin and soft tissue infections were the commonest reason for admission however, they lumped together 'skin and soft tissue infection' without definition, and included in the categorisation were cellulitis, infected chronic leg ulcers, soft-tissue abscesses, and necrotising fasciitis, which are all different. The categories are therefore unclear, as cellulitis can be present in isolation, but would most likely be present with any infected wound, with necrotising fasciitis, and possibly with an abscess (EWMA, 2013), but in this case it is listed as a separate diagnosis.

Orangio et al (1984) reviewed 34 PWID admitted with soft tissue infections to a Jamaican hospital between October 1981 and June 1982. They compared the microbial results to that of other drug injectors without infections admitted for detoxification. In

the infected group, a variety of soft tissue infections were noted; enteric and oropharyngeal organisms predominated, with a high incidence of poly-microbial infection. However, demographics for each, together with definitions, for example of ‘ulcer’, are missing.

Henriksen et al (1994) reviewed 145 hospitalizations in 89 PWID with acute soft tissue infections in an orthopaedic unit in Copenhagen, Denmark. ‘Soft tissue infection’ was not defined but included superficial abscesses, deep abscesses, cellulitis, purulent arthritis, and tenosynovitis. Most infections were in the groin, and a few also suffered serious complications such as DVT, pneumonia, septicaemia, or thrombosis of the femoral artery resulting in amputation. Most of the infections were poly-microbial which was unusual in the non-injector. The authors state that this was not entirely due to the nature of the substance injected, nor to the use of tap water to dissolve substances, but more likely due to the use of contaminated syringes and needles. In particular, they identified the presence of oro-pharyngeal bacteria, due to putting the needle in the user’s mouth, and cleaning the skin with saliva.

Similar results from a study of corresponding size were found by Summanen et al (1995) when they compared specimens from cutaneous or subcutaneous abscesses in IVDUs to non-IVDUs. 67% of the IVDUs organisms were of oral origin. The identification of oral bacteria suggest that there are aspects of injecting process such as licking and use of saliva that could be explored further (Binswanger et al 2000; Deutscher and Perlman, 2008), together with aspects of hygiene such as clean equipment, skin cleansing and hand-washing and their role in skin breakdown (Phillips et al, 2013).

Defining infection

The European Wound Management Association provides this definition of infection: ‘invasion and multiplication of micro-organisms in body tissues, evoking an

inflammatory response (systemic and/ or local) and causing local signs of inflammation, tissue destruction, and fever' (EWMA, 2013).

The traditional criteria for wound infection may be 1) abscess 2) cellulitis 3) discharge (serous exudate with inflammation; seropurulent; haemopurulent or pus) (Cutting and Harding, 1994). A more modern approach includes other factors such as delayed healing, discolouration, friable granulation tissue that bleeds easily, unexpected pain or tenderness, pocketing and bridging of the wound tissue, abnormal smell and wound breakdown. Not all of these criteria would be present at one time, but clinical assessment is important to diagnose infection (Cutting and Harding, 1994; EWMA, 2005; EWMA, 2013).

Wounds are breaks in the skin and are not sterile. If investigated, bacteria and other micro-organisms will be cultured from them (EWMA, 2005). Once there is a break in the integumentary layer then the body's protective surface is breached and a portal for entry of organisms is established. However, it may take some time for these to become pathogens and cause disease or infection.

A break in the skin does not mean that the wound is infected – other signs and symptoms such as redness, swelling, heat, pain and a spreading cellulitic response would be more likely to indicate infection. This is an important difference.

If a wound was clinically infected then treatment would be focussed on anti-microbial therapy such as antibiotics. If it was contaminated or colonised, then topical treatment would be more appropriate (Leaper, 1998; EWMA, 2006). This is commonly understood by specialised wound practitioners, but may be misunderstood by others who are less expert and who may see an open wound and assume it is infected by appearance alone.

Hope et al (2008), in a survey of PWID self-reporting injecting practices and symptoms of injecting site infections, considered the symptoms of injection site infections to be

‘abscess (pus-filled swelling) or open wound/ sore at an injection site as these are most likely to be due to bacterial infection’. An abscess is usually a closed wound unless it has been drained or burst, and is indeed a sign of infection. However, the assumption that an open wound at an injection site is likely to be infected is incorrect, and suggests that open wounds at injecting sites on the leg which have been present four weeks or more, and are therefore ‘ulcers’ (SIGN, 2010), are being misclassified. It is also possible that other open wounds in other sites without the signs of infections such as redness, swelling, pain, malodour etc. have also been classified incorrectly. Hope et al (2008) found that infection was associated with injecting in particular sites but it is unclear whether this included the leg, but did include the groin.

In the ‘Shooting Up Report - 2013’ 28% of PWID reported a recent injecting site infection (Public Health Groups, 2014) and despite being described as a ‘major’ problem the authors do not define what is meant by a site infection; instead they state that an experience of an abscess, sore or open wound would be ‘possible symptoms of an injecting site infection’. In a later study, Hope et al (2014) discuss injecting site infections and state ‘a sore / open wound will most probably be infected’. This is a misunderstanding, and the authors go on to say that the sore may have been caused by excessive use of acidifier. However, excess acidifier may result in a chemical burn and again this does not mean the wound is infected (EWMA, 2005; EWMA, 2006). This message that open wounds are infected could give license to incorrectly, and potentially dangerously, prescription of antibiotics without truly identifying an infection leading to the occurrence of resistant strains (Leaper, 1998; Kearns et al, 2004). It is of concern that wounds and infections may be misreported, leading to over- or under-estimation of problems and potentially inappropriate treatment.

It would appear that abscesses can present without cellulitis, and cellulitis may be present without an open wound or abscess. Clinical examination would appear the best way to identify wound infection, but it should be possible to define cellulitis or abscess for reporting purposes.

Abscesses

In 1950, Hussey and Katz reported that they were unable to find any published reference to skin abscesses in drug injectors but they commented that it is likely that such abscesses were considered a matter of course, and were not worth reporting. Since then, abscesses were commonly reported but not defined (Billir and Murr, 2004; Lloyd-Smith et al, 2005).

A report from the early 1980's (Horn et al, 1987) identified that after inadvertent overdose, DVT (typically ileo-femoral thromboses) followed by abscess were the commonest reasons for the admission of drug injectors to a Glasgow hospital. The abscesses were mostly in the groin and almost exclusively caused by staphylococcal infection possibly originating from the skin.

Under-reporting may also have occurred in the literature due to failure to recognise or report the true nature of skin damage. For example, Makower et al (1992) studied drug injectors attending A & E in Glasgow and noted abscess of the lower limb but no leg ulcers. It is possible that these 'abscesses' were chronic ulcers and not assessed or recognised as such. There is apparent confusion of definition with terms such as abscess and ulcers being used interchangeably (Reese and Sullivan, 1997).

Spijkerman et al (1996) undertook a prospective study of 758 PWID over 8 years to investigate incidence rates and risk factors for skin abscesses and reported that more frequent injectors, and especially females as they have less visible veins than men, have a higher incidence of skin abscesses. However 'abscess' was undefined and it is unclear whether these were infected, sterile or not abscesses but ulcers.

Gonzalez et al (1993) undertook a four-year retrospective review of 57 patients with upper extremity abscesses associated with drug injection admitted to a hospital in Chicago, US. All of the abscesses were due to intravenous injection or skin popping. Three patients with abscesses present for more than six months had osteomyelitis.

Murphy et al (2001) performed a case control study with 151 IDUs with abscesses requiring incision and drainage and 267 IDUs who did not have abscesses nor skin infection. They found that skin popping, use of a dirty needle and speed-balling increased the tendency to form an abscess. Skin cleansing with alcohol was also identified as potentially preventing abscess. However, the definition of abscesses was not provided within the paper.

It is difficult to compare papers and draw conclusions when the meaning of the words related to skin breakdown and potential infection are not defined and can be misunderstood.

Scars / track marks

Track marks are early and visible scars of injecting usually seen overlying veins on the forearms resulting from repeated unsterile injections, irritants, crushed tablets, foreign body reaction and infection causing thrombophlebitis and sclerosing of the veins (Kirchenbaum and Midenberg, 1982; Maliphant and Scott, 2005; Darke et al, 2015). Damage to the veins may be a precursor to more widespread venous disease.

Lumps

Foreign body granulomas are seen in injectors (Fellner and Ledesma, 1990) and injecting crushed tablets as well adulterants of starch and talc are implicated as causative factors (Stuck and Doyle, 1987; Darke et al, 2015). Missed hits may also create lumps which could be sterile abscesses, or blocked veins (Derricott et al, 1999). Although common, it is unclear what the implications of such lumps are on skin breakdown.

2.8 Impact of injecting on health

This section explores the role that injecting may have on systemic health.

Blood-borne viruses (BBV)

A predominant issue for harm reduction services is the incidence of blood-borne viruses, commonly HIV and Hepatitis B and C (Cullen et al, 2005; Cooper and Mills, 2006). Hepatitis C (Hep C) is highly prevalent amongst Scotland's PWID (Prevost et al, 2015), and can lead to cirrhosis and liver failure, but it is unclear whether BBV have a role in skin breakdown (Hutchinson et al, 2006).

Redondo et al (2002) report a single case of chronic leg ulceration in an HIV positive patient who had been skin popping. The ulcer was deep, with healthy granulation tissue. Arterial pulses were present but Ankle Brachial Pressure Index (ABPI) was not reported. Dramatic improvement was noted with antiretroviral drugs, steroid therapy and a hydrocolloid dressing with almost complete healing within two weeks. This was without compression, suggesting that it was unlikely that the ulcer was venous in origin but instead was a more acute wound, but it is unclear if this was linked to HIV.

Arterial disease

Many PWID may have arterial damage from previous infection, surgery or arterial misadventure (Ting and Cheng, 1997). Pieper et al (2009a) identified peripheral arterial disease in 16.7% of a sample of people in methadone clinics but it was impossible to identify in the study what the reasons for this were.

Fellner and Ledesma (1990) report a single case of a woman with ulceration overlying the medial malleolus, with pain and swelling of the foot following injection of heroin. The ulcer was punched out, necrotic and draining fluid. The authors consider that 'drug ulcers of the addict' are often painful and found over bony prominences, with pressure as a factor, and what they describe is symptomatic of arterial disease (Moffatt et al, 2007, p108). Many drug injectors are also tobacco smokers which impacts on coronary health (SIGN, 2006; Shin et al, 2013). Arterial and vascular disease may contribute to skin breakdown and poor healing (Moffatt et al, 2007, p99).

Lymphatic disease

Along with impaired venous return, lymphatic blockages due to injecting can cause oedema, puffy hand or foot syndrome, and if persistent, lead to brawny, non-pitting and persistent oedema which can increase the risk of ulceration (Kirchenbaum and Midenberg, 1982; Pieper, 1996a).

Neurological disease

Drug injecting is associated with a variety of neurological complications including haemorrhagic and ischaemic strokes, seizures, movement disorders and cerebral atrophy (Neiman et al, 2000). Traumatic injection neuropathy can also occur in the foot due to repeated injury from injections, and allergic reactions, vasculitis, and ischaemia and extravasation can damage perineural structures (Finelli and Taylor, 1977; Kirchenbaum and Midenberg, 1982). Neurological damage to the leg can create limb dependency, leading to venous stasis and risk of ulceration (Moffatt et al, 2007, p139).

Systemic infections attributed to injecting

Serious disease can manifest itself initially in the skin, and apparently trivial wound infections in PWID can present with systemic effects which might otherwise be dismissed as direct results of drug intoxication such as collapse, paralysis or odd neurological symptoms. A number of organisms have been responsible for illness and death in drug injectors such as clostridia novyi, botulinum and tetani (McGuigan et al, 2002; Beeching and Crowcroft, 2005; ECDC, 2015). Heroin can be contaminated with soil where clostridia spores can lie dormant; dissolving heroin in acid and heating may stimulate germination of spores and is likely to destroy the bacteria that could compete with it (Zerell et al, 2005; Baumgardner, 2012).

Anthrax infections have occurred in drug injectors in Scotland, and can be initially difficult to differentiate from other injecting site infections. It can be challenging to treat and has a high mortality rate (Grunow et al, 2013).

Necrotising fasciitis is a severe infection that spreads rapidly along soft tissue planes; the disease is insidious and often the true severity is not initially apparent (Gonzalez et al, 1996). A number of bacteria may be implicated, including group A streptococcus and there is also a high mortality rate (Bernaldo de Quiros et al, 1997; Neal, 1999).

Other systemic infections

Other infections including endocarditis, epidural abscesses, and renal lesions are not uncommon with a number of case reports of PWID published (Arbulu et al, 1993; Fred and Hariharan, 1997; Prendergast et al, 1997; Formica and Perazella, 1998).

Systemic infections may affect the vascular system and may lead to skin breakdown and possibly death in PWID.

2.9 Leg ulceration

This section examines the existing literature surrounding the prevalence, aetiology and risk factors of leg ulceration and relates this to PWID.

Ulceration of the lower leg is a common problem in Western countries (Callam, 1992; Scottish Leg Ulcer Trial Participants, 2002; Hall et al, 2014) affecting approximately 1% of the population. Leg ulceration is a common source of morbidity in the elderly (Franks et al, 2004) and there are a number of concomitant factors such as peripheral vascular disease, trauma, haematological factors, diabetes, and vasculitis, but most ulcers are multi-factorial (Burton, 1993). The majority of sufferers with leg ulceration have a chronic condition which causes pain, embarrassment, and social isolation and once healed, the ulcers can readily recur (Dale et al, 1983; Lees and Lambert, 1992; Jawien et al, 2003). Venous ulcers alone have been estimated to cost between £300 and £600 million per year in health expenditure in the UK (Hall et al, 2014).

Definition of leg ulceration

Graham et al (2003) undertook a systematic review of prevalence studies of lower limb ulceration and found that the definition of ‘ulcer’ was inconsistent, the population was ill-defined, and there were differences within study designs that meant data could not be pooled effectively. More recently, Hall et al (2014) undertook a point prevalence study of complex wounds in one city in the UK and also identified problems with comparisons due to the inability to identify an internationally agreed definition of a leg ulcer. The absence of consistent definition appears to be a constant theme within the wound care literature.

The definition of chronic leg ulcer for the purposes of this study is ‘a break in the skin between the ankle and the knee of 4 weeks or more duration’ (SIGN, 1998; SIGN, 2010). This is a definition commonly used and understood as it enables the differentiation between an acute healing wound and an ulcer that requires altogether different treatment.

Prevalence of leg ulceration

Leg ulceration has been increasingly reported amongst PWID (Pieper et al, 1998; Godley, 2007; Guild, 2008; Beynon et al, 2010; Devey, 2010; Goodall, 2010; Greene, 2010; Powell, 2011b) although the precise prevalence was unknown, and no recent prevalence studies have been found to update this.

Risk factors for leg ulceration

In older people, venous ulcers are primarily caused by a failure of the calf muscle pump to work efficiently, which can lead to valvular incompetence within the deep, superficial or perforating veins of the lower leg (Nelson, 1996). Venous stasis may then occur which is exaggerated in patients with mobility problems or those whose occupation necessitates long periods of standing or sitting with little active movement (O'Hare, 1995). The valve damage may cause influx of blood at high pressure from the

larger veins into smaller fragile capillaries causing damage which results in cell death and subsequent ulceration (Dormandy, 1997).

Assessment of leg ulceration

Within the UK typical care of venous ulceration comprises objective assessment, including a Doppler test and calculation of ABPI, high-compression bandaging and appropriate referral (Franks et al, 2004; SIGN, 2010).

The assessment comprises careful history taking of known risk factors for vascular disease: tobacco smoking, alcohol intake, BMI (Body Mass Index), nutritional intake, medication, cardiac history including claudication, diabetes, joint and mobility problems, DVT, cellulitis, leg fractures and occupations that involved standing for long periods, parity (for females), as well as clinical signs of venous disease: varicose veins, ankle flare, and skin changes such as lipodermatosclerosis or skin staining (SIGN, 2010). The assessment should identify causative factors to enable treatment planning tailored to the likely cause of the ulceration (Moffatt et al, 2007, p47).

Studies related to causation in injecting drugs users who are younger are limited however, some insight about presentation, risk and impact of ulceration can be gleaned from case reports and overviews.

Butcher (2000) describes a client with a twenty-year history of injecting and a three-year history of chronic leg ulceration, who had marked pitting oedema, ankle flare, and heavy brown staining of the skin to the lower two-thirds of the calf. He had an irregularly shaped ulcer 6.5 x 5cm and several satellite ulcers.

Devey (2010) describes a client who had been femoral injecting for 12 years and had ulceration with venous changes – ankle flare, oedema, varicose veins, hypertrophic skin changes, and varicose eczema.

Forshaw and Power (2001) report a 41 year old injector with multiple lower limb ulceration distributed along the line of the long saphenous vein, who had injected a mixture of drugs including amphetamine, crack, heroin and methadone both intravenously, and subcutaneously, in the lower limb. The ulcers were deep, linear with irregular necrotic borders, an offensive smell, and surrounding cellulitis. The authors hypothesise that ulceration in a drug injector is caused by possible acute thrombophlebitis from repeated injection into a vein, whilst surrounding peri-venous and subcutaneous injections may cause tissue destruction, cellulitis and abscess formation. They consider this may have been compounded by venous insufficiency, lymphatic destruction and lymphoedema secondary to the sclerosing effects of multiple injections.

Mittal and Pahuja (2000) describe four cases of multiple leg ulcers in Indian males with a history of drug injecting. Specific demographic and wound data is not provided for each case, but the patients had a history of injecting buprenorphine, diazepam, pentazocine, and norphin. All four showed sclerosis, pigmentation, and non-pitting oedema of the lower legs with dermal fibrosis, proliferation of dermal capillaries and pseudoepitheliomatous hyperplasia. It is unclear whether this pathology might relate to all injectors or to these specific drugs, which are not in common use in Scotland.

Pardes et al (1993) describe four patients with leg ulceration following popping – one had multiple ulcerations though the specific sites are not stated, one had an ulcer overlying the left medial malleolus, one had ulceration that extended from ankle to middle of calf, with a smaller ulceration over the right medial malleolus, and the fourth had an ulcer on his right leg with site unspecified. In two patients there was evidence of venous insufficiency. There is a lack of detail in the reporting of each case with investigations described as ‘normal’, but no specific investigation named. In each case the ulcers appeared years after injecting in the area had ceased. The authors surmise that skin popping led to lymphatic damage or some degree of microvascular compromise that took a long time to ulcerate, but also state that the reason why the ulcers developed is unclear.

Beynon et al (2010) note the premature aging effect of drug use, and in particular the effect on the lower legs. Damage that occurs in the active period of injecting persists and advances long after injecting has ceased, and legs in particular can prematurely age by around 20 – 30 years. Venous ulceration can occur during drug injecting or years after injecting has ceased (Pieper, 1996b; Lawson, 2010). In a retrospective study of venous ulcer healing in injecting drug users (Pieper, 1996a), the average age of participants was 42 years. She cites the main risk factors for venous insufficiency in PWID as deep vein thrombosis, vein injury from multiple injections, and pathological changes from the sclerosants and adulterants contained in the injected drug. According to Pieper (1996a) leg ulcers of PWID tend to be larger in area and more numerous than those reported in other venous ulcer studies.

These case reports together show young PWID have ulceration of longevity, with marked signs of venous disease or chronic venous insufficiency. Ulceration may appear long after injecting has ceased, and may be multiple and in various sites on the lower limbs.

Chronic venous insufficiency

In an American study of 204 PWID, chronic venous insufficiency (CVI) was found to be a common occurrence amongst 87% of participants (Pieper and Templin, 2001).

CVI manifests itself below the knee with oedema, heaviness and fatigue, together with burning sensations near potential varicosities. The skin may become dry, fibrotic and darker in colour, and eventually ulcers may develop. The most common causes of CVI are deep vein obstruction, such as thrombosis, and superficial vein regurgitation due to dysfunctional valves (Pieper and Templin, 2001).

CVI commonly occurs in the third or fourth decade of life for PWID (Pieper, 1996a) and in the sixth or seventh decade for other persons, often with a history of leg injury or phlebitis (Burton, 1994; Scott et al, 1995). Chronic venous disorders (CVD) are

classified in a staging system that ranges from no visible or palpable signs of venous disease through the signs of CVI, varicose veins, oedema, skin changes to ulceration as end-stage venous disease (Eklof et al, 2004).

Pieper et al (1998) administered a questionnaire to 32 drug injectors about their drug history and experiences of pain with venous ulcers. Greater pain was associated with larger wound areas. The study also revealed that 14 participants (44%) had a history of DVT, and 21 (66%) had a history of lower leg cellulitis. 31 participants had used heroin. 29 persons had been groin injectors.

Chiang et al (1990) report on eight cases (6 men, 2 women) who had been injecting into the veins of their lower extremities; 4 participants had also injected in their groins; 7 patients (12 limbs) had experienced ulceration, and there was recurrence in 10 limbs. The age range of the patients was 28 to 40 years. Venography revealed obstructive venous disease in 7 limbs, 3 showed venous collaterals and one had valvular incompetence. The authors consider that chronic venous stasis is seen in younger patients but that a strong muscle pump may moderate the effects of venous obstruction.

Chronic venous insufficiency characterised by swelling, pain, ulceration, preceded by injecting in the legs and groin, appears to be prevalent in PWID. Venous ulceration is treatable by reversing venous hypertension with the use of graduated compression therapy (The Alexander House Group, 1992).

Thrombosis

Scott et al (1995), in a case control study investigating risk factors for chronic venous insufficiency in an elderly population, found that DVT was a pre-disposing factor. Injecting is also associated with a higher risk of clotting, thrombosis and embolism particularly if the femoral vein is targeted (Fah et al, 2002; Glenesk, 2008).

Vascular damage often begins with thrombophlebitis (Maliphant and Scott, 2005) which has been reported as a complication of injecting in the lower limb (Stuck and

Doyle, 1987). The thrombophlebitis appears as swelling, induration, erythema and tenderness along the course of the vein and can precede deep venous thrombosis. After larger or more prominent veins are used, obliterated, or 'burnt out', smaller and more peripheral vessels are used. These have less adventitial support, and extravasation can occur easily with resulting adjacent infections. With continued abuse the superficial veins of the legs and feet become thrombosed and cordlike. The most common area for this is the greater saphenous vein at the medial malleolus with proximal extension (Kirchenbaum and Midenberg, 1982; Mottahedeh and Da Silva, 2003).

Formation of DVT in the lower limb is thought to be due to trauma caused by injecting and the natural coagulation response of the body to injury (Baldeweg, 2000; Syed and Beeching, 2005). Formica and Perazella (1998) report a female drug user who after losing intravenous access began subcutaneous injecting into her legs and buttocks. She had experienced several bouts of cellulitis in the lower leg, complicated by chronic non-healing ulcers as well as superficial and deep venous thrombosis (DVT). She had an inferior vena cava filter installed due to the frequent episodes of DVT.

McColl et al (2001) reviewed 322 women aged 16 – 70 years who presented between 1993 and 1997 with venous thromboembolism in Glasgow. Injecting drugs using the femoral vein was a common risk factor in 13.7% (n = 44). All women with drug related thrombosis presented with DVT. The mechanism of thrombosis was also thought to be due to the trauma of repeated femoral vein puncture leading to endothelial damage and the injection of irritant materials.

In 1999, Syed and Beeching reviewed all DVT patients (n = 232) admitted to a large district hospital. Intravenous drug use was the causative factor in 48% of those of 40 years of age or younger (Syed and Beeching, 2005).

Three cases of chronic leg ulceration are reported by Sudhindran (1997) in a journal letter. No detail about the ulceration, or the patients, is provided but the author states that all three patients were injectors with a history of groin injecting. All had suffered femoral vein thrombosis, and the ulcers were considered to be post-thrombotic.

Woodburn and Murie (1997) state that PWID can develop post-thrombotic ulceration, but they would also expect to see symptoms of underlying venous disease. They consider that ulceration may occur after intra-arterial injection, and skin necrosis may follow vasculitis and capillary thrombosis, and therefore compression therapy would be of little use.

MacKenzie et al (2000) identified increasing use of the femoral vein for access in a retrospective study of patients admitted to the Infection Unit in Aberdeen with DVT. Twenty patients were identified with injection-related iliofemoral venous thrombosis. Concurrent with the clot, 9 patients also had groin abscesses. Following treatment, seven patients were left with a chronically swollen post-phlebotic leg.

Gorman et al (2000) state that post-thrombotic syndrome complicates 50 – 75% of DVT. Clinical features include pain, swelling, dermatitis and ulceration. McColl et al (2001) considers that there is clinical uncertainty about the best method of treating intravenous drug users with DVT. Erratic compliance issues with oral anti-coagulants can lead to under and over-coagulation.

Importantly, deep vein thrombosis is common in drug users, but there may also be sequelae in the form of post-thrombotic syndrome particularly if the clot is proximal to the calf as reported in many femoral injectors (Nicolaidis et al, 1980).

Summary of risk factors

Within the existing literature a number of signs and symptoms have been reported in injectors who have experienced ulceration including cellulitis, abscesses and infection, thrombosis and DVT. Some authors suggested causative factors which include groin injecting, arterial hits, repeated injecting in the same area, injecting cocaine, poor hygiene and adulterants in the drugs injected. All of these factors need to be explored in more depth to identify risks for skin breakdown in PWID.

2.10 Harm reduction

Harm reduction seeks to reduce the damaging effects of drugs by teaching skills and offering individualised health information and resources (Schmidt and Williams, 1999). It is wider than individual behaviours and needs to address public health needs also (Kippax and Race, 2003).

No specific harm reduction studies were found that related to reducing the development of leg ulceration. Many commercial materials such as ‘The Safer Injecting Handbook’ (Preston and Derricott, 2013) describe ways to make the injecting process safer, and state that problems that can occur such as infection and ulceration however, these form part of a list of complications and are not sufficiently focussed to demonstrate a clear link. No materials could be found that discussed what sequence of events might lead to ulceration.

2.11 Challenges and the need for this study

Whilst there is literature about leg ulceration, literature about injecting drug use, and literature about PWID, there is little truly known about ulceration in young PWID. However, clinical experience, observation, and case reports reveal there is a growing leg ulcer problem in young PWID (Godley, 2007; Guild 2008; Powell, 2011b), and the extent of this is unknown, risk factors are not clear and prevention methods are unidentified.

Other authors have already called for more work to be done in this field:

- McColl et al (2001) recommended that the long-term sequelae of venous thromboembolism in PWID should be investigated.
- Maliphant and Scott (2005) investigated femoral injecting and recommended a longitudinal study to examine the relationship between groin injecting and loss of vein patency. They also suggested that work was required to determine the prevalence of groin injecting and the incidence of associated problems.

- Taylor et al (2005) recommended the development of surveillance systems nationally and internationally to monitor the incidence of serious soft-tissue infections among PWID.

Finally, in 2006, Rhodes et al noted an absence of published data on physical injecting sites and the need for such data in future work (Rhodes et al, 2006).

2.12 Research questions

Whilst it is clear that leg ulceration is a problem for PWID, it is not known what the extent of the problem is, and therefore the first research question was:

- 1) What is the extent of skin problems and chronic leg ulceration in young people who inject drugs?**

There are a number of issues identified in the literature that may contribute to leg ulceration such as injecting in the legs and groin, hygiene, and homelessness, but direct risk factors for leg ulceration are unknown. This led to the second research question:

- 2) What causes chronic leg ulceration in young PWID?**

Once it is known what causes the ulceration, how can the risk be reduced and leg ulceration prevented?

This leads to the third research question:

- 3) What are appropriate harm reduction measures in young PWID?**

Identifying the aetiology will allow the exploration of targeted harm reduction methods.

Chapter summary

The initial literature search revealed no empirical studies that identified the prevalence of skin problems and leg ulceration in PWID, nor were there any empirical research papers that identified causation of leg ulceration in PWID. Consequently there was no literature recommending harm reduction methods to prevent leg ulceration. There was

clearly a gap within the evidence base relating to leg ulceration in PWID, and a difficulty as there was poor definition of terms throughout. The narrative review therefore looked more widely at potential contributing factors within the published literature related to aspects of drug use that might contribute to skin breakdown and leg ulceration.

Having identified these research questions, Chapter 3 will discuss how these questions may be answered.

Chapter 3

Methodology, Related Methods and Plan for Analysis

Introduction

This chapter begins by examining the underpinning philosophies and various clinical and health research methods which were considered in order to generate knowledge to inform practice (Gerrish and Lacey, 2006, p5).

The chapter then outlines the sequential explanatory mixed methods approach to this applied health research study that was chosen to answer the research questions:

1. **What is the extent of skin problems and chronic leg ulceration in young PWID?**
2. **What causes chronic leg ulceration in young PWID?**
3. **What are appropriate harm reduction measures for leg ulceration in young PWID?**

The chapter concludes with a description of the ethical considerations.

3.1 The underpinning philosophies

All research has a philosophical foundation, and there are assumptions upon which this study is based. In the following section different philosophical ideas are considered with relevance to the research questions.

Positivism

Positivism is a theoretical position strongly associated with quantitative, or empirical, research that believes that scientific truth can only be derived from that which is observable by the human senses (Gerrish and Lacey, 2006, p538) and that which can be counted such as in numerical form. Positivism seeks to derive theory from evidence but it can be argued that there is no single definitive positivist view (Paley, 2001).

Positivism also explains the world in terms of ‘universal laws’. Some laws may be universal (such as the law of gravity) but the circumstances within which laws are applied may differ. Sometimes this may produce the same effects and sometimes this may differ. It is unlikely that the exploration of leg ulceration in young PWID within a specific population in a specific city would be the same in a completely different group in a different country, as it is known that drug injecting practices differ across the world. For example, heroin is the most commonly injected drug, but it is derived in different ways in various countries, and therefore its purity, appearance, and ultimately its effects may differ. The development of ulceration is therefore likely to be a complex and potentially multi-causal problem that may be influenced by many different things.

Foucauldian and post-structuralist traditions (Dyson and Brown, 2006, p55) challenge traditional positivist research on the basis that positivists may not make clear the conditions under which the research was undertaken – thus hiding certain aspects of the research process (Dyson and Brown, 2006, p66). Post-structuralists consider that the reality that we think we know may just be one of several possibilities (Dyson and Brown, 2006, p54). The activities of the researcher can create rather than reflect the social world for example, who is to know what reality is, since it may be what is perceived by the human researcher and may be dependent on a number of different relationships. For example, questionnaires may be devised in such a way as to encourage responses that may not be the preferred answer of participants but may demonstrate the restricted views of the researcher, thus creating bias and false outcomes.

Adopting a positivist stance means that it may not be possible to find a cause for leg ulceration in PWID as this may not be regarded as something observable. The ulcer itself is observable on the skin, but what has caused it may not be clearly seen and may be affected by different physical and social circumstances. PWID often have very complex lifestyles that are challenging to observe and understand. Positivism assumes

that phenomena are measureable using the deductive principles of the scientific method (Bowling, 1997, p110). However, in this proposed study there is so little known about the phenomena under investigation that knowledge needs to be developed from data collected. Positivists also believe in cause and effect which is determinism (Parahoo, 2006, p40), but cause in a rather weak sense because the cause may not be observable or measureable (Paley, 2001). However, postpositivism believes that this is not absolute and so it is more realistic to identify ‘probable causes’, and therefore postpositivism is more suited to underpinning contemporary empirical research (Clark, 1998; Routledge, 2007). Science is still deemed to require precision, logical reasoning and attention to evidence but is not confined only to what can be observed (Clark, 1998). Data are acceptable in inferable forms such as self-reports inherent in interviews or questionnaires (Clark, 1998). From data such as these, theories of causal and risk factors may be proposed, and tested using an in-depth study.

Scientific Realism

Scientific realism is potentially insightful – ‘it is able to probe what is ultimately generating the way things are. It doesn’t stop short; it asks why things are happening’ (Dyson and Brown, 2006, p43). For example, are leg ulcers occurring because of a particular social environment, or a combination of social and physical environments – are they linked to homelessness, for example? ‘Scientific realists take the view that, just because you cannot directly apprehend a concept or a process does not mean that it does not have real consequences’ (Dyson and Brown, 2006, p85). Therefore it is important to observe but also to take into account the context and other factors that may occur that are potentially hidden, and which positivism would ignore. It would be realistic to identify probable causes of ulceration based on data accumulated, even if these cannot be observed or directly proven.

Critical Realism

Generating evidence that may be as close as possible to the truth is a critical realist approach which combines the search for a high level of objectivity within data collection, whilst appreciating that the 'absolute truth' might not be attained (Parahoo, 2006, p41; Burns and Grove, 2005, p23). Asking PWID to recall and explain illegal activities may mean that information given is not necessarily the truth, either because they do not wish to tell the truth, or because they do not remember as a result of time-delays in recall, or possibly a drug-related memory loss. Similarly participants may under-estimate or over-estimate drug use. In addition, the Hawthorne effect of participants telling the researcher what they think the researcher might want to hear may affect the absolute truth within the data (Gerrish and Lacey, 2006, p250).

Controlling bias in any study design is a major challenge. The construction of a questionnaire and the phraseology of individual questions might include bias from the researcher's own natural view point (Porter, 1993). Adopting a systematic and rigorous approach, with intent to reduce potential variables and bias, will enhance the accuracy of the research (Bowling, 1997); however, realism is essential because much of the data will be based on the recall of participants.

The combined use of differing methods within this study, such as the triangulation of qualitative and quantitative work, embraces the ethos of postpositivism recognizing the value of different approaches to developing nursing knowledge (Clark, 1998).

However, scientific realism accepts that probable causes of leg ulceration may be identified but that these may be circumstantial. Other authors have encountered similar challenges in undertaking work that has an empirical base but requires application to the real-life circumstances involved in nursing (Giuliano, 2003). 'Contemporary empiricism' is the term used by Giuliano (2003) as a method to deal with the dilemma associated with the objectivity of empiricism and the subjectivity of human experience more associated with nursing individuals. Contemporary / Scientific / Critical realism are closely overlapping approaches. The blurring of the edges of established

philosophical ideas such as empiricism appears to be an emerging theme within the nursing literature and is used as a way of dealing with the application of research into the vagaries of nursing practice.

Philosophical stance for this study

Critical realism is the approach which will underpin this study, allowing consideration of a number of factors and is based on three levels of reality:

- The '*empirical*', comprised of experienced events such as leg ulceration.
- The '*actual*', consists of events whether experienced or not such as the drug using history, but also of other things that may not have been considered by the researcher.
- The '*causal*', which consists of structural mechanisms which generate events such as the environment, or the injected drug (Porter, 1998, p171).

This is not a hard and determinist philosophical stance, it does not consider that events will always cause things to happen in a particular way. It accepts that many systems or events may be occurring at any one time, all potentially having an influence on outcome. Critical realism allows the rational interpretation of evidence to examine what exists and to point a way forward (Porter, 1998, p179). The opportunity to investigate aspects of leg ulceration in PWID by determining the extent of the problem, and then exploring it further, is rooted in critical realism and this study provides a basis to inform practice and from which other studies may follow.

Therefore a mixed methods approach was proposed, to maximise the information gathered, by exploring both the experiences, and behaviours together with circumstances, of the injector who has or has had leg ulceration. Mixed methods research studies are defined by Tashakkori and Teddlie (2003, p11) as using 'qualitative and quantitative data collection and analysis techniques in either parallel or sequential phases'. In this study, empirical data were acquired to determine the extent of leg ulceration and possible factors involved in the development of leg ulceration in

PWID, by asking specific questions to build up a picture of drug using activity and then these aspects, specific to leg ulceration, were further explored in more detail by using a qualitative approach (Carter and Henderson, 2005, p216).

Qualitative research is often seen as diametrically opposed to empiricism however, this view has been questioned (Clark 1998; Paley, 2001; Martin and Stenner, 2004) and similarities between qualitative and quantitative research are apparent. The two methods can complement each other (Carter and Henderson, 2005, p216). The quantification of research is clear within both methods, as a statistical count and inference is apparent within the analysis of quantitative methods, whilst identifying themes and number of occurrences within the qualitative narrative is broadly similar in approach. Therefore the mixed methods approach for this study uses two methods of data collection, and requires two different methods of analysis, but both methods must be open to scrutiny, and be transparent, valid and reliable. Statistical methods of analysis were utilised for the quantitative data and are widely accepted as scientifically valid and will be discussed in more detail later in this chapter.

In the qualitative stage, analysis of the narrative acquired through semi-structured interviews may be viewed as less scientific. It is more time-consuming, and to be accepted it is even more important that the route to analysis is transparent and reliable and this will also be discussed later in this chapter.

The two separate methods – quantitative and qualitative have different epistemological stances but a combined approach and subsequent analysis requires an adjusted philosophical paradigm (Tashakkori and Teddlie, 2003). The research aims and questions should be answered by using all approaches to understand the problem (Creswell, 2014). The approach evolved further from the original postpositivist and realist stance into a more pragmatic view. Giddings (2006) argues that mixed methods is a pragmatic research approach that fits comfortably with postpositivist epistemology which suggests the same world view (Creswell, 2014) remains throughout.

The pragmatist approach allows more than one method to be used in research, and looks to many approaches toward collecting and analysing data – depending on what best fits the research question. In this study the research question cannot be answered by one method alone so a pragmatic approach and the resulting mixed methods of an explanatory sequential design has been used (Creswell, 2014, p224). It may be argued that a mixed methods approach in terms of theoretical and philosophical underpinning is still developing (Giddings, 2006) and as such there are many approaches, all of which can contribute to mixed methods.

Chapter 2 showed that the evidence relating to leg ulceration in young PWID is limited. Equally, the causative, contributory and contextual factors are also unknown. It would therefore be appropriate to conduct an empirical study to produce data that may both inform and help develop existing policy and practice by identifying the scale of this problem but also provide a foundation of knowledge for practice and create a baseline for future studies related to patient care (Giuliano, 2003).

Quantitative research aims to deal with quantities and relationships between variables and is useful for collecting numerical or measurable data. A large number of observations may be made, and by using a process of induction, it will be possible to draw conclusions (Parahoo, 2006, p34) but it is always difficult to achieve absolute rigour, especially within human studies. The inductive method involves moving from the specific to the general and consists of description, classification, correlation, causation and prediction (Parahoo, 2006, p34; Powers and Knapp, 1995, p86).

Conclusions may be drawn but they may not be regarded as absolutely factual as so many variables will exist within human studies. Quantitative studies may also include qualitative elements, such as points of clarification or further explanation within a questionnaire, and vice versa, qualitative research may also include quantitative elements where, for example, numbers of respondent answers may be counted.

However, nursing promotes well-being and any nursing theory takes into account context and environment and therefore nursing research must extend beyond the medical model, biological models and basic empirical science (Rocha et al, 2000).

Qualitative research aims to explore attitudes, behaviours and feelings, within context, and may be more useful to explore what exists especially when so little is known about a phenomenon. For example, a number of injectors may state that they inject into their legs. The number could be counted and a numerical value gained. However, other types of enquiry are needed if *why* they inject into their legs is to be explored (Giuliano, 2003). This sort of information would be better gathered using qualitative techniques such as semi-structured interviews, allowing exploration, rather than questionnaire data which can limit answers.

Therefore using the two approaches, quantitative and qualitative, appears to suit this study where the information required extends beyond empirical data. The use of both qualitative and quantitative methods within one study may be termed 'mixed methods' and each 'method' will be addressed in detail in this chapter (Creswell and Plano Clark, 2011, p3).

This study will aim to generate knowledge that will guide clinical practice, so it is important that the methods adopted should lead to the generation of data that could be generalised to a wider group. Generalisation would require an explicit chain of reasoning between the general knowledge accrued, the individual data and the context from which it is derived (Lincoln and Guba, 1985, p110). Generalisation may be accepted for quantitative research due to sampling and statistical methods which are representative, but is less accepted in qualitative research.

However, the results from both methods should help inform future practice, whether or not they are truly generalisable. Methodology, methods, reliability, validity, analysis and presentation therefore all need to be transparent to readers, and will be discussed in detail within this chapter.

3.2 Aims of research design

The main aim of the study was to develop a greater understanding of the risk and causal factors involved in the development of chronic leg ulceration in young PWID.

The secondary aim was to analyse these findings and use them to suggest appropriate harm reduction methods to prevent chronic leg ulceration.

3.3 Research design process

Research designs used with PWID within Scotland were explored to identify the best and most practical approach for this study within the given time frame of a PhD degree.

3.4 Quantitative designs

Randomised controlled trial

The gold standard of empirical research is considered as the ‘randomised controlled trial’ (RCT). To undertake such research, a sample population that can be identified and followed and compared is essential and outcomes may require to be measured and observed over time (Gerrish and Lacey, 2006, p239). This would be difficult as the sample population of PWID is largely unknown and challenging to follow. However, this may be useful for a follow-up study once more is known about the injecting population who have wounds. As ‘the gold standard’ cannot be applied, it is even more important that the methods chosen are clearly articulated and rigorously conducted so as not be viewed as a ‘second best’ option, rather than an alternative approach.

Case control studies

Several studies have used case-control methods to identify risk factors in disease development in PWID (Passaro et al, 1998; Bellis et al, 2001; Roy et al, 2004; Taylor et al, 2005). However, all had access to case notes or relevant information from drug misuse databases. The Information Services Division (ISD) of the Scottish Government

maintains The Scottish Drug Misuse Database (SDMD) which is a national information source on the misuse of drugs in Scotland. The SDMD is based on systematic recording of a national dataset on clients seen at a broad range of services. The database holds information on demographic and behavioural characteristics of new clients coming to the attention of medical services (for example general practice or hospitals) and specialist drug services. Information relating to wounds and leg ulcers is not available on the ISD database, and case notes are not easily accessible, and so would not provide the type of information required for this study.

Longitudinal studies

Pieper and Templin (2001) recommend longitudinal studies to discover patterns in disease development and the effects of interventions but they do not describe how this might be undertaken in order to achieve success with this population. However, as the long-standing Edinburgh Addiction Cohort studies and the DORIS study in Glasgow have shown, it is possible to follow up a significant proportion of PWID (McKeganey et al, 2008; Macleod et al, 2010). However, recruitment and the long-term nature of prospective and longitudinal studies may be challenging and time-consuming in PWID due in part to the often transient and chaotic nature of their lives, frequent incarceration and early mortality, as well as the difficulty in achieving follow-up with individuals who may have no fixed address or reliable contact details (Pieper and DiNardo, 1998; Martin and Stenner, 2004; Syed and Beeching, 2005; Kemm, 2006). Whilst a longitudinal design might have been useful there was limited time available to achieve the necessary follow-up.

Adaptive methods

Atkinson's study conducted with homeless men in Glasgow adopted an interventional adaptive approach to investigating a vulnerable population (Atkinson, 2000, pxi). The researcher visited homeless men within their hostel accommodation to make assessments and referrals and then to evaluate the effect of the interaction on the men.

Using an interventional approach with a group of PWID with leg ulcers would not enable the scale of the problem and causative factors to be identified. Providing interventions such as assessment and wound management would limit participatory numbers, be fraught with ethical dilemmas, and reduce time available for data collection, but would have been a useful way to assess prevalence of infection.

Epidemiology

Epidemiology is the study of ‘how often health related events occur in different groups of people, why variations in the pattern of health and disease exist between populations and the application of this study to the control of health problems’ (Martin, 2005). In relation to the epidemiology of leg ulceration, there is some knowledge about the incidence and prevalence within the Scottish population (Scottish Leg Ulcer Trial Participants, 2002) and some more dated, but seminal, evidence relating to aetiology (Dale et al, 1983; Callam et al, 1987). However, there is no record in the literature of the incidence or prevalence of leg ulceration in PWID. Drug injecting is simply not reported as an aetiological factor in these studies and others (Callam et al, 1987; Moffatt and Franks, 1994; Moffatt et al, 2004). Whilst it may be presumed that there is a relationship between injecting into veins and the development of venous disease, of which the end-stage is regarded as ulceration (Burnard et al, 1982; Eklof et al, 2004), the factors which contribute to this are not clear. For example, do all individuals who inject into their legs develop ulceration? What is the likely time frame for this to occur? Is there a relationship between different types of drug injected and ulceration? Is there a relationship between the technique of injecting and skin breakdown? If these questions can be answered, then they should indicate how ulceration can be prevented.

With the limited knowledge currently held, it is impossible to develop a single hypothesis or set of theories by which to question participants. An open and critical, realistic, epidemiological approach allows such exploration and, by using a process of induction, ideas and knowledge about leg ulceration in PWID can be gained.

Survey methods

Surveys can be used to collect data within the variety of quantitative approaches described (Bowling, 2005, p190). The researcher collects data on the occurrence or progression of an outcome of interest without intervening, or attempting to alter circumstances (Martin, 2005, p101).

Pieper writes prolifically about venous disease in PWID (for example, Pieper and Dinardo, 1998; Pieper et al, 2000; Pieper et al, 2010a) but has not specifically examined prevalence, nor risk. However, she describes using robust and fairly consistent survey methods successfully in her research such as an administered questionnaire at a primary care clinic to investigate non-attendance (Pieper and DiNardo, 1998). She also administered a questionnaire with a physical examination of the lower leg to investigate chronic venous insufficiency (Pieper and Templin, 2001), and an administered pain assessment tool and questionnaire, at a primary care wound clinic where 80% of attendees had venous ulcers as a result of injecting drug use (Pieper et al, 1998). Utilising a survey allowed a large amount of relevant data to be collected quickly which would be helpful for gathering prevalence and risk factor data.

Cross-sectional retrospective design

Abelson et al (2006) developed a cross-sectional retrospective study design to identify differences between early and late onset injecting and recruited participants by convenience sampling to obtain a broad spectrum. Structured questionnaires were administered by face-to-face interview and participants were asked a range of questions relating to their injecting careers. Whilst the study relied on accurate recall, it had advantages in that participants could be approached and interviewed at first opportunity and therefore had not to rely upon appointments or follow-up. This design would allow data to be gathered on skin breakdown, history, injecting behaviours and risk factors which was a practical option for this study.

In summary

None of the quantitative approaches alone could have been used to answer all of the research questions. However, using an applied health research approach with a cross-sectional survey enabled the collection of prevalence data and information about injecting habits and skin breakdown to start to answer the research question '*What is the extent of skin problems and chronic leg ulceration in young PWID?*' and to some extent, the second research question '*What causes chronic leg ulceration in young PWID?*'.

Adding a second qualitative study to explore the survey data in depth and gather information about harm reduction from injectors themselves provided answers to the third research question '*What are appropriate harm reduction measures in young PWID?*'. Two studies like this comprised a 'mixed methods' design.

In the next section qualitative designs are explored to identify the best approach to a subsequent study.

3.5 Potential qualitative designs

Utilising a qualitative approach, sometimes viewed as interpretivism, allows an in-depth understanding of people's thoughts or behaviour (Parahoo, 2006, p62). The view of interpretivists is that human behaviour can only be understood within the context that it occurs, and the thinking processes involved are studied. For example, injectors may know that using clean needles will reduce the risk of vein damage, but may reuse old needles (*behaviour*) as they are not keen to visit the local needle exchange, and are unable to acquire fresh ones from another source (*context*). Parahoo (2006, p63) describes qualitative research 'as a means to understand perceptions and actions of participants', which is exactly what this study needed to do. Interpretivists see their methods and approaches as representing reality as closely as possible which is similar to the postpositivist approach of critical realism (Parahoo, 2006, p43). Further adopting

the realist approach allowed a more holistic exploration of leg ulceration in young PWID by investigating participants' own perceptions of the problem and the contextual factors such as environment, social issues and practical issues such as injecting equipment which may have affected their ulceration.

Phenomenology

Phenomenology looks at the meaning of experiences and could be a useful approach if the experience of living with a leg ulcer was to be explored (Briggs and Flemming, 2007). However, phenomenology would not help identify all the elements that contribute to leg ulceration occurring in young PWID or allow exploration of risk or harm reduction methods.

Grounded theory

Grounded theory looks at how individuals and groups make meaning together (Gerrish and Lacey, 2006, p190), and how particular concepts and activities fit together to form theory. The 'theory' is inductively derived from the phenomenon under investigation (Lathlean, 2006, p418). Drug injecting may be a cultural activity, but it also occurs in lonely habitats. Whilst interactions are important and may be very relevant to developing ulceration such as when individuals inject each other, there is some more basic physical data that need to be gathered that would not necessarily or so fully be obtained by using grounded theory. Often emerging data are compared to the existing literature as an ongoing process. Where there is virtually no literature, as with leg ulceration in PWID, this approach would be difficult to apply and it would not be possible to undertake a meaningful grounded theory study to answer the research questions posed.

Ethnographic approach

Ethnography seeks to study behaviour, interaction, customs and rituals, values and institutions within a culture or subculture (Gerrish and Lacey, 2006, p535). It is a useful method to help understand patterns in drug injecting habits, and factors that might relate to techniques or behaviour, but often ethnographic studies will involve data collection over a long period of time (Hammersley and Atkinson, 1995, p24). The period of time required for this approach is impractical for this mixed methods study. However, it is important to consider the culture of drug use carefully as it cannot be separated from the individual, who will be providing the information required to develop the insight into the practices and behaviours that might lead to leg ulceration (Murtagh, 2007). For example there must be interaction between the drug injectors and the supplier of the drug, and often with others who may, possibly, teach techniques such as injecting.

Taylor undertook an ethnographic study in which she was a participant observer amongst a group of over fifty women over a period of fifteen months (Taylor, 1993, p8). Her study of a female injecting community was the first to examine the lives of women drug users in this way, and the ethnographic method ensured that the research was grounded. Taylor describes an initial naivety to her approach because of unfamiliarity with PWID, despite background reading and theoretical knowledge. Taylor's philosophical approach utilised Weber's theory of social action that in order to understand social actions, the meaning attached to those actions by individuals undertaking them must be understood (Weber, 1947, cited in Taylor, 1994, p7). Taylor used the symbolic interactionist perspective (Blumer, 1969, and Mead, 1939, cited in Taylor, 1993, p7), with the aim of being able to witness and participate in the 'action' that was being investigated, and she used a feminist approach as her study concentrated on women, but from a perspective that viewed them as rational active individuals and not as stereotypical 'pathetic' creatures often portrayed in the media.

Observing drug users' injecting habits, within their own environment and culture, would be very interesting and informative but would not necessarily provide empirical

answers to the question of what causes leg ulcers. The researcher would be developing assumptions about what might cause skin breakdown and create ulceration but these would be subjective and potentially biased.

Familiarity and knowledge as well as speculative assumptions had been developed prior to starting this investigation, specifically through working with PWID, but now an empirical study was needed to prove causation by examining a large sample and using a consistent approach to ensure rigour. Exploring aspects of leg ulceration, within a physical environment familiar to drug injectors, such as their local IEP service, in which they feel safe, will combine a practical approach with the ideal. Gathering qualitative data using a quasi-ethnographic approach would appear to be appropriate for use in this study. It is 'quasi' because the study timescale, and the immersion within the drug user's culture and environment will be very limited, but the cultural aspects of ethnography are essential (Murtagh, 2007).

Case studies

The extent to which a case study approach might inform the questions being addressed in this thesis was limited. Case study research allows a phenomenon to be explored within its context (Gerrish and Lacey, 2006, p302), and allows a holistic view to be developed by induction (Giuliano, 2003). A case could be a current or former injector, who either had a leg ulcer or had previously had a leg ulcer. Case studies would allow a depth of exploration into individual circumstances, as participants could be interviewed in familiar environments, such as needle exchanges and drug treatment agencies, about their own circumstances – a 'naturalistic enquiry' (Lincoln and Guba, 1985). This means the research remains true to the nature of the phenomenon under investigation (Porter, 1993). Each participant 'case' could be explored using interviews and could be combined with document analyses, observation, and physical assessment (Zucker, 2001; Yin, 2003). Potentially, clinical case note review and patient assessment may corroborate and enhance the data collected from case study interviews.

However, due to the complex nature of leg ulcer investigation and treatment, it was impractical to conduct clinical assessment or seek access to medical or nursing notes.

There are already many published case reports or histories, but many of these are dated or are of limited value due to missing details such as demographics, medical and social history, drug usage and specific wound information (e.g. Hussey and Katz, 1950; Ritland and Butterfield, 1973; Butcher, 2000; Acton, 2008). Adding to these, even in an empirical way, would be of little benefit.

Focus groups

Focus groups with participants were considered as a method to collect the data but rejected as it would be challenging to make arrangements to gather a group of potentially chaotic individuals together at a pre-determined time and place (Carter and Henderson, 2005, p221). In addition, PWID participate in illegal activities, and expecting the sharing of personal information about drug injecting habits with other injectors would be unethical and breach confidentiality. Also, bringing a group of potentially volatile and unpredictable individuals together in a group with a sole researcher might be unsafe.

In summary

This study needed to build on what had gone before by specifically focussing on what was already known, developing that knowledge further and eliminating gaps. Never having been injector, and despite having insight from working with PWID, there is a limit to the depth of understanding without personal experience. It was thought highly likely that PWID would have ideas themselves about what has caused their skin to breakdown, such as 'a bad hit'. The definition of a 'bad hit' to one drug injector might be missing a vein, whilst to another it may be using too much acidifier. By using an open method of questioning, such definitions and contributory factors were explored and clarified.

The information gained therefore, was drawn directly from participants who had experienced leg ulceration and without the ‘contamination’ of a view from other healthcare professionals (such as in case-notes). In-depth interviews conducted with participants had the capacity to describe, explain and explore issues from the perspective of participants (Gerrish and Lacey, 2006, p338).

Individuals with existing ulcers were able to provide information regarding recent behaviours and injecting practices that illuminated the problem. Those that had experienced ulceration and healed had views about what caused their own ulcers.

A risk with this method was the uncontrolled amount of data that could have been generated, and the potential level of subjectivity that interpretivist inductive methods might contain (Giuliano, 2003). However, the researcher was cognisant of reaching data saturation once no new relevant concepts emerged (Gerrish and Lacey, 2006, p200).

3.6 Qualitative analysis

Key features of qualitative analysis are definition of concepts, mapping the range and nature of phenomena, creating typologies and finding associations, providing explanations and developing strategies (Ritchie and Spencer, 1994, p176). There are a number of different approaches to analysis and the correct selection of methods is paramount, especially as concerns have been raised about the reproducibility and validity of results generated from qualitative data analysis and generalisability (Ritchie and Spencer, 1994, p175; Schofield, 2000).

Qualitative data have been criticised and disregarded because of the lack of visible access to both the research process and the analysis, possibly because of the difficulty in managing and presenting such a large volume of generated data. Often the material gathered is unwieldy and unstructured (Ritchie and Spencer, 1994, p175).

If the research findings were to be useful in policy making and in practice, and potentially applicable to a wider population, it was vital that the analytic method was transparent in order that it was clear how the findings were obtained.

Analytic induction

The analyst tries to formulate generalisations that hold true across all of the data (Lathlean, 2006, p418), and the researcher gathers data until no further data emerges that is inconsistent with a hypothetical explanation of phenomena (Lathlean, 2006, p421). As a hypothesis is difficult due to the dearth of literature, data collection may take a very long time to reach saturation. Although this method shares attributes of positivism and realism concurrent with the study approach, there are problems, not least because of the necessary, if tentative, hypothesis (Burns and Grove, 2005, p555).

Analytic induction may help identify circumstances that allow a condition to occur, for example injecting is likely to be linked to leg ulceration as this is already known, but analytic induction will not explain why all injectors do not develop ulceration. Since this is the very question that needs to be answered, this form of analysis is not suitable (Lathlean, 2006, p421).

Framework analysis

This study drew on framework analysis of the data collected given its suitability to policy research contexts and to applied research where key investigative objectives are set out in advance. It was initially described by Ritchie and Spencer (1994) and has several key features which were central to the framework's development:

- Grounded or generative: it is heavily based in and driven by, the original accounts and observations of the people it is about.

- Dynamic: it is open to change, addition and amendment throughout the analytic process.
- Systematic: it allows methodical treatment of all similar units of analysis.
- Comprehensive: it allows a full, and not partial or selective, review of the material collected.
- Enables easy retrieval: it allows access to, and retrieval of, the original textual material.
- Allows between - and within-case analysis: it enables comparisons between, and associations within, cases to be made.
- Accessible to others: the analytic process, and the interpretations derived from it, can be viewed and judged by people other than the primary analyst.

(Taken From Ritchie and Spencer, 1994, p176)

This provides a systematic and transparent process that is useful as it provides a clearly defined procedure and uses deductive methods. The method has been designed so that it can be viewed and assessed by people other than the primary researcher (Pope et al, 2000; Lathlean, 2006, p420; Ward et al, 2013; Spencer et al, 2014). It follows a well-defined procedure, but allows responsiveness, reconsideration and re-working of ideas as data is collected and analysed as an on-going process (Morse et al, 2002; Furber, 2010). Reliability of the data can be apparent as the data can be consistently assigned to the same category, either by different researchers, or the process can be viewed by others where each should reach the same conclusion as the researcher, as the method is transparent (Silverman, 1993, p145).

It may be ideal to allow participants to read and review transcripts of their own interviews, in order to check for accuracy and true meaning (Palfreyman et al, 2007). However, it may be challenging to arrange follow-up with PWID (Millburn and Brittenden, 2006) and similarly, a high proportion of PWID have difficulties with literacy (Yates, 2006) and may be unable to read a lengthy transcript. Therefore a method of analysis that can clearly demonstrate results that may be reproduced with the

same data by another researcher is ideal. For this reason, methods have been explored that may reduce the subjectivity of qualitative data interpretation, analysis and results. Framework analysis is becoming increasingly popular in health services research (Donovan and Sanders, 2005, p532) and has been used successfully in a previous study of PWID – investigating quality of life in those with leg ulceration (Palfreyman et al, 2007).

Another study used Ritchie and Spencer’s framework to identify themes when exploring user views of prison health services (Condon et al, 2007). The detail and implementation of the framework is not explained within their published paper however, they do not describe the analysis as a limitation and their aim, of exploring user views, is similar to that of this study in identifying drug user’s views on causative factors and harm reduction for leg ulceration.

The framework can be used to analyse different types of questions such as contextual, diagnostic, evaluative and strategic. As this study sought to answer questions related to ‘context’ – identifying what exists and ‘diagnostic’ – seeking the reasons or causes for what exists (Ritchie and Spencer, 1994, p174; Spencer et al, 2014, p336), it therefore was a suitable method for analysing the data generated from this study. The validity and reliability of the data will be apparent as the method of analysis allows itself to be transparent and open.

Framework analysis is compatible with QSR NVivo, the software package used to chart and organise the data but interpretation is still required (Ward et al, 2013).

Data collection was more structured than in some qualitative studies, and the method was useful within a tight timeframe where data needs to be linked with other findings. It involved five key stages:

1. Familiarisation – the researcher becomes familiar with the range and diversity of material gathered and begins the process of abstraction and conceptualization, making research notes.

2. Identifying a thematic framework – research notes are reviewed, key issues, concepts and themes are identified, examined and referenced- this involves the setting up of a thematic framework within which the material could be sifted and sorted, drawing upon the original research aims, making sure the original research questions are addressed. It involves making judgments about meaning, about the relevance and importance of issues and about connections between ideas.
3. Indexing – refers to where the thematic framework is systematically applied to the textual data which are the interview transcriptions. All the data are read and annotated against the framework and an indexing system applied. Judgments are made about the meaning of the data and although this process may be viewed as subjective, by indexing, the process is transparent and can be viewed and checked by others. Several themes can be identified within one sentence and from the coding it is possible to see patterns developing within the data, with repetition of codes.
4. Charting – at this stage a picture of the data as a whole is developed and the data are lifted from their original context and grouped according to their appropriate thematic reference. Charts are devised with headings and subheadings derived from the research questions or the thematic framework and summaries of the data are entered into the charts.
5. Mapping and interpretation - once all the data has been sifted and charted within core themes, the analyst pulls together the key characteristics of the data and maps and interprets the data as a whole, returning to the original key criteria for qualitative analysis identified earlier. Patterns are identified, and clarity and importance of different issues are weighed up.

(Taken from Ritchie and Spencer, 1994, p178).

These stages formed the framework by which the qualitative data in this study were analysed.

3.7 Sequential explanatory mixed methods design

None of the methods described on their own provided an ideal model for identification of prevalence and risk factors, but a combination was drawn upon to create a mixed methods approach to answer all the research questions.

There is criticism of this approach (Fakis et al, 2014) in that quantitative and qualitative methods are polarized and cannot be combined and that the theoretical underpinnings are so different as to be in conflict. However, others argue that the synthesis of two approaches is not only possible but desirable and that the need for exploring questions from all angles is suited to mixed methods (Creswell, 2003).

In this study the research questions required to be explored using the two approaches and the synthesis of the analysis will allow the research aims and objectives to be met, which would not occur with either method alone. An essential component of rigour in research designs is to ensure the choice of correct methodologies and philosophical underpinnings (Wilson and McCormack, 2006). ‘Mixed methods’ in this study was a sequential explanatory design comprising a quantitative study which informs a subsequent qualitative study.

3.8 Research design

A questionnaire survey eliciting quantifiable data as the first phase of the mixed methods study allowed a broad sweep of information to be gathered from PWID. The results were analysed enabling a possible theory or theories to be developed about causative factors and influences. The data were then used to generate hypotheses that were explored in depth within Phase 2 using in-depth interviews with a smaller sample of PWID with experience of leg ulceration as a sequential explanatory mixed methods study. The data gathered from the quantitative approach were combined and matched to the findings of the qualitative approach to enrich the study outcomes and generate conclusions to the research and thus this was a sequential explanatory design.

Phase 1 is the quantitative data collection and this will be described in the next section.

3.9 Phase 1 method

A retrospective descriptive survey of young PWID was conducted using structured interviews with a specially designed and piloted questionnaire to try to discover the extent of the problem, acquire information about individual experiences, and identify patterns in injecting habits. This method was selected to allow a wide spread of data to be collected in a short time frame to identify the extent and range of skin problems, and leg ulceration, and likely risk and causal factors. The research was conducted within environments familiar to participants such as drug treatment agencies and needle exchanges, allowing a naturalistic inquiry (Lincoln and Guba, 1985).

3.10 Questionnaire development

The questionnaire (Appendix 2) was developed specifically for the purposes of this study although it had been influenced by other studies that have utilised questionnaires with PWID (Smith et al, 1989; Makower et al, 1992; Passaro et al, 1998; Pieper et al, 1998; Pieper and Templin, 2001; Darke et al, 2001; Boys et al, 2002; Taylor et al, 2005; Abelson et al, 2006; Andresz et al, 2006).

The questionnaire needed to be administered quickly, so required to be relatively short as many PWID tend to be in a hurry – especially if they have attended a needle exchange to pick up their injecting equipment and have already acquired their drugs.

The questionnaire was split into sections:

- Demographics
- Questions about current injecting
- Questions about past injecting (for former injectors and long-term injectors)

- Questions about skin and or leg wounds
- General questions about participant's physical health

Brief demographics were collected consisting of initials, gender, date of birth and area of residence (postcode) – this was to provide a picture of the sample and to enable elimination of duplicate interviews (Taylor et al, 2005). There were also questions about length of time that injecting had occurred, and how old the participants were when they started injecting.

There were two similar sections about injecting – one for current activities and one for past habits. For those who had been injecting for over 25 years, if their habits had changed then both sections were completed – for current practice, and what they used to do, for descriptive analysis only.

Questions were asked about drug preparation techniques, and injecting activities (including skin cleansing), sharing of drugs and equipment, use of injecting paraphernalia, routes, and amounts of drug injected. Most of these were standard piloted questions drawn from either the NESI survey, which utilised an interview administered questionnaire which had been used successfully to measure injecting risk behaviours within similar settings, (Health Protection Scotland and the University of the West of Scotland, 2008) or from Taylor's study investigating an infective outbreak in Glasgow in 2000 (Taylor et al, 2005).

Additional questions related to injecting habits were also developed specific to this study and drawn from findings within the literature review. Questions such as cleansing of the skin and washing hands, licking of needles and use of saliva in preparing drugs as these had been reported as a risk factors in other studies (Binswanger et al, 2000; Murphy et al, 2001; Mottahedeh and Da Silva, 2003; Mercure et al, 2008; Phillips et al, 2013).

Questions were asked about ease of finding a vein, injecting in which body sites, hand dominance as that may affect technique, and whether participants had skin and muscle popped as these activities are implicated in skin breakdown (Murphy et al, 2001).

Known risk for leg ulceration

Specific questions which are common components of leg ulcer assessment were asked. These related to known venous and arterial signs such as varicose veins or claudication together with known risk factors for vascular disease: tobacco smoking; alcohol intake; BMI (Body Mass Index); nutritional intake; medication; cardiac history; diabetes; joint and mobility problems; DVT; cellulitis; leg fractures and occupations that involved standing for long periods; parity (for females), as well as clinical signs of venous disease: varicose veins and skin changes such as lipodermatosclerosis or skin staining (Eklof et al, 2004; SIGN, 2010).

Questions about infection, with the exception of abscess, were not asked as the complexity of definition and the requirement for recall of very specific signs was problematic and discussed earlier within Chapter 2.

Prevalence

The gathering of prevalence data consisted of counting the number of participants who had experienced a leg ulcer, and then counting of specified skin problems experienced at any time following the commencement of injecting activity.

Definition of skin problems

Previously, the definition of particular skin problems had been poorly addressed in the literature and injecting injuries were often referred to as ‘soft-tissue infection’, ‘abscesses’ or ‘ulcers’, yet these tended not to be defined and were very subjective

terms (Schnall et al, 1994; Reese and Sullivan, 1997; Graham et al, 2003; Takahashi et al, 2003).

One Scottish study (Scott, 2008) investigating the impact of supply of injecting paraphernalia in two Scottish cities used skin problems and injecting injuries as an outcome measure. These injecting injuries, apparent in the skin, were defined, which was helpful, but the source documents for the definitions were largely unclear though a pharmaceutical manual was referred to. The definition of ulcers included 'skin redness'. This is not a standard 'wound' or 'tissue viability' definition.

Terminology was important and clear definitions for skin problems and even for a venous leg ulcer has been difficult to find in previous studies (Hall et al, 2014). As no published definitions of injecting wounds could be found that were comparable, terms of known skin complications arising from injecting were developed and refined to ensure rigour based on existing literature and on clinical expertise (Darke et al, 2001; Finnie and Nicolson, 2002a; Scott, 2008). These are displayed in Table 2.

Utilising the same researcher and the same set of definitions ensured maximum accuracy in the documentation of skin problems, within the limitations of self-report and recall. Participants were asked for clarification of the meaning of words they used to describe injecting injuries such as 'abscess' or 'acid burn', in order that the same definitions were applied to the same type of description.

The position of lower extremity wounds was ascertained carefully to avoid confusion between the reporting of foot wounds and the reporting of leg ulcers. Previous work has recognised the importance of clarity of position of wounds especially when the term 'ulceration' is used which can be misunderstood (Firth et al, 2010).

Chronic refers to any wound that has been present for 4 weeks or more (SIGN, 2010).

Skin problem	Definition
Leg ulcer	A break in the skin between the knee and the ankle that remains unhealed for four weeks or more
Lumps	Hard swellings without broken skin, not red or hot or particularly painful
Track marks	Scratch marks, raised red veins, raised hardened veins
Abscesses	Raised red hot painful lumps, with or without obvious pus / broken skin – possibly required lancing/ surgery or have spontaneously burst
Acid Burns	Painful, blistered or broken skin directly attributed to use of acid
Broken skin	Injecting injury that has caused a break in the skin, wounds, or scabs that have healed in less than 4 weeks
Chronic wounds	Any break in the skin (not a leg ulcer) that has been present 4 weeks or more
Rashes	Multiple red or pink spots, raised or flat, that last longer than the short period following injection
Other	Any skin changes as a result of injecting that are not listed above

Table 2 Definition of skin problems

General health

Questions were asked about physical health to identify any significant co-morbidity, to identify risk factors that are known to impact on the development of leg ulceration or affect skin breakdown and subsequent healing. This included questions on smoking with known cardiovascular risk, alcohol, blood-borne viruses, medication and nutrition. Participants were also asked if they had access to empathetic healthcare.

Good nutrition is an essential component of wound healing and it is known that PWID are often malnourished and vitamin deficient (Johnston, 2007; Neale et al, 2011). Many go hungry because they cannot afford food and instead channel their income towards drugs (Anema et al, 2010). Advice was sought from a nutritionist in order to include simple questions on nutrition and body mass index (BMI).

This was also an opportunity to acquire useful insight from participants so space for free text comment was provided on what participants thought might cause wounds in some injectors but not in others. Participants were also given an opportunity to raise any questions with the researcher on completion.

Recall

A literature review undertaken by Darke (1998) examined self-report data in relation to drug use and comparators of criminal records, biomarkers, and collateral interviews. It concluded that self-report data was sufficiently reliable and valid to provide accurate descriptions of drug use, drug-related problems and history even after ten years has elapsed.

McElrath et al (1994) acknowledged potential difficulties with data collection amongst PWID who were required to recall events such as risk-taking behaviour. They undertook a longitudinal study with 366 PWID, using structured interviews to gather data, following up participants and asking them to recall behaviours reported previously at 6, 12, 18 or 24 months. Their findings supported the reliability of the use of retrospective self-reports.

Morrison et al (1997) approached PWID attending needle exchanges and asked them to participate in a study about injecting-related harm. The method comprised a semi-structured questionnaire and a medical examination, thus allowing a comparison between self-reported injuries and a clinician's assessment. PWID accounts of their injecting-related problems were found to be consistent with the clinician's findings. Another small but multi-centre study undertaken with 196 PWID across five cities in the US found self-reporting on injecting practices, drug use and sexual behaviours to be consistent and discrepancies only arose in relation to poorly worded questions (Needle et al, 1995).

A later large study (Napper et al, 2010) evaluated the validity of self-reporting heroin and cocaine users (n = 4027) about recent amphetamine use and compared this to urine samples. Self-reports demonstrated moderate to high validity and good reliability in test-retest data.

In addition, a number of previous studies have demonstrated that recall is more reliable, given the use of psychoactive drugs, than might have been expected (Mossey and Shapiro, 1982; Idler and Benyamini, 1997; Morrison et al, 1997; Pieper and Templin, 2001; Bell and Salmon, 2012).

By using interviews, acquiring accurate retrospective data is entirely dependent on the ability of participants to recall correctly, but these studies appear to show that this was a reasonably reliable method of gathering data. The questionnaire naturally focused on asking what was 'normal' or 'usual' for the participant in terms of injecting behaviours however, it may not have been the 'usual' practices that caused the skin problems. It may well be that on occasions the participant was 'rattled' (drug withdrawal characterised by sweating, shaking and malaise), desperate, injected by others, or unable to remember what caused the problems, and it may be possible that these incidents could not be captured at all. The limitation is that the data could not be verified against medical records or other objective means (Roose et al, 2009).

Reliability and validity

The questionnaire allowed data to be collected in a standardised manner and was administered by the same researcher each time and most answers were fixed responses which aided validity. Many of the components within the questionnaire had been utilised by other researchers in other studies and the development of key definitions for skin problems ensured that the same meaning was recorded for each participant by the same researcher providing content validity (Bowling, 2005; Bannigan and Watson, 2009).

The main issue relating to reliability was recall and whether the same participant would answer the same question in the same way if asked repeatedly (Ratray and Jones, 2007). The reliability of recall in drug users was discussed earlier in this chapter and appeared to be good.

3.11 Sample Phase 1

Geographical base

It has been estimated that in Scotland alone there are almost 60,000 problem drug users (ISD, 2011) but it is unclear exactly how many of these are injecting due to the difficulties in capturing the information (Hay and Smit, 2003; Hay and Gannon, 2006; ISD, 2012). It is known that Glasgow, West of Scotland's major city, has the highest rate of problematic drug use in Scotland, with prevalence rates remaining consistent in the last five years, and thought to be around 13,900 individuals (ISD, 2011) and including the largest number of injectors in Scotland (ISD, 2012).

Glasgow was selected as the study area. Problem drug use and its associated challenges are common and there are a number of statutory and non-statutory drugs agencies based in the city. Drug use is concentrated within areas of deprivation although there are IEP and methadone services across the city. As drug use has its own sub-cultures and PWID often educate peers within their own geographical areas, actual injecting practices can vary from suburb to suburb (Macleod et al, 1998). A wide geographic sample even within one city, therefore, was important to ensure variations due to locality were captured. Participants were recruited from eight different venues (IEP services and methadone clinics) in the north, south, east, and west of Glasgow.

Defining 'young' PWID

Leg ulceration is typically a disease of elderly people, but it was important to define the term 'young' to differentiate between elderly individuals who develop ulceration as a

progression of disease partly attributable to old age, and the presence of leg ulceration in younger people which is unusual. It is the appearance of ulceration in young people who are or have been drug injectors which is being investigated.

By including older people within the study population, there was increasing likelihood of age-related disease becoming a factor in the development of leg ulceration and therefore the epidemiological picture would become blurred. The upper age was selected as an age classed often as entering middle age (44 years) and beyond, where general health may start to demonstrate features of aging. This may further complicate the history of individuals by introducing systemic disease which could be associated with the development of ulceration such as vascular problems, diabetes and rheumatoid disease.

The majority of drug injectors fall into the 15 – 44 years age range (ISD, 2012), and the research has deliberately excluded under-age participants to avoid the challenges of including children, so only those aged 16 years and over have been included. Additionally excluding drug injectors over the age of 44 years aimed to reduce the influence of age-related disease impacting on ulcer development.

Sampling strategy Phase 1

An ideal sample is a miniature version of the population, but it was not known accurately how many injectors there were in Glasgow, how many were male and female, and what the age groups were. It was impossible within the constraints of practical research to survey the whole of the drug injecting population within Scotland (the target population) to identify the true scale of skin problems (Gerrish and Lacey, 2006, p173) and it was more practical to identify a smaller sample. However, sampling strategies for drug using populations are fraught with difficulties as many drug injectors have unstable accommodation, are frequently incarcerated, and engaged in chaotic life styles which meant arranging appointments for interview or follow-up was difficult or impossible (Robinson et al, 2006; Powell, 2011b).

Geographical sampling, taking a sample of people resident from a particular part of the city, is not ideal because drug injectors are often difficult to locate. There is also a proportion of 'hidden' PWID as they do not present at drug treatment agencies and can hold down jobs and live a relatively 'normal' life away from authorities (Sieber, 1992, p133; Shewan and Dalgarno, 2005). Some information regarding demographics can be gleaned from the SDMD (ISD, 2012) but this information is obtained from the completion of SMR25a forms (Scottish Morbidity Record) which are completed within substance-misuse organisations. The SDMD does not therefore pick up the 'hidden' unengaged and so the population of PWID as a whole is unknown.

A potential recruitment method was via the internet which might enable contact with hidden populations. However, a review by Miller and Sonderlund (2010) indicated that although internet recruitment might be useful, it was unlikely to lead to samples from which generalisable conclusions could be made, and in any case it is unknown how many drug injectors would have access to and use the internet. Therefore this was not going to be used in this study.

After considerable discussion with other researchers and workers in the field, it was concluded unlikely that there was any practical method of sampling the 'hidden' population of drug injectors because these individuals may, or may not, access IEP services, and in many cases may not wish to be identified (Robinson et al, 2006).

Similarly the very chaotic drug injectors who do not access drugs services in any form were also going to be difficult to track down. PWID who attend IEP services may not necessarily attend the same one on a regular or frequent basis and may visit various centres for paraphernalia, depending on what is most convenient for them at a particular time.

Therefore the drug injecting population is a rather unknown quantity, as ages, gender, and addresses are largely unclear. These problems made developing a sampling frame

difficult, and equally, whilst the study aimed to be representative, it could not truly be, as the population was not known. With assistance from service providers and taking the 'best' from previous studies, a plan for sampling was developed.

Probability sampling relies on having a sampling frame and a known population, so non-probability sampling needed to be used, which is typical for an exploratory study (Gerrish and Lacey, 2006, p175).

A previous example of this was a study undertaken successfully by Morrison et al (1997) who approached all PWID (n = 147) attending IEP services within Glasgow during late 1995 and asked them to participate. The researchers used quota sampling because of wide variations in numbers attending each exchange; 112 agreed to participate, and of the 35 that refused, 86% of them said they were short of time, an issue that will likely have led to under-representation of those with more chaotic lifestyles. Limitations of this method of sampling are that the sample may not be representative and may be skewed but larger numbers can be achieved.

For this study a convenience sample was selected as the best compromise.

Opportunistic quota sampling was used which is a non-probability method, and used where a large number of people fitting a particular category need to be recruited, such as young PWID, but where selection of the sample is not otherwise specified for example, the population is constantly shifting, is geographically transient, and precise demographics are unknown (Robinson et al, 2006; Gerrish and Lacey, 2006, p182; Howie, 2008). Quota sampling also provided the best opportunity for a cross-sectional (by geography) sample by approaching all PWID, who met the inclusion criteria, accessing the busiest IEP services and methadone services across the city until the desired number was reached.

Reimbursement / Inducement

It is possible that participants may be inconvenienced by taking part, giving up free time to answer questions that may have no direct benefit for them (Aveyard and Hawley, 2007, p353). Some participants may agree to take part voluntarily, particularly where there is an existing relationship (Mustasa, 2001). However, it is widely recognised that PWID do not participate in research unless they are offered some form of payment (Sieber, 1992) and many previous studies with PWID have offered ‘an inducement’ or ‘honorarium’ for participation in research, sometimes in the form of reimbursed travelling expenses (Dietze et al, 2005, Mackridge et al, 2010), or food (Taylor et al, 2005), cash (Binswanger et al, 2000; Davis and Rhodes, 2004) or vouchers (Passaaro et al, 1998; Craine et al, 2004). The local police also offered £10 for participation in ID parades.

Other authors have described offering health promotion literature (Craine et al, 2004), free BBV testing, and counselling (Kwiatkowski et al, 2002) instead of payment. Payment may be seen as coercion or offering money for drugs and this could be considered ethically unacceptable (Ensign, 2003; Ensign and Ammerman, 2008). However, PWID often forego food and can be malnourished and hungry and for these reasons, and in common with other studies with this client group (Pieper and DiNardo, 1998; Darke et al, 2001; Shewan and Dalgarno, 2005; Craine et al, 2004; Taylor et al, 2005; Ensign and Ammerman, 2008) it was intended to offer a small food voucher by means of thanks.

Advice was sought from local researchers as other studies within Glasgow offered a reward for participation and it was important to be comparable but not to provide cash to fund illicit habits. ‘Payment’ amounts have varied, and seem to relate to the amount of time or inconvenience experienced.

Phase 1 took about 10 to 25 minutes to take part and a £2 shopping voucher was given as an acknowledgment of time.

For Phase 2, which took 40 – 50 minutes, a drink and a biscuit were offered, together with a £20 shopping voucher.

In addition, information was provided to each participant giving details of services they could access for healthcare and substance misuse subsequent to each interview (Appendix 3).

McKeganey et al (1989) explored HIV related risk behaviour in Glasgow and asked questions relating to demographics, length of injecting, and sharing of equipment. They acknowledged the brevity of their questionnaire and noted the need not to interfere with the service from which the recruitment was found. They also felt that it was important to retain a friendly and informative approach to questioning which meant that all the questions could be asked each time without compromising the informality. Given that so many studies have taken place amongst PWID in Glasgow (McKeganey et al, 2008) it was vital, and of course expected, that this study would treat the participants well, and leave them with a good experience such that they might be willing to participate in future studies.

3.12 The Pilot Study

The pilot study tested the planned research tools and proposed method and analysis for the main study, and was conducted with ten participants in a busy needle exchange within NHS Lothian. Feedback was sought from participants on the method. The interviews took an average of 15 minutes to do (ranging from 10 – 25 minutes). Recruitment was achieved within four afternoon sessions. Participants were happy with the method and research tools.

It was decided not to amend the timings within the information sheet which stated that it may take 25 minutes to answer the questions, although most interviews took less.

However, some amendments were made to the questionnaire. These were principally changes to coding to make data entry easier. Some questions were re-ordered; there were some minor additions to fixed responses, and typographical errors were corrected. An additional question was suggested following a review by the staff within needle exchange which was ‘Do you ever lick the needle prior to injecting?’ These were minor amendments that did not require re-referral for Ethical Review.

3.13 Data Collection

Venues for data collection

Within Glasgow, the Pharmacy team at Addiction Services (GAS) helped identify suitable venues for recruiting a wide geographical spread of participants across the city, utilising areas where there were known to be larger populations of drug injectors, and therefore busier services. Glasgow has a Drug Crisis Centre (GDCC) which offers short-term detoxification, rehabilitation, stabilisation and an IEP service. Also many of Glasgow’s retail pharmacists offered methadone administration and IEP (Roberts and Hunter, 2004). Such venues were places which PWID visited regularly and were familiar with, and were generally non-authoritarian. These locations had a private space in which interviews could be undertaken but where health professionals, support workers, or other staff were close at hand. This ensured privacy for the interviewee and also if a problem arose, help could be summoned easily.

The pharmacist from GAS made an initial approach to potential recruitment areas, and distributed information packs with details of the study, including ethical and governance clearance, contact numbers, and copies of other paperwork such as the questionnaire. Subsequently information leaflets (Appendix 4) and posters (Appendix 5) were distributed for display. Posters in each place of recruitment allowed potential participants the opportunity to consider taking part and information leaflets explained the purpose of the study, the possible advantages and disadvantages of taking part, together with the participant’s rights such as to withdraw at any time without giving a

reason or affecting treatment or services. This was similar in technique to that used successfully by Darke et al (2001) and Davidson et al (2002).

The researcher telephoned each service to arrange a start date, and to answer any queries from the service leads. Staff in each venue had the opportunity to read information, or discuss the study with the researcher, in advance of recruitment and were supplied with cards containing contact details for the researcher in case any potential participants wished to find out more. Due to the nature of drug using activities and potentially chaotic lives, where drug injectors can find it difficult to stick to routines and keep appointments, as much information as possible was provided within the study venues, in advance of a potential participant being approached to take part. The researcher checked that the posters and leaflets were displayed two weeks prior to the commencement of recruitment in each area. A dedicated mobile phone and phone number were used for the study.

After completion, a letter was written to each service lead thanking them for their assistance and offering a copy of the results when these were available.

Recruitment

Participants were recruited to the study by being approached and asked if they would be interested in taking part in some research. Depending on the venue, either the researcher did this, or a member of staff. Current and former drug injectors were identified as those attending for IEP (likely to be current injectors) or methadone clinics (likely to be either current or former injectors). Drug injectors are notorious for failing to attend appointments, and therefore once potential participants were approached, if they were agreeable, then the questionnaire was administered very shortly afterwards (O'Brien and Schroedl, 1991; Roy et al, 2003; Millburn and Brittenden, 2006).

With the exception of intoxicated participants, all potential participants were approached as an attempt to reduce selection bias within the sample (Gerrish and Lacey, 2006, p180). It was impossible to keep a tally of the number of exclusions or refusals to take part as in some areas the service staff preferred to approach the

participants themselves. There were individuals willing to participate but were excluded as they were too old or they had never injected.

Inclusion / exclusion criteria

Inclusion criteria were any individuals with a current or previous history of injecting, aged 16 to 44 years, who could understand and speak English. The nature of the sample meant that some individuals were visibly under the influence of alcohol and / or drugs in such a way that would affect their competence to participate and a judgement regarding competence was made by staff and / or the researcher at each study site prior to potential participants being approached. If it became apparent during the interview that the participant was intoxicated, the interview was terminated and any data gathered before that point was destroyed.

Interviews

Empathy and a non-judgemental stance were imperative when obtaining a history from a participant. It was important to put the participant at their ease, to be welcoming and encourage them to talk and disclose information in response to the questions. It was also useful to have a working knowledge of Glasgow slang and street drug terminology (Pieper, 1996a) and to use language that was familiar, accessible and clear.

The researcher began by informing potential participants of the nature of the study by providing an information sheet (Appendix 6) and offering to read this out. She then checked eligibility to participate to ensure inclusion criteria was met. Strenuous attempts were made to ensure that participants had every opportunity to ask questions about the research prior to, during, and after, the interview. Participants were assured that their participation, or non-participation would not in any way affect their medical care, services or benefits and it was explained that they were under absolutely no obligation to take part and could withdraw at any time, including after the data has been collected without any repercussions whatsoever.

Interviews required participants to discuss their drug use which included illegal activity and it was explained that any information provided for the study would be confidential and anonymised, and would not be passed onto a third party except where activities might be divulged that suggested serious harm to self or others (other than injecting), such as child protection issues. In Taylor and Kearney's study (2005) respondents were thought to be more likely to provide truthful answers if the resulting responses were not thought to be used to incriminate them, so this was made clear. Self-reporting may be inaccurate if the person perceives their answers as being interpreted as socially undesirable or perceives negative consequence as arising from the giving of the answers (Pieper and Templin, 2001). This possibility of divulgence was explained to participants and should risk to self or others become apparent then contact with an appropriate professional would be made in order to acquire the correct support for them. Participants were made aware of this both verbally and in writing.

Consent to participate was sought in all cases and a consent form and copy to keep was discussed and signed by both participant and researcher (Appendix 7). It was possible that the research questions might have raised issues that participants found distressing for whatever reason. Support was identified for each participant (usually the participant's own drugs worker or another member of local staff) in order that any issues raised could be discussed, independently of the research. Written contact details of support, including various health and drug treatment agencies, was given to all the participants on an individual basis.

The questionnaire was administered within a short face-to-face interview, and all questions were read out as dyslexia and difficulties with literacy are prevalent amongst PWID (Yates, 2006). Every interview was conducted by the same researcher. Whilst the question responses were fixed within the questionnaire, these were not given to the participant but instead their answer to the questions was matched to the best fit response. If it was unclear what the participant meant they were asked to choose the best answer of those responses provided.

3.14 Data Entry

Data were entered into SPSS version 15.0 (SPSS Inc) on a personal computer. Files were dated and saved consecutively and securely, and backed-up on a flash drive and another computer in a different location.

A code number was allocated to each participant. Identifiers of initials and dates of birth, which were entered on the questionnaires, were used purely to ensure there were no duplicate participants as data was gathered across a number of sites over 35 days. These identifiers were deleted from the database once recruitment was complete.

The majority of potential participants who were approached agreed to take part, and recruitment went very smoothly. Some of this may be attributed to good planning and a familiarity on behalf of the researcher with the participant population but good working relationships and a lot of goodwill from service providers also helped. This research was embedded in over seven years of clinical practice with drug injectors and may have avoided some of the initial challenges faced by other researchers, such as negotiating access (Taylor, 1993; Yates, 2006). It is possible that word of mouth might have encouraged potential participants to take part. The approach to recruitment was similar to other local studies which had successfully overcome many of the traditional problems of recruitment of injectors (University of the West of Scotland, Health Protection Scotland, University of Strathclyde and the West of Scotland Specialist Virology Centre, 2012).

3.15 Recruitment Phase 1

Data collection occurred over 35 days, from 12.08.08 until 05.12.08 (Table 3). Sample numbers were recruited fairly quickly and smoothly. 204 participants were interviewed. Interviews were conducted across the city within eight venues which provided IEP and methadone services (Table 3).

Venue	Type of venue	Area	Number of recruitment sessions	Number people recruited	Number excluded	Total
1	Methadone service	South-east	2	8	0	8
2	Pharmacy	Centre	6	56	1 incomplete 1 duplicate	54
3	Drugs service	South-east	10	43	1 duplicate	42
4	Pharmacy	West	2	10	0	10
5	Pharmacy	North	3	16	0	16
6	Pharmacy	South	5	22	0	22
7	Pharmacy no exchange	Centre	2	12	1 duplicate	11
8	Pharmacy	East	5	37	0	37
Total			35	204	4	200

Table 3 Recruitment venues and participant numbers

On three occasions, participants who the researcher thought had been interviewed before were adamant they had not previously been interviewed. The researcher felt obliged to conduct a second interview. When initials and dates of birth were checked, the three interviewees were found to be duplicates. The participants knew of the incentive / honorarium and may have wished to collect another £2 voucher. The data from these second three interviews were removed from the database. Following this, the researcher carried a print-out of client identifiers (initials and dates of birth) to ensure further duplication did not occur. A fourth interview (27) was abandoned mid-way as the participant disclosed information that suggested they were a danger to themselves. The participant requested that the interview cease, and discussion centred on suitable sources of support for the participant. The service lead was notified of the situation and contacts were made to individuals who knew the participant and who could offer support. Incomplete data from the fourth interview were also removed and

not included in the analysis. This left 200 participant interviews; all questions were answered and there were no missing data.

However, some questions were not applicable to all participants such as questions about current injecting habits, to those who were no longer injecting, and the questionnaire was designed in such a way that questions could be divided into sections for each group. For the purposes of SPSS analysis some of these 'not applicable' questions were coded as 'missing' using the SPSS definition as this allowed the 'not applicable' answers to be excluded from analysis. At times further explanation was required such as defining or elaborating on terms used, e.g. question F125 asked participants if they got pain in their calf on walking (claudication). The question was designed to identify whether the participant suffered from ischaemic pain in their leg as opposed to muscular pain and if the participant answered 'yes, they got pain in their leg on walking', then further exploration was used by the researcher to ensure this was the sort of pain relieved by resting to allow the calf muscle to revascularise and for walking to resume.

3.16 Consistency Checks

Ideally data would have been entered twice and compared to ensure accuracy, or every entry checked against the hard copy (Tabachnick and Fidell, 1996, p58). However, with the sample size and large number of variables, it was more practical to produce a random sample of 10% of data entered into SPSS for checking.

Twenty questionnaires were drawn and each data entry was matched against the hard copy. Checks for consistency were made by an independent source familiar with statistical packages. For each identifier there were 153 variables. Of the total of 3060 variables entered, there were 6 errors. These errors were incorrect or a transposed code entry. This was an error rate of 0.19%. This level of error was negligible and could be regarded as 'noise'. However further checking was undertaken to ensure there were no erroneous outliers amongst the entered data and data were plotted and counted to check

for this. The detected errors were checked against the hard copies and amended where necessary.

Identifiers of initials and dates of birth were removed.

Recoding

Where a high number of variables existed, such as the 72 different codes for venous injecting sites (Questions C25, C26, C27, C28 and D59, D60, and D61), the codes were revised to provide more meaningful groupings for analysis. Single injecting sites such as the response to ‘where do you usually inject?’ were categorized into arms and hands, groins, legs, feet, thighs, and neck, irrespective of whether participants injected into the right or left side. Questions C26 and D59 ‘Which sites have you used ever?’ produced a range of 72 possible variations. These too were aggregated into eleven variables as it was important to analyse the development of skin breakdown in relation to specific injecting sites.

Question C44 and D77 asked whether the participants had skin or muscle popped. If they had, then the subsequent question (C45, C78) was ‘in which site?’. The sites were grouped into popping in buttocks and / or upper body, popping in thighs and above, popping in lower legs and above, popping in feet and above, and popping in lower legs only.

Question F121 asked what medications participants took, prescribed or otherwise. Again, there were many given answers. These were examined for frequencies and grouped, providing ten categories. The predominant medication was methadone, either alone or with combinations of hypnotics, antidepressants, and antipsychotic drugs. A few participants took inhalers for asthma and some took analgesics.

Question C15 and D50 asked about what was injected in addition to what they inject most often. For the purposes of coding multiple drug use, ‘cocaine’ and ‘crack’ were both grouped together as cocaine. Those injecting more than one other drug were very

few and were also grouped into either ‘cocaine and one or more drugs’ or ‘two or more drugs’.

Types of filter (Questions C38 and D71) yielded straightforward responses, but five participants used two or more types of filter and a code 9 was added as a group for these ones.

3.17 Phase 1 Analysis

Power

A sample of 200 was sufficiently powerful to be able to detect a small to medium effect size at $p = .05$ and power = .80 for the types of statistical analysis done (Cohen, 1992). Previous studies of drug injectors in Glasgow suggested that this level of recruitment was possible, and the number was practical to attain the data within the timescale of the study similar to other studies (Morrison et al, 1997; McKeganey et al, 2008).

Statistical analysis

Data were analysed using descriptive and inferential statistics. The confidence interval used is 95% for all tests, a level of confidence generally accepted as minimizing the risk of a Type 2 error whilst not unduly increasing the likelihood of a Type 1 error.

The sample was analysed as a whole or, where appropriate, in two groups *current* injectors ($n = 128$) defined as those that were currently injecting or had injected in the last 6 months (24 weeks), and *former* injectors ($n = 72$), those that had stopped injecting or had not injected for over 6 months (over 24 weeks). Groupings for analyses will be explained within each section of the results (Chapter 4).

There were eight long-term injectors (who were also current injectors) who had been injecting for 25 years or more and their practice had sometimes changed over time and where relevant this is also described.

Where appropriate, results have been presented in percentages, and these have been rounded to the nearest 0.5%. Statistical tests of association Pearson R Chi-Square, and Fisher's exact test, where small numbers are in categories within 2 x 2 tables, were used to detect significance between two categorical variables (Greasley, 2008, p75; Watson et al, 2006, p161).

Logistic regression tests were used to predict if leg ulceration was caused by specific factors by controlling for other variables that happened at the same time such as age, length of injecting career, or progression to groin injecting (Pallant, 2007; Field, 2009). It is possible that some of the statistically significant results could be falsely apparent, due to the presence of confounding variables, or co-factors such as length of injecting history going hand in hand with the likelihood of beginning to groin inject as other sites become unavailable. It was necessary therefore to examine and control for some of these co-factors by utilising regression testing. Regression can ascertain associations once confounding variables are adjusted (Field, 2009, p264). However, questions such as those asked in this study tend to have categorical outcomes, and therefore an extension of regression, called logistic regression may be used (Field, 2009, p265).

Logistic regression is a form of multiple regression, with an outcome variable that is categorical (e.g. have you ever had a leg ulcer – yes / no), with predictor variables that are continuous (length of injecting time) or categorical (have you had a DVT - yes / no) (Field, 2009, p265). Logistic regression is often popular in the health sciences as the discrete outcome in logistic regression can be disease / no disease (Tabachnick & Fidell, 1996, p575). This makes logistic regression highly suitable for further analysis on the data from this study as the factors that predict leg ulcer are of interest.

Logistic regression can be used to generate models to predict such things in medicine e.g. such as whether a DVT will lead to a leg ulcer (Field, 2009, p265).

Logistic regression is more flexible than some other techniques and does not require predictor variables to be linear, parametric or of equal variance (Tabachnick & Fidell, 1996, p575). Logistic regression analysis examines the relationship between a dichotomous variable (having a leg ulcer) and one or more explanatory variables.

Some data entered into SPSS were recoded to allow further regression analysis using SPSS. Dichotomous variables were all recoded into categories that were aligned to '0' for a negative response or 'no', and '1' for a positive response or 'yes' (Pallant, 2007, p173).

Recoding occurred where scales were used, which amended graduated numbered responses to simply 'yes' and 'no', dichotomous variables. Therefore the above question was recoded as follows, using 0 to reflect 'no' and 1 to represent 'yes':

Do you use a filter? Always 5/ Most of the time 4/ Rarely 3/ Never 2 / Unsure 1

Became:

Do you use a filter? Always 1/ Most of the time 1/ Rarely1 / Never 0 / Unsure 1

Those who were unsure were grouped into the least positive response depending on the question. For example- those unsure if they always washed their hands were classed as a negative – 'no' or '0'.

The researcher felt that where respondents were unsure it seemed they were reluctant to admit to a poor practice. If respondents knew they 'should' wash their hands, but if they didn't, they were perhaps reluctant to admit this and just said they weren't sure.

Similarly they might know it was not good practice to lick their needle, and so by saying they were unsure they were not admitting to a practice they did. However, this is supposition on behalf of the researcher, but there were only small numbers who were 'unsure'.

For the purposes of regression analysis, and in order to analyse the sample as a whole, the data were grouped into one sample group, not distinguishing between current and former injectors. The majority of participants (n = 128) were 'current injectors'. Recall was likely to be more accurate for recent activities and so it was decided to select the most recent response of the eight long-term injectors for the regression analysis. The development of the direct logistic regression models are explained within Chapter 4.

Utilising a questionnaire limited the depth and breadth of knowledge acquired about skin problems and for this reason, a further study (Phase 2) was conducted utilising qualitative methods which were designed to gain greater insight (McGrath and Phillips, 2007). Comparing the data gathered with Phase 1, and corroborating evidence between the two phases, improved rigour for the study as a whole.

Phase 2, the qualitative study, will be described in the following section, followed by the processes of ethical and governance approval.

3.18 Phase 2

Building on the empirical data obtained in the first phase, Phase 2 explored with current or former young PWID who had leg ulceration their behaviours, perceptions and thoughts about the causes of leg ulceration, and about harm reduction methods. This phase was designed to generate in-depth knowledge related to chronic leg ulceration from the participants' view point and answer the remaining research question: '*What are appropriate harm reduction measures for leg ulceration in young PWID?*'

3.19 Interviews

A framework for semi-structured interviews was developed, based on the findings from the empirical data (Appendix 8). The framework formed a guide for questions, but there was scope for altering the questions and exploring more deeply, depending on the

participant responses (Gerrish and Lacey, 2006, p226). This method had been used successfully to explore quality of life with a sample of seven PWID (as part of a larger study) with venous ulcers (Palfreyman et al, 2007). Participants also had opportunities to expand on areas they thought were important. The framework for questions was developed and defined once the empirical data had been analysed from Phase 1.

Credibility

At all stages rigour was achieved through ensuring that processes of reliability and validity within data collection and analysis were applied (Morse et al, 2002). Lincoln and Guba's (1985) inquiry method using the 'trustworthiness' criteria which includes credibility, applicability, dependability and confirmability was used. This parallels the conventional criteria of scientific inquiry of internal and external validity, reliability and neutrality respectively which are often cited as a method to ensure validity of a qualitative study. The concept of 'trustworthiness', mimicking the empirical definitions of reliability and validity, utilises standards of evaluation to determine overall significance, relevance and impact of qualitative research. However, these evaluative attempts at determining rigour are usually applied at the end of a study, when it may be too late to correct serious problems (Morse et al, 2002). Instead, verification strategies were applied within the conduct of the study itself. Firstly, methodological coherence such as checking that the method was suitable to answer the research question, and then checking back when data were gathered ensured the interview schedule had been followed, for each of the interviews as it was conducted.

Secondly, the sample must be appropriate, and consist of participants who best represented or have knowledge of the research topic. As the sample comprised only current drug injectors, or former drug injectors, who had experience of leg ulceration, this criterion was met.

Thirdly, collecting and analysing material concurrently formed a mutual interaction between what is known and what one needs to know, and this also helped identify when data saturation was reached.

Fourthly, thinking theoretically – ideas emerging from the data were confirmed in the new data gathered and fresh ideas that emerged were also reflected in data already collected so a continual process of reflecting back and looking forward with the data occurred, along with checking and rechecking.

Finally, theory development occurred between the micro-perspective of the data, and the macro-perspective of theoretical understanding. This verification strategy has been adapted from Morse et al (2002).

Reflexivity was also important as the researcher approached the research with an existing identity, associated experiences and preconceptions which might influence the interpretation of data. Being aware and reflective of this potential influence and bias was important (Lathlean, 2006, p420; Watt, 2007). The responsiveness of the researcher to the generated data contributed to rigour, particularly in relation to analysis where categorisation needed to be supported by data and the investigator needed to be creative, sensitive and insightful (Morse et al, 2002). Themes and subsequent conclusions from the research needed to be supported by robust evidence and a method of analysis that allowed this to be transparent was essential.

Sample Phase 2

A representative sample was sought of males and females, young, current or former drug injectors (aged 16 – 44 years) with new (4 – 24 weeks), existing (25 weeks or more), and healed leg ulceration, taking into account similarities such as gender balance identified from Phase 1.

Inclusion / Exclusion Criteria

Inclusion criteria comprised individuals with a current or previous history of injecting, leg ulceration active or healed, and aged 16 to 44 years (as for Phase 1), who could understand and speak English. As discussed earlier in the definition of skin problems section (3.10), a leg ulcer was defined as ‘a break in the skin between the ankle and the knee that has been present four weeks or more’ (SIGN, 2010).

Clinic staff approached all clients that to their knowledge had been a drug injector and had a leg ulcer, unless they deemed them as not fit to consent. Participants were excluded if they did not appear competent to either understand what they were consenting to take part in, or to be able to answer questions. This sort of warning or awareness is common practice within drug services to ensure the safety of all parties and occurred successfully in Phase 1.

Participants and / or data were excluded if they did not meet the inclusion criteria, if they had never injected and had never had a leg ulcer, and were outwith the age range of 16 – 44 years.

Sampling strategy: Phase 2

A sampling frame, shown in Table 4, was devised based on the demographics of Phase 1, designed to capture a similar representative proportional sample.

Gender	25% females (3)	75% males (9)
Injecting status	50% current injectors (6)	50% former injectors (6)
Leg ulcers	50% present 4 – 24 weeks (6)	50% present 25 weeks or more or healed (6)

Table 4 Sampling frame

Convenience sampling was used for recruitment. Potential participants were likely to have engaged with healthcare services for treatment so areas known to treat PWID with leg ulceration were selected for recruitment.

Recruitment

Data collection was planned with the staff from the Physical Health Team for homeless people in NHS Glasgow and Clyde. The researcher met with the staff in advance to explain the study and deliver posters (Appendix 9) and leaflets to be distributed and displayed two weeks prior to the commencement of recruitment within the areas of the Health Centre and the Drug Crisis Centre where data collection would take place.

Patients who met the inclusion criteria were approached by clinical staff and asked if they wished to take part and either an interview date was arranged to coincide with clinical care, or participants were invited to attend on suitable dates pre-arranged so that the researcher would be present at the venue. Recruitment took place from April 2012 until December 2012. Most of the interviews were conducted in a private room within the Health Centre, and on three occasions within participant's homes where the researcher was accompanied by NHS staff who were undertaking clinical care at the same time.

Data collection

On the interview day, the researcher introduced herself to participants and reiterated the purpose of the research interview and the proposed duration together with topics for discussion. An information sheet (Appendix 10) was given to each participant and time to read or go through the sheet with the researcher was provided. Verbal consent to proceed was given and the participants signed a written consent form (Appendix 11), a copy of which was retained by the researcher and another copy by the participant. Participants were advised that they were not obliged to take part, and they could

withdraw themselves and any data they provided, without penalty at any time. They were given an opportunity to ask any questions. As before, support for each participant was identified and details of appropriate health and social care agencies were given.

As discussed in the section on reimbursement (3.11), each participant received an honorarium of a £20 voucher as an acknowledgment of their time and willingness to take part. On conclusion a letter was written to each service lead thanking them for their assistance and offering a copy of the results when these were available.

Seventeen interviews were conducted using a semi-structured interview schedule (Appendix 8) with current or former injectors who had experienced a leg ulcer. Thirteen interviews were conducted in the first two months which initially populated most of the sampling frame however, the last few participants, particularly females, were exceedingly difficult to recruit due to low numbers attending clinical services at that time. Arrangements and appointments were made with a number of potential participants who failed to turn up.

An extension to ethical approval and governance was sought and granted three times, and the eventual decision was then made to stop recruiting in January 2013, when 17 interviews had been completed. The termination of recruitment was a practical decision and whilst the sampling frame was not fulfilled exactly as planned (Table 5), all participants had injected and experienced leg ulceration. It appeared to the researcher that data saturation was occurring relatively early in relation to the key aims and research questions.

Gender	25 % females (planned 3) actual = 4	75% males (planned 9) actual 13 (2 excluded) = 11
Injecting status	50% current (planned 6) actual = 7	50% former injectors (planned 6) actual 10 (2 excluded) = 8
Leg ulcers	50% 4 – 24 weeks (6) actual = 5	50% 25 weeks or more or healed (6) actual 12 (2 excluded) = 10

Table 5 Completed sampling frame

All interviews were recorded on two digital microphones. Each file was downloaded onto a password-protected computer and transferred to the transcriber by password-protected ‘drop box’. Each interview was numerically coded and transcribed verbatim thus ensuring reliability (Silverman, 1993, p149). Each transcription was checked against the recordings for accuracy by the interviewer.

3.20 Sample

As PWID are often difficult to locate for follow-up studies, it was originally intended to ask those participants who had experienced a leg ulcer whether it would be possible to contact them to participate in Phase 2. Fifteen participants agreed to be contacted. An information sheet was given and they were asked to provide written consent to be contacted again. Contact details were collected, and kept separately from other information in a locked drawer for the researcher’s own use.

On completion of Phase 1 recruitment in December 2008, a letter was written to those who had provided a postal address, and phone calls to update on progress were made to the other potential participants or their contact person. Agreement was made that each potential Phase 2 participant would be contacted again in Spring 2009, once it was clearer what Phase 2 might entail. Three of the letters were returned as undelivered.

As some time had passed since Phase 1, discussions with NHS staff revealed that a number of the leg ulcer patients that they had treated that were likely to have participated in Phase 1, had died. It was felt that looking for these original participants might distress relatives who were generally named as the first point of contact by the participants. So no participants from Phase 1 were approached again to take part in Phase 2.

Of the 17 people recruited to the Phase 2 study, 13 were male, and 4 female. One male participant (participant number 7) was excluded as he was 49 years of age and outwith the inclusion criteria. He had been recruited by NHS staff who had been unaware of his age when he had agreed to take part and he was desperate to receive his honorarium. The interview went ahead but the data gathered from the interview was not included in the analysis although his contribution was valuable in providing further insight. The data gathered from the first interview (participant number 1) were effectively used as a trial run, and were also excluded.

The research aims were very specific:

- To analyse potential causal / risk factors in the development of chronic leg ulceration in young PWID.
- To identify appropriate harm reduction measures relevant to service delivery and treatment in Scotland and beyond.

During the interviews participants talked about the impact of ulceration on their lives and this impact related closely to potential harm reduction messages. Therefore the three explored areas were causes of leg ulceration, impact of ulceration and harm reduction.

3.21 Phase 2 Analysis

In line with the sequential explanatory design, the qualitative stage was explicitly linked to the earlier quantitative stage and sought to confirm, elaborate and explain the

quantitative results as well as providing further detail and new knowledge, built on what was learned in the first phase (Creswell and Plano Clark, 2011, p221 - 234).

The data analysis sought to find associations, seek explanations for ulceration, the impact of ulceration on participant's lives and develop new ideas about the causation and possibilities for prevention.

Representation of qualitative data in an empirical manner such as in tables, (a graphical or visual approach), and devising ratios to note numbers of themes, may assist readers in interpreting qualitative data more accurately (Bachor, 2002), so some data were tabulated within the findings.

3.22 Procedure for framework analysis

Stage 1: Familiarisation

This stage related to data management – becoming familiar with the transcripts / data by reading and re-reading, identifying the initial themes and developing a coding matrix and assigning data to the themes and categories in the coding matrix (Smith and Firth, 2011).

The transcripts were copied directly into QSR NVivo Version 10, whilst being read and re-read to create familiarity. This immersion in the data was made easier as the researcher also conducted the interviews and checked all the transcripts so there already was a degree of familiarity. As part of this stage, notes were made about themes and issues arising.

Stage 2: Identifying a thematic framework

During the earlier first stage, familiarisation occurred but at the same time the process of abstraction and conceptualisation began to occur (Ritchie and Spencer, 1994, p179;

Spencer et al, 2014). From this material, themes, key issues and concepts arose and were recorded, drawing on the *a priori* issues such as the original research question, themes and issues and questions raised by participants.

Key themes that arose from the data were:

- causes of leg ulceration
- impact of injecting and of leg ulceration (this was useful in identifying key harm reduction messages)
- harm reduction

These themes were entered into NVivo and sub-themes linked to the main themes were added as the data were interrogated.

Causes of leg ulceration – sub-themes:

Abscesses	Acidifiers used	Cause of ulcer	Diet
Drugs injected	Family history	Groin injecting	Hit arteries
Homelessness	How injecting started	How the ulcer started	Injecting into wounds
Injecting technique	Mental health	Personal hygiene	Thrombosis
Tools used			

Table 6 Themes of causation

Impact of injecting and leg ulceration – sub-themes:

Effect on mobility	Embarrassment	Exudate or discharge	Family impact
Infection	Itch	Lack of sleep	Other ill health
Pain	Risk	Scarring	Smell
Social impact	Swelling or oedema	Thrombosis, clots or DVT	Venous disease

Table 7 Themes of impact of injecting and ulceration

Harm Reduction – sub-themes:

Prevention	How ulcer heals	Denial
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Table 8 Themes of harm reduction

Stage 3: Indexing

Data from the transcripts were applied to the themes and sub-themes with NVivo – at this stage some of the themes were re-worked, as the interviews were re-visited (Ward et al, 2013). The transcripts were read and re-read again, and data reapplied to the themes (or nodes in NVivo) to ensure nothing was missed and as the themes and sub-themes developed the data were matched back again. This process was done three times. As the interviews were semi-structured, questions and discussion varied between participants with the intention of enabling conversations to ‘flow’ and for participants to talk freely. As a result the questions were broadly similar for each participant but not all the same questions were asked. This was not unusual where the interview technique was flexible and responsive (Pope et al, 2007).

Stage 4: Charting

This stage allowed the data to be reduced and summarised within framework matrixes in NVivo. These matrices allowed the direct quotes to be linked to the summary so that there could be checking and matching across the themes and attributed to the original text. These summaries formed the beginning of true analysis and interpretation with the researcher making sense of the texts and drawing together the data succinctly within matrices in NVivo (Pope et al, 2007). Three matrices were developed and linked to the study aims and research questions – ‘Cause of ulceration’, ‘Impact of ulceration’ and ‘Harm Reduction’. These matrices contain illustrative quotations where these are interesting or explanatory and were used to illustrate interpretation in the next stage (Gale et al, 2013).

Stage 5: Mapping and Interpretation

The notes, framework matrices and text data were reviewed and the range of data explored again (Pope et al, 2000). The textual interview data had been ‘managed’ within NVivo and ordered into themes to facilitate interpretation. During interviews notes were taken simultaneously to allow some demographics to be recorded such as the age of the participant, gender and postcode. This information was tabulated to create a summary of the participants and rule out duplication. It was also possible to tabulate other information gathered during the course of the interviews in which similar information was acquired for each participant such as length of injecting career or site of the ulcer. These data could be counted and a summary of simple information produced (Pope et al, 2007). Some of these data were also used to describe a case, e.g. participant number, age group, gender, injecting status and whether an old or recent leg ulcer (all variables from the sampling frame), within the framework matrices. These data were tabulated and presented in Chapter 5.

The final stage of framework analysis was to synthesise the data and descriptive summaries were incorporated into explanatory accounts (Furber, 2010). The ‘scaffolds’ of matrices were useful in making sense of the data and allowing interpretation between cases to illuminate each of the themes arising from the interviews based on the research questions (Smith and Firth, 2011).

The findings are presented in Chapter 5.

3.23 Synthesis of Phase 1 and 2

The quantitative results from Phase 1 informed the development and execution of Phase 2. The results of Phase 1 are presented in Chapter 4. The qualitative findings from Phase 2 are presented in Chapter 5. The results from both phases were brought together within Chapter 6 and the extent to which the findings from both phases were convergent and complementary are considered (Erzberger and Kelle, 2003).

3.24 Ethics, Access and Data Management

User involvement

Whilst vulnerable groups may be more readily coerced, harmed or manipulated by researchers, conversely they may also be stigmatized and excluded from conventional types of research (Pieper, 2005; Exchange supplies, 2007). The drug using population is often considered vulnerable, disenfranchised or marginalized. However, this may not be recognized or agreed by PWID and it is important not to exclude such individuals from research because of an assumed possibility that they may be vulnerable (Steel, 2004). In fact, many PWID are survivors of very difficult circumstances and can be articulate and eager to share experiences (Taylor, 1993, p8; Ensign, 2003).

Social circumstances and living arrangements may be misunderstood by researchers, often leading to a lack of cultural sensitivity and / or difficulties undertaking research both in accessing areas to undertake research and recruit participants, and in developing sound methods by which to answer research questions (Sieber, 1992, p109 & p128; Steel, 2004). Ensign (2003) describes the ethical challenges of conducting research amongst vulnerable populations such as homeless youths. There is significant overlap between homeless populations and PWID and Ensign's (2003) observations were helpful in defining ethical boundaries for research with such a group. Ensign's further experience (Ensign, 2006) led her to recommend that participants within a group of homeless young people should be involved in the development of the research design.

The research tools in this study were piloted with a small group of service users at an IEP service in Lothian and their views were sought and incorporated into the research design.

Confidentiality and data storage

All data collected were anonymised. Only the researcher and her supervisors had access to the data. Hard copies of data collection materials that may potentially identify an individual such as completed questionnaires and consent forms were kept separately and locked within a fireproof cupboard within the University. The questionnaires will be stored and destroyed ten years after study completion. The consent forms were destroyed after the completion of the study.

All electronic data were anonymised, and will be stored within password-protected files for ten years. Code numbers were used to differentiate between participants within the data analysis. Such information was stored, and will be later destroyed, in accordance with the Data Protection Act (1998).

Participants were assured that their personal data and information were confidential and would not be passed to a third party and would not be used for any other purpose. All data used in the presentation and dissemination of results will be completely anonymous.

Researcher and nurse

There were ethical dilemmas arising as a result of being both a researcher and a nurse. Data were collected in a city where the researcher had both trained and worked as a nurse and more recently had worked specifically with services for homeless people and PWID. Her experiences with this client group and relationships with service staff were very helpful in informing the research design, and ensured a practical, workable, and successful method of recruitment. Whilst she withdrew from clinical practice in Glasgow prior to commencing this study to avoid any conflicts in care, feelings of obligation on behalf of NHS patients, or breaches of confidentiality she nevertheless encountered, and interviewed, former patients whom she had cared for, which potentially contaminated some of the data, given that she had been informally enquiring

of patients what they thought was causing their skin problems and musing about the possibilities.

It was challenging to change from the 'nurse' to the 'researcher' and at times the roles were very difficult to separate, and indeed the participants also considered that she had both roles. Participants raised concerns or asked questions that as a nurse she could and should have answered. However, as a researcher, it was not her place. This was a challenge that had to be considered and reflected on as to what was best for the participant sitting in front of her, with contradictions in duty of care, and professional responsibilities towards referral for on-going support. The support of clinical colleagues was helpful, providing support to participants when required.

Support for the Researcher and Personal Safety

Researcher safety

A safety protocol was established for each venue in order to ensure researcher safety when interviewing participants in private. A mobile phone and portable alarm were carried by the researcher at all times.

In accordance with other studies (Taylor et al, 2005), no questions were asked about individual dealers or sources of specific batches of heroin which could lead to divulgence of criminal activity and knowledge that could cause subsequent risk to the researcher.

It was possible that undertaking the research and listening to participants divulge information about their personal lives might have caused inadvertent distress to the researcher. Professional colleagues were identified who were willing to provide support / debriefing for the emotional burden that might be experienced by the researcher.

Ethical Approval

This study adhered to ethical principles essential in research. Appropriate and necessary ethical permission was sought separately for each phase of the study, and obtained from the University's Ethics Committee, and also Greater Glasgow NHS Research Ethics Committee prior to each part of the study commencing.

The Department of Nursing and Midwifery Research Ethics committee (DREC) required students to submit for ethical approval through the Department prior to seeking NHS approval. The study received approval from DREC to proceed to NHS approval in May 2008.

As the study involved recruitment at two Health Board sites – NHS Lothian (for the pilot study) and NHS Glasgow and Clyde (for the main study), the study was classed as 'multi-centre' and therefore required the approval application to be channelled through the Central Allocation System. The study was allocated to Glasgow West Ethics Committee 1. The application was reviewed on 2nd June 2008 and, subject to some minor amendments, was approved (reference 08/S0703/78) on 7th July 2008.

Ethical approval for Phase 2 was sought and obtained from the West of Scotland NHS Research Ethics Committee 1 (reference 10/S0703/52) on 13th September 2010.

The researcher received an enhanced disclosure check from Disclosure Scotland (number 120100054895822) and subsequently a PVG scheme membership (number 200000000327865). Indemnity insurance for the researcher was in place.

3.25 Governance and Access

Governance approval to undertake the Pilot Study was gained from NHS Lothian Research and Development Office in June 2008. Research Governance approval from

NHS Glasgow and Clyde was obtained in July 2008. Access was negotiated with each of the NHS areas within which the researcher gathered data.

Governance approval from NHS Glasgow and Clyde for Phase 2 was granted in September 2010, and access was sought and permitted by the Health and Homelessness Team within NHS Glasgow and Clyde.

Chapter summary

This study comprised two phases in a sequential explanatory mixed methods design. The first, Phase 1, grounded within a critical realist approach, sought to answer the first research question – *‘What is the extent of skin problems and chronic leg ulceration in young PWID?’* by utilising a survey technique within an epidemiological approach. Phase 2 was grounded within postpositivism and pragmatism and utilised semi-structured qualitative interviews to complete the answer to the second - *‘What causes chronic leg ulceration in young PWID?’* and answer the third research question *‘What are appropriate harm reduction measures for leg ulceration in young PWID?’*.

The next chapter, Chapter 4, will outline the results from Phase 1 and the findings from Phase 2 will be described in Chapter 5.

Chapter 4

Phase 1: Results and Analysis

Introduction

The thesis, so far, has set out why the gap in knowledge relating to leg ulceration in young people who inject drugs is important. This next chapter builds on the methods described in Chapter 3 and reports the results of Phase 1, the quantitative survey.

Within the first section basic descriptive statistics will be reported providing an overview of the sample's demographic composition, physical health, and key points related to injecting. The prevalence of leg ulceration and skin problems within the sample is outlined. The next section will detail risk factors of significance for leg ulceration. Concluding this chapter is a discussion of these findings.

4.1 Study Sample

The final dataset comprised 200 people of whom 148 were males (74%) and 52 were females (26%). The age of the participants at the time of interview ranged from 21 to 44 years old (Mean 34.62 years SD 5.61). Table 9 provides an overview of the sample's characteristics including injecting status and length of injecting career.

Demographics of sample		Male		Female		Total	
		No.	%	No.	%	No.	%
Gender		148	74.0	52	26.0	200	100.0
Age group	20 - 24 yrs	6	4.0	5	9.5	11	5.5
	25 - 29 yrs	20	13.5	9	17.5	29	14.5
	30 - 34 yrs	38	25.5	12	23.0	50	25.0
	35 - 39 yrs	47	32.0	18	34.5	65	32.5
	40 - 44 yrs	37	25.0	8	15.5	45	22.5
	Total	148		52		200	
Injecting status	Current injector	97	65.0	31	60.0	128	64.0
	Former injector	51	35.0	21	40.0	72	36.0
	Total	148		52		200	
Length of injecting career (years)	Less than a year	13	9.0	6	11.5	19	9.5
	1- 5 years	35	23.5	12	23.0	47	23.5
	6 - 10 years	35	23.5	14	27.0	49	24.5
	11- 20 years	44	30.0	15	29.0	59	29.5
	Over 20 years	21	14.0	5	9.5	26	13.0
	Total	148		52		200	
Age when started injecting (years)	Under 16yrs	28	19.0	7	13.5	35	17.5
	16-19 yrs	42	28.5	15	29.0	57	28.5
	20-24 yrs	38	25.5	17	32.5	55	27.5
	25-29 yrs	23	15.5	9	17.5	32	16.0
	30-34 yrs	13	9.0	4	7.5	17	8.5
	35-39yrs	4	2.5	0	0.0	4	2.0
	Total	148		52		200	

Table 9 Sample demographics

More than half of the sample were current injectors (64%, n = 128), and 36% (n = 72) had stopped injecting more than 6 months previously.

Participants had injected for varying lengths of time ranging from less than a year to 31 years with a mean of 10.26 years (SD 7.7).

A small number (9.5%, n = 19) had injected for less than a year, and similarly at the other end of the scale, only 26 (13%) had injected for more than 20 years.

The youngest started injecting when they were 12 years old, and the oldest aged 39 years, with a mean age of 21.19 years (SD 5.9). The majority of participants (73.5%, n = 147) were injecting before they reached their twenty-fifth birthday.

Geographical spread

The sample represented a wide geographical spread of areas across the city centre with peaks in known areas of high drug use (City-centre and East-end). There were some participants from other areas (3%, n = 6) and some were of no fixed abode (NFA) (4%, n = 8) (Table 10).

Recruitment Areas		
Areas of Glasgow	Number of participants	%
Centre	49	24.5
North	24	12.0
South	27	13.5
South-east	2	1.0
South-west	9	4.5
East	52	26.0
West	17	8.5
Other	6	3.0
NFA	8	4.0
Total	200	100.0

Table 10 Recruitment areas

Housing

At the time of interview, half (n = 100) were living in their own home – either a tenancy, private rental or mortgaged property, 22.5% (n = 45) were living in a hostel or supported accommodation, 19% (n = 38) were living with friends or relatives, and 3% (n = 6) were living in a bed and breakfast. 1.5% (n = 3) were sleeping rough and 4% (n = 8) were NFA.

The majority (80.5% n = 161) had been homeless at some time in their lives. Only 39 (19.5%) participants had never been homeless. 83 participants (41.5%) had been homeless within the last 6 months.

4.2 Physical Health

Participants were asked about their physical health, their medical history and about known risk factors for leg ulceration.

Nutritional status

Most participants considered themselves normal weight for their height (Table 11).

A quarter of participants (27.5%, n = 55) reported no fixed eating pattern, and 9.5% (n = 19) snacked all day, but 44.5% (n = 89) did report managing to eat 2 or 3 meals a day and 18.5% (n = 37) ate one meal a day.

Only 23% (n = 46) ate fruit every day, and almost half the participants ate fruit less than once a day (42.5%, n = 85). 34.5% (n = 69) never ate fruit.

		Male		Female		Total	
		No.	%	No.	%	No.	%
Nutrition							
Body Mass Index estimate (BMI)	underweight	55	37.0	12	23.0	67	33.5
	normal weight	75	51.0	24	46.0	99	49.5
	overweight	18	12.0	14	27.0	32	16.0
	obese	0	0.0	2	4.0	2	1.0
Total		148		52		200	

Table 11 Nutritional status

Smoking and alcohol use

Almost all participants were tobacco smokers and the greatest proportion were heavy smokers (43.5%, n = 87) consuming more than 20 cigarettes or ½ oz. of tobacco daily. 25.5% (n = 51) were moderate smokers, consuming 10 – 20 cigarettes daily or ¼ - ½

oz. tobacco. The remaining participants (30%, n = 60) were light smokers, smoking less than ten cigarettes or ¼ oz. tobacco daily.

		Male		Female		Total	
		No.	%	No.	%	No.	%
Smoking status							
Current smoker	Yes	147	99.5	51	100	198	99
	No	1	0.5	1	0.5	2	1
Total		148		52		200	

Table 12 Smoking status

Most smoked tobacco (roll-ups) (43%, n = 86) citing this as a cheaper option. 24% smoked cigarettes (n = 48), 0.5% (n = 1) smoked a pipe, and 5% smoked cannabis (n = 10). 26.5% (n = 53), smoked a combination of these items.

Participants were asked about their alcohol consumption in the previous six months. 50% (n = 100) had not had alcohol in the last 6 months. 9% (n = 18) drank alcohol once a month or less, and 4.5% (n = 9) drank twice a month. 8.5% (n = 17) drank once a week, 8% (n = 16) drank two - three times a week, and the rest drank four or more times a week (20%, n = 40).

Medications

Participants were asked if they took any medication (other than what they injected), prescribed or otherwise. 97% (n = 194) were taking other medications, 3% (n = 6) took nothing else. Five people who took no other medication were current injectors. Of the medications taken, 91% of the sample (n = 182) took an opiate substitute. 43.5% (n = 87) of those taking an opiate substitute were also currently injecting. A high percentage (47.5%, n = 95) were taking medication acting on the central nervous system (CNS), whether this was antidepressants, antipsychotics or anti-manic medication or combinations. Of these, 89 (43.5% of sample) were also taking an opiate substitute in combination with a CNS active drug.

Blood-borne viruses (BBV)

40.5% (n = 81) reported that they had been diagnosed with a BBV such as hepatitis or HIV.

Cardiac disease

A small number of participants (13.5%, n = 27) had been diagnosed with a heart problem.

Claudication

A sign of arterial disease and / or peripheral vascular disease is often claudication (pain in their calf on walking). Further exploration was sometimes required to ensure that the pain described was that of claudication which might indicate ischaemia, rather than muscular or ulcer pain. Following explanation, 16% (n = 32) of participants reported suffering from claudication.

Diabetes

Only four participants had been diagnosed with diabetes (2%, n = 4).

Walking problems

Almost a fifth had problems with mobility or been diagnosed with joint problems or arthritis (19.5%, n = 39).

Hand dominance

Most participants (84.5% n= 169) were right-handed, 9.5% (n = 19) were left-handed and 6% (n = 12) described themselves as ambidextrous.

Access to healthcare

Most participants had contact with health professionals such as a GP or Practice Nurse. (99%, n = 198). Only two participants did not.

Of those who did have contact with a health professional, a fifth felt they were unable to talk to them (20%, n = 40).

Most would go to their GP or Practice Nurse for advice about a skin problem (66.5%, n = 133). 16% (n = 32) would consult their drugs worker or a worker at the needle exchange, 8.5% (n = 17) would go to Accident and Emergency (A & E) and 6% (n = 12) would seek advice from other sources. 3% (n = 6) would not seek advice from anyone.

4.3 Signs of Venous Disease

Varicose veins

Just over a quarter (29%, n = 58) had varicose veins. A third knew of a family history of venous disease such as varicose veins or leg ulceration (32% , n = 64), whilst the remainder either did not know, or thought there had not been a family history (68%, n = 136).

Skin staining

Fifteen percent (n = 30) reported skin staining on their legs and 21 of these people had also experienced a leg ulcer.

Known risk for venous disease

Known risk factors for venous disease were reported by some participants (Table 13).

Risk Factor - venous disease	Present		Absent		Total
	Number	%	Number	%	
Deep vein thrombosis (DVT) leg	65	32.0	135	67.5	200
Fractured legs	56	28.0	144	72.0	200
Cellulitis	36	18.0	164	82.0	200
Standing for long periods	149	74.5	51	25.5	200

Table 13 Known risk of venous disease

Parity

There were 52 females in the sample, and 80% (n = 42) had given birth. Table 14 denotes the number of births.

Parity	Number of women
0 babies	10
1 baby	20
2 babies	9
3 babies	9
4 or more babies	4
Total	52

Table 14 Number of births

4.4 Injecting Habits of the Sample

These results are displayed in Table 15 (injecting habits).

Injecting habits		Current injector		Former injector		Total	
		No.	%	No.	%	No.	%
Drugs injected most often	heroin	105	82.0	63	87.5	168	84.0
	cocaine	22	17.0	4	5.5	26	13.0
	amphetamine	1	1.0	1	1.5	2	1.0
	benzodiazepines	0	0.0	1	1.5	1	0.5
	other	0	0.0	3	4.0	3	1.5
	Total	128	100.0	72	100.0	200	100.0
How often inject on average	Less than every 2/3 days	30	24.0	7	9.5		
	Every 2/3 days	17	13.0	3	4.0		
	Once a day	23	18.0	11	15.5		
	Twice a day	24	19.0	14	19.5		
	Three times a day	17	13.0	18	25.0		
	Four times a day	4	3.0	6	8.5		
	More than 4 times a day	13	10.0	13	18.0		
	Total	128	100.0	72	100.0		
How often inject at most	Less than every 2/3 days	17	13.0	7	9.5		
	Every 2/3 days	10	8.0	2	3.0		
	Once a day	11	9.0	2	3.0		
	Twice a day	13	10.0	4	5.5		
	Three times a day	16	13.0	11	15.5		
	Four times a day	8	6.0	3	4.0		
	More than 4 times a day	53	41.0	43	59.5		
	Total	128	100.0	72	100.0		

Table 15 Injecting habits

Drugs injected

Most of the participants were or had been heroin injectors. Most injected at least once a day and sometimes far more frequently.

When asked what other drugs were injected current injectors also reported injecting cocaine or crack (n = 43, 34%), some reported mixing it with other drugs (n = 13, 10%). Four people also injected benzodiazepines (3%). One injected amphetamines. 51 (40%) did not inject anything else.

Former injectors also reported injecting cocaine (n = 15, 21%), and 18 (25%) reported mixing cocaine with one or more other drugs. Eight reported injecting benzodiazepines (11%), one reported injecting buprenorphine, and three (4%) reported other drugs such as Diconal. Six people reported injecting two or more different drugs (8%).

Initiation into injecting

The majority of injectors were taught to inject by a friend or by watching others (Table 16). The participants differentiated between ‘friends’ i.e. people who they trusted, and acquaintances - people they knew.

Initiation	Current Injector	%	Former Injector	%	Total	%
Dealer	1	1.0	0	0.0	1	0.5
Friend	46	36.0	33	46.0	79	39.5
Partner	14	11.0	9	13.0	23	11.5
Watching others	48	37.0	18	25.0	66	33.0
Family	8	6.0	5	7.0	13	6.5
Acquaintances	5	4.0	5	7.0	10	5.0
Baby Sitter	1	1.0	0	0.0	1	0.5
Prison mate	0	0.0	1	1.0	1	0.5
Other	5	4.0	1	1.0	6	3.0
Total	128	100.0	72	100.0	200	100.0

Table 16 Who taught injectors to inject

Who undertakes injecting

Most participants injected themselves (Table 17). Of those that did not, friends, acquaintances and partners helped.

Who undertakes injecting	Current Injector	%	Former Injector	%	Total	%
Always inject themselves	97	76.0	41	57.0	138	69.0
Sometimes inject themselves	14	11.0	12	17.0	26	13.0
Never inject themselves	17	13.0	19	26.0	36	18.0
Total	128	100.0	72	100.0	200	100.0

Table 17 Who undertakes injecting

First injecting site

Participants were asked which vein site they had first injected into. The majority (95%, n = 122) of current injectors started injecting in their arms or hands. The remaining 5% started in their groin (3%, n = 4), legs (1%, n = 1) or feet (1%, n = 1).

96% (n = 69) of former injectors had also started injecting in their arms and hands. The remaining 4% started injecting in their groin (n = 2) and feet (n = 1).

Injecting sites

Most injectors had used their arms and hands to inject into. A wide variety of vein sites were used (72 different permutations) so for the purposes of analysis, these sites were grouped into upper body, and specific areas of the lower body (Table 18).

Injecting sites		Current injector		Former injector	
		No.	%	No.	%
Injecting sites used most often	Arms/hands	77	60.0	46	64.0
	Groin	39	30.5	22	30.5
	Lower legs	9	7.0	2	2.5
	Thighs	0	0.0	1	1.5
	Arms and groins	2	1.5	0	0.0
	Arms groins and lower legs	1	1.0	0	0.0
	Arms and lower legs	0	0.0	1	1.5
	Total	128	100.0	72	100.0
Other sites injected	Upper body only	33	26.0	22	30.5
	Groin	0	0.0	2	3.0
	Upper body and feet	4	3.0	3	4.0
	Upper body, groin, lower legs & feet	7	5.5	9	12.5
	Upper body, groin, thighs, lower legs	0	0.0	1	1.5
	Upper body, thighs, lower legs & feet	2	1.5	2	2.5
	Upper body and lower legs	9	7.0	7	9.5
	Upper body, groins, thighs, lower legs, feet	40	31.0	13	18.0
	Upper body, groins and feet	5	4.0	4	5.5
	Upper body and groin	19	15.0	2	3.0
	Upper body, groins, lower legs	6	4.5	1	1.5
	Upper body, lower legs, and feet	2	1.5	6	8.5
	No other site	1	1.0	0	0.0
	Total	128	100.0	72	100.0

Table 18 Injecting sites

‘Popping’ (injecting into skin or muscle)

Just over a third of current injectors (37.5%, n = 48) had injected into skin / subcutaneous tissue or muscle. Almost half of former injectors (47%, n = 34) had injected into skin / subcutaneous tissue or muscle.

Skin hygiene

It was more common amongst injectors to clean their skin before injecting than wash their hands, and a variety of skin cleansers were used. If using alcohol swabs, not everyone allowed the skin to dry (Table 19).

		Current injector		Former injector	
		No.	%	No.	%
Hygiene	Always wash hands	51	40.0	15	21.0
	Mostly wash hands	0	0.0	5	7.0
	Sometimes wash hands	15	12.0	0	0.0
	Rarely wash hands	17	13.0	7	9.5
	Never wash hands	45	35.0	43	59.5
	Unsure	0	0.0	2	3.0
	Total		128	100.0	72
Clean skin before injecting	Always	69	54.0	34	47.0
	Most of the time	0	0.0	8	11.0
	Sometimes	11	8.5	0	0.0
	Rarely	23	18.0	10	14.0
	Never	0	0.0	20	28.0
	Unsure	25	19.5	0	0.0
	Total		128	100.0	72
Skin cleanser used	Soap and water	0	0.0	2	4.0
	Alcohol swab	102	98.0	50	96.0
	Saliva	0	0.0	0	0.0
	Other	2	2.0	0	0.0
	Total		104	100.0	52
Allowed alcohol to dry	Always	37	36.0	12	24.0
	Mostly	0	0.0	7	14.0
	Sometimes	16	16.0	0	0.0
	Rarely	34	33.0	6	12.0
	Never	4	4.0	21	42.0
	Unsure	11	11.0	4	8.0
	Total		102	100.0	50

Table 19 Skin hygiene

4.5 Injecting Equipment

Water

The majority of injectors used tap water to make up their drugs (Table 20).

Type of water	Current injector		Former injector	
	No.	%	No.	%
Tap water	91	71.0	52	72.0
Bottled water	11	8.5	6	8.5
Boiled water	26	20.5	11	15.0
Sterile water	0	0.0	2	3.0
Other	0	0.0	1	1.5
Total	128	100.0	72	100.0

Table 20 Water used

Acidifier

The majority of current injectors used the pharmaceutical citric acid distributed in sachets by drugs services. Other acidifiers were also used (Table 21).

Acidifier used		Current injector		Former injector	
		No.	%	No.	%
Acidifier	Citric acid	118	92.0	64	89.0
	Vitamin C	0	0.0	1	1.5
	Lemon juice	1	1.0	1	1.5
	Vinegar	0	0.0	3	4.0
	Other	1	1.0	0	0.0
	Don't use	8	6.0	3	4.0
	Total	128	100.0	72	100.0
Other acidifiers used	Citric acid	0		2	
	Vitamin C	1		1	
	Lemon juice	34		17	
	Vinegar	11		17	
	Non-pharmaceutical vitamin c	2		0	
	Combinations of acids	5		2	
	Other	1		3	
	Total	54		42	

Table 21 Acidifiers used

Needles and syringes

Most injectors used a new needle and syringe every time (Table 22).

		Current injector		Former injector	
		No.	%	No.	%
Used new needle and syringe	Yes	80	62.5	37	51.0
	No	48	37.5	35	49.0
	Total	128	100.0	72	100.0
Used 1ml insulin syringes	yes	98	77.0	53	74.0
	No	30	23.0	19	26.0
	Total	128	100.0	72	100.0

Table 22 Equipment used

The majority of injectors used insulin syringes, the standard integrated 1ml needle and syringe, issued by IEP services at that time.

Those participants who did not usually use insulin syringes were asked what needles and syringes (barrels) they used instead. Most injectors used blue needles (long and short) and 2ml barrels. Very few used green needles and 1ml barrels (n = 2). Insulin syringes, which were most commonly distributed at the beginning of this study, were fragile and intended for subcutaneous use only and this practice has since changed.

However, many of those who had been injecting for over 25 years reported previously using whatever they could ‘get their hands on’, and commented that they had often stolen new or used paraphernalia from hospitals. This was before needle exchanges were set up in the city. One former injector reported that there was no pattern or consistency to his use but that he used ‘larger’ needles for Diconal injections (an analgesic used more commonly in the past).

Filters

Almost all participants filtered their drugs. 98% (n = 126) of current injectors always used a filter, and one person used one most of the time. One person never used a filter.

99% (n = 71) of the former injectors used a filter, with 96% (n = 69) always using a filter.

Various types of filter were used (Table 23). Only a few used the sterile filter available from some drugs services as this was generally viewed as unsuitable.

Filters used	Current injector		Former injector	
	No.	%	No.	%
Cigarette filter	99	77.0	60	83.0
Roll-up filter	6	4.5	2	3.0
Sterile filter	2	1.5	2	3.0
Home-made	12	9.5	7	9.5
Pillow or cushion	1	1.0	0	0.0
Old sock	2	1.5	0	0.0
Two or more types	5	4.0	0	0.0
No filter	1	1.0	1	1.5
Total	128	100.0	72	100.0

Table 23 Filters used

Participants were also asked if they used a fresh unused filter each time they injected. 60% (n = 77) of current injectors always used a fresh filter, whilst 28% (n = 36) used one most of the time. Of the former injectors, 67% (n = 48) always used a fresh filter, and a further 35% (n = 18) used one most of the time.

4.6 Injecting Technique

99% of current injectors injected in the same way each time. 97% (n = 70) of the former injectors injected in the same way each time whilst 3% (n = 2) injected in the same way most of the time.

Licking needles

69 participants had licked their needles (34.5%) although the frequency was not consistent (Table 24).

Licked needle	Current injector		Former injector	
	No.	%	No.	%
Always	8	6.0	8	11.0
Most of the time	9	7.0	8	11.0
Rarely	26	20.0	10	14.0
Never	85	67.0	46	64.0
Total	128	100.0	72	100.0

Table 24 Licking needles

Finding a vein

Participants were asked if they always found a vein. Of the current injectors most (63%, n = 81) claimed to always find a vein. Just over half the former injectors (53%, n = 38) always found a vein.

Hitting nerves or arteries

Participants were asked about hitting nerves and arteries as part of their injecting experience. Of the current injectors 61% (n = 78) had hit a nerve and 60% (n = 77) had reported hitting an artery. Of the former injectors 49% (n = 35) reported hitting a nerve, and 46% (n = 35) had hit an artery.

4.7 Leg Ulcer Prevalence

Thirty participants had experienced a leg ulcer: 21 males (14% of the total males) and 9 females (17% of the total females); 17% (n = 12) of former injectors and 14% (n = 18) of current injectors. Five people (of eight) who had been injecting for more than 25 years had a leg ulcer and 14 (7% of the sample) had active ulceration at the time of the interview.

Participants who had had a wound on their leg were asked questions relating to whether it had healed, recurred, whether they had injected in the area and how the wound had been cared for. Thirty-five participants (17.5%) had had a wound on their leg. Of those,

29 had wounds that healed up. Of the 29 who healed, 13 wounds subsequently recurred. Of those that recurred, three had a solitary recurrence, in three people the wound recurred twice, and in seven people the wound recurred three or more times. Six leg wounds did not heal.

Five participants had had a wound on their leg which was described as an abscess by participants, and all had healed up.

Despite the number of recurrences for some, the participants who had had a leg ulcer were able to say conclusively where they lived when they had it. Thirteen were in their own home, sixteen were homeless and one was incarcerated.

Injecting in the leg wound area

Of the 35 who had developed a leg wound, 26 had injected in the area previously to the wound appearing.

Subsequent to the wound developing, 7 participants used it to inject into, 2 always used that site, 1 injected into it for 3 years, 1 used it when most chaotic and 3 were unsure how often they used it.

Treatment of leg ulceration

Nineteen participants of the thirty participants who had had a leg ulcer had a Doppler test, which is a pre-requisite to compression therapy. All reported having compression therapy.

4.8 Prevalence of Skin Problems

In response to the question ‘Have you ever had a skin problem?’, 60% (n = 120) said yes. Participants who had experienced skin problems were asked further questions about the type of skin problem they had. These were defined and explored with each participant to ensure that a standard definition (see Table 25 below) was used.

Skin problem	Definition
Lumps	Hard swellings without broken skin, not red or hot or particularly painful
Track marks	Scratch marks, raised red veins, raised hardened veins
Abscesses	Raised red hot painful lumps, with or without obvious pus / broken skin – possibly required lancing/ surgery or have spontaneously burst
Acid Burns	Painful, blistered or broken skin directly attributed to use of acid
Broken skin	Injecting injury that has caused a break in the skin, wounds, or scabs that have healed in less than 4 weeks
Chronic wounds	Any break in the skin (not a leg ulcer) that has been present 4 weeks or more
Rashes	Multiple red or pink spots, raised or flat that last longer than the short period following injection

Table 25 Definitions of skin problems

Of these, the majority complained of abscesses. 5% (n = 11) complained of other skin problems and these were bruising and varicose veins, phlebitis, cellulitis, haematoma, scarring and thin skin. Some participants had more than one skin problem (Table 26).

		Current Injector		Former Injector		Total	
		No.	%	No.	%	No.	%
Individuals reporting a skin problem		80	67.0	40	33.0	120	60.0
Type of skin problem							
	Leg ulcer	17	8.0	13	11.5	30	9.0
	Abscesses	58	27.0	32	28.0	90	27.0
	Lumps	40	18.5	18	16.0	58	17.5
	Track marks	40	18.5	16	14.0	56	17.0
	Acid burns	21	9.5	8	7.0	29	9.0
	Chronic wound	17	8.0	11	9.5	28	8.5
	Broken skin	15	7.0	10	8.5	25	7.5
	Other skin problems	6	2.5	5	4.5	11	3.5
	Rashes	2	1.0	1	1.0	3	1.0
	Total	216		114		330	
		Males (n = 148)		Females (n = 52)		Total (n = 200)	
		No.	%	No.	%	No.	%
Type of skin problem by gender							
	Leg ulcer	21	9.5	9	8.5	30	9.0
	Abscesses	65	28.5	25	24.0	90	27.0
	Lumps	38	16.5	20	19.5	58	17.5
	Track marks	37	16.5	19	18.5	56	17.0
	Chronic wound	20	9.0	8	7.5	28	8.5
	Acid burns	19	8.5	10	9.5	29	9.0
	Broken skin	15	6.5	10	9.5	25	7.5
	Other skin problems	9	4.0	2	2.0	11	3.5
	Rashes	2	1.0	1	1.0	3	1.0
	Total problems	226		104		330	

Table 26 Frequencies of skin problems for current and former injectors / males and females

4.9 Risk Factors for Leg Ulceration

The proportion of participants with leg ulceration was quite low and therefore drawing causal links with statistical significance for some of the factors described was not possible due to the small numbers. Numbers were too small to test for significance for age group, hand dominance, interview location, postcode, frequency of injecting, drugs injected, substance used to dissolve heroin, types of water used, types and use of filters and acidifier, washing hands and cleaning skin, types of skin cleanser used, whether

participants injected themselves, who taught them to inject, site injected first, site injected most, frequency of injecting, injecting at wound site, parity, drinking alcohol, body mass index (BMI), nutrition, smoking, and having diabetes.

In the following section risk factors are described where statistical tests were conducted and those of importance in the development of leg ulceration are identified (Table 27). The use of only larger numbers helped avoid a Type 1 error.

As can be seen from Table 27 those variables that were not found to be significant in the development of leg ulceration for this sample were gender, homelessness, history of leg fracture, licking needles, skin or muscle popping and pregnancy.

Table 27 Risk factors for leg ulceration		Yes had leg ulcer		Never had leg ulcer		Total		p value *	χ ²	Test used	Cramer's V
Risk Factors		No.	%	No.	%	No.	%				
Gender	Male	21	70.0	127	74.5	148	74.0	0.588	.294	Pearson Chi-square	.038
	Female	9	30.0	43	25.5	52	26.0				
	Total	30		170		200					
Homeless ever	Yes	26	86.5	135	79.5	161	80.5	0.355	.855	Pearson Chi-square	.065
	No	4	13.5	35	20.5	39	19.5				
	Total	30		170		200					
Injected 5 years or less	Yes	3	10.0	63	37.0	66	33.0	0.004*	8.444	Pearson Chi-square	.205
	Injected 6 years and more	27	90.0	107	63.0	134	67.0				
	Total	30		170		200					
Used (insulin) 1ml syringes	Yes	15	50.0	34	20.0	49	24.5	≤0.001*	12.407	Pearson Chi-square	.249
	No	15	50.0	136	80.0	151	75.5				
	Total	30		170		200					
Used a new needle and syringe each time	Yes	12	40.0	105	62.0	117	58.5	0.026*	4.976	Pearson Chi-square	.158
	No	18	60.0	65	38.0	83	41.5				
	Total	30		170		200					
Licked needle	Yes	12	40.0	57	33.5	69	34.5	0.492	.472	Pearson Chi-square	.049
	No	18	60.0	113	66.5	131	65.5				
	Total	30		170		200					
Used a filter	Yes	29	96.5	169	99.5	198	99.0	0.56		Fisher's exact test	.022
	No	1	3.5	1	0.5	2	1.0				
	Total	30		170		200					
Lower leg injector	Yes	24	80.0	54	32.0	78	39.0	≤0.001*	24.939	Pearson Chi-square	.353
	No	6	20.0	116	68.0	122	61.0				
	Total	30		170		200					
Groin injector	Yes	28	93.5	83	49.0	111	55.5	≤0.001*	66.242	Pearson Chi-square	.576
	No	2	6.5	87	51.0	89	44.5				
	Total	30		170		200					
Hit an artery	Yes	27	90.0	82	48.0	109	54.5	≤0.001*	17.937	Pearson Chi-square	.299
	No	3	10.0	88	52.0	91	45.5				
	Total	30		170		200					
Hit a nerve	Yes	24	80.0	88	52.0	112	56.0	0.004*	8.251	Pearson Chi-square	.203
	No	6	20.0	82	48.0	88	44.0				
	Total	30		170		200					
Always find a vein	Yes	9	30.0	110	64.5	119	59.5	≤0.001*	12.746	Pearson Chi-square	.252
	No	21	70.0	60	35.5	81	40.5				
	Total	30		170		200					
Skin or muscle popping	Yes	17	56.5	105	62.0	122	61.0	0.058	3.581	Pearson Chi-square	.134
	No	13	43.5	65	38.0	78	39.0				
	Total	30		170		200					
Blood borne virus	Yes	18	60.0	63	37.0	81	40.5	0.018*	5.569	Pearson Chi-square	.167
	No	12	40.0	107	63.0	119	59.5				
	Total	30		170		200					
Smoking	Yes	29	97.0	170	100.0	199		1	1.000	Fisher's exact test	.030
	No	1	3.0	0	0.0	1					
	Total	30		170		200					
Heart problems	Yes	11	36.5	16	9.5	27	13.5	≤0.001*		Fisher's exact test	.285
	No	19	63.5	154	90.5	173	86.5				
	Total	30		170		200					
Claudication	Yes	18	60.0	14	8.0	32	16.0	≤0.001*		Fisher's exact test	.504
	No	12	40.0	156	92.0	168	84.0				
	Total	30		170		200					
Walking problems	Yes	15	50.0	24	14.0	39	19.5	≤0.001*	20.916	Pearson Chi-square	.323
	No	15	50.0	146	86.0	161	80.5				
	Total	30		170		200					
History of leg fracture	Yes	12	40.0	44	26.0	56	28.0	0.112	2.521	Pearson Chi-square	.112
	No	18	60.0	126	74.0	144	72.0				
	Total	30		170		200					
Pregnancy (n = 52 females)	Yes	8	89.0	34	79.0	42	81.0	0.497	.462	Pearson Chi-square	.940
	No	1	11.0	9	21.0	10	19.0				
	Total	9		43		52					

*p < .05

4.10 Injecting behaviours

Injecting career

A Pearson Chi-square test of association between leg ulceration and length of injecting career (0 - 5 years and 6 years and over) was conducted and it was found that the length of injecting career was statistically significant in the development of leg ulceration ($p = 0.004$).

Insulin syringes

A test of association between whether or not participants had used 1ml insulin syringes and the development of leg ulceration was undertaken and found to be statistically significant ($p \leq 0.001$). Participants with a leg ulcer are more likely to have used an insulin syringe.

Using a new needle and syringe

A test of association between the use of a new needle and syringe every time and the development of leg ulceration was statistically significant ($p = 0.026$) and so participants with leg ulcers were less likely to use fresh equipment.

Leg injecting

The data gathered for all participants were compiled to identify which participants had ever used the legs as an injecting site. 30% ($n = 78$) of participants had injected in their legs, and of these, 24 had developed a leg ulcer. The association was found to be statistically significant ($p = \leq 0.001$).

Groin injecting

55.5% of the sample had used the groin to inject ($n = 111$) and a test of association demonstrated that groin injecting was positively associated with developing leg ulceration ($p \leq 0.001$).

Hitting nerves or arteries

A test of association showed that hitting an artery when injecting was statistically significant in the development of leg ulceration ($p \leq 0.001$) and so was hitting a nerve ($p = 0.004$).

Finding a vein

Those less able to find a vein were more likely to develop leg ulceration ($p \leq 0.001$).

4.11 Physical health

Blood-borne viruses

A Chi-square test was used to determine whether the diagnosis of a BBV (such as HIV or Hepatitis B or C) was a risk factor in the development of leg ulceration. The association was found to be significant ($p = 0.018$). This result does not take into account those participants who had never been tested (and could also have been positive), and therefore answered that they had never been diagnosed with a BBV.

Heart problems

A Fisher's exact test was used to determine the statistical significance of being diagnosed with heart problems and developing leg ulceration, $p \leq 0.001$, and therefore those diagnosed with heart problems are more likely to develop leg ulceration.

Claudication

A Fisher's exact test was undertaken to determine whether claudication was associated with leg ulceration, $p \leq 0.001$, so claudication is associated with leg ulceration.

Walking problems

A Chi-square test showed that arthritis, joint and walking problems are associated with leg ulceration ($p = \leq 0.001$). However it is not clear whether these problems preceded the ulceration, or were a consequence of the ulceration.

4.12 Risk factors for venous disease

Turning to known risk factors for venous disease, most of these were similar to non-injecting groups (Moffatt et al, 2007, p78). As can be seen from Table 28 the variables that were not found to be significant in the development of leg ulceration for this sample were family history of venous disease and standing for long periods.

Potential Risk Factors		Yes had leg ulcer		Never had leg ulcer		Total		p value *	χ^2	Test used	Cramer's V
		No.	%	No.	%	No.	%				
Deep vein thrombosis (DVT)	Yes	29	96.5	36	21.0	65	32.5	$\leq 0.001^*$	66.242	Pearson Chi-square	.576
	No	1	3.5	134	79.0	135	67.5				
	Total	30		170		200					
Family history venous disease	Yes	11	36.5	53	31.0	64	32.0	0.552	.353	Pearson Chi-square	.042
	No	19	63.5	117	69.0	136	68.0				
	Total	30		170		200					
Varicose veins	Yes	22	73.5	36	21.0	58	29.0	$\leq 0.001^*$	33.690	Pearson Chi-square	.410
	No	8	26.5	134	79.0	142	71.0				
	Total	30		170		200					
Skin staining	Yes	9	30.0	9	5.5	18	9.0	$\leq 0.001^*$		Fisher's exact test	.647
	No	21	70.0	161	94.5	182	91.0				
	Total	30		170		200					
Cellulitis	Yes	20	66.5	16	9.5	36	18.0	$\leq 0.001^*$	56.634	Pearson Chi-square	.532
	No	10	33.5	154	90.5	164	82.0				
	Total	30		170		200					
Standing for long periods	Yes	22	73.5	127	74.5	149	74.5	0.874	.025	Pearson Chi-square	.011
	No	8	26.5	43	25.5	51	25.5				
	Total	30		170		200					
								*p < .05			

Table 28 Risk factors for venous disease

Deep vein thrombosis (DVT)

Some participants had experienced more than one DVT; 23 had DVTs in the lower legs, 41 had DVT in the upper legs, and 3 were unsure where their DVT was.

A Chi-square test was undertaken which showed that DVT was associated with leg ulceration ($p = \leq 0.001$).

Varicose veins

A Chi-square test showed that varicose veins are associated with the development of leg ulceration ($p = \leq 0.001$).

Skin staining on legs

A Fisher's exact test showed that skin staining on the leg was associated with leg ulceration in this sample ($p \leq 0.001$). However, it is unclear again whether or not this preceded the development of leg ulceration.

Cellulitis

A Chi-square test showed that cellulitis or 'red leg' is associated with leg ulceration in PWID ($p \leq 0.001$). However it is unclear whether or not this preceded the development of leg ulceration.

DVT and injecting in lower legs

The association between those with a DVT and those that injected in the lower legs ever was also tested using a Chi-square test of association (Table 29). This was statistically significant ($p = \leq 0.001$).

DVT and groin injecting

The association with DVT and groin injecting was also tested using a Chi-square test of association. This was statistically significant ($p = \leq 0.001$).

DVT and injecting		DVT		No DVT		Total		p value*	χ^2	Test used	Cramer's V
		No.	%	No.	%	No.	%				
Injected in lower legs	Yes	40	61.5	38	28.0	78	39.0	$\leq 0.001^*$	20.562	Pearson Chi-square	.321
	No	25	38.5	97	72.0	122	61.0				
	Total	65		135		200					
Groin injecting	Yes	61	94.0	50	37.0	111	55.5	$\leq 0.001^*$	57.332	Pearson Chi-square	.535
	No	4	6.0	85	63.0	89	44.5				
	Total	65		135		200					
								*p < .05			

Table 29 Association between DVT and injecting in the groin and lower legs

Skin problems and the link to leg ulceration

Chi-square tests of association were undertaken to identify if there was statistical significance between developing leg ulceration and experiencing some skin problems. Most skin problems were significant in developing leg ulceration unsurprisingly indicating that leg ulceration is more likely to occur where there are other skin problems also. The numbers were too small to analyse for rashes or 'other' skin problems.

Type of skin problem	χ^2	<i>p</i>
Lumps	5.609	0.018*
Track marks or scratches	6.429	0.011*
Abscesses	4.8	0.028*
Acid burns	3.826	0.05*
Broken skin	16.616	< 0.001*
Chronic wounds	88.046	< 0.001*
		*p < .05

Table 30 Relationship between skin problems and leg ulceration

Regression questions and results

Many of the associations identified in the previous section may have been confounded by other variables.

Direct logistic regression was thus used to ascertain if statistical relationships remained once these potential confounders were adjusted.

As injectors grow older they may be more likely to develop age-related problems such as venous disease. Whilst this was managed within the sample by only including those aged below 44 years of age, it is possible that injectors are more likely to develop ulceration as they are older and this coincides with injecting for a long time. Similarly if PWID have progressively damaged their veins as their injecting continues, they are then more likely to access riskier sites such as groin. Injecting in the groin carries the risk of hitting arteries and nerves which were significantly associated with leg ulceration earlier. So which of these variables are significant? The first three models will examine which of the variables, while controlling for the others, are significant. The evolving models are detailed in Tables 31, 32 and 33.

Model 1: *Are injectors more likely to get a leg ulcer if they are older or because they have injected for a long time? How significant are age and length of injecting career on the development of leg ulceration?*

The model assessed the impact of two factors: length of injecting (grouped into 0 - 5 years and 6 years and over) and age now (under 35 or 35 years and over). The full model was statistically significant ($X^2(2, n = 200) = 25.18$ $p \leq 0.001$) indicating that the model was able to distinguish between respondents who had and had not had leg ulceration. As shown in Table 31, both of the independent variables made a uniquely statistically significant contribution to the model. The strongest predictor of developing a leg ulcer was *age* with an odds ratio of 7.62. This indicated that those aged over 35 years were over 7 times more likely to develop leg ulceration than those who were younger than 35 years, controlling for length of injecting career. However, there were only two age groups. The odds ratio of injecting career was 3.61 indicating

that the longer someone injects for they are more than 3 times more likely to get a leg ulcer controlling for other factors in the model.

Model 2: *Injectors are more likely to use their groin if they have been injecting for a long time. So how significant is groin injecting when controlling for age and length of injecting career?*

The logistic regression model was then revised to add in groin injecting to length of injecting career and age. The model containing three predictors was statistically significant ($X^2(3, n = 200) = 38.06$ $p \leq 0.001$) indicating that the model was able to distinguish between respondents who had and had not had leg ulceration. As shown in Table X, two of the independent variables made a uniquely statistically significant contribution to the model, groin injecting and age. The strongest predictor of developing a leg ulcer was *groin injecting* ($p = 0.004$) with an odds ratio of 9.23. This indicated that groin injectors were over nine times more likely to develop leg ulceration than those who were not groin injectors, controlling for age and length of injecting career. Those aged over 35 years were over six times (odds ratio 6.89) as likely to develop a leg ulcer as those under 35 ($p = 0.003$).

Model 3: *As PWID become older, they are more likely to develop chaotic injecting habits and inject in more risky places such as the groin. Injecting in the groin increases the likelihood of hitting a nerve or an artery. These are individually statistically significant in the development of leg ulceration, but which of these factors was most likely to cause leg ulceration?*

The model contained three independent variables (groin injecting ever, ever hit a nerve, ever hit an artery). The model was statistically significant ($X^2(3, n = 200) = 46.213$ $p \leq 0.001$) indicating that the model was able to distinguish between respondents who had and had not had a leg ulcer. Only one of the independent variables, *groin injecting*, made a uniquely statistically significant contribution to the model. This was the strongest predictor of developing a leg ulcer recording an odds ratio of 6.17. This

indicated that participants who had a leg ulcer were over six times more likely to have groin injected than those who did not, controlling for hitting nerves and arteries. Poor technique, such as hitting nerves and arteries, is less important than simply injecting in the groin.

Groin injecting was significant in the last model, but as people continue to inject for a long time they may also inject into their legs.

Logistic regression predicting the likelihood of developing a leg ulcer										
		Unadjusted Odds Ratio (95% CI)					Adjusted Odds Ratio (95% CI)			
		Odds ratio	Lower	Upper	<i>p</i>	Odds ratio	Lower	Upper	<i>p</i>	
Model 1	Length of injecting career and age									
	Age under 35 or over 35 years	9.434	2.757	32.279	.000	7.623	2.197	26.448	0.001*	
	Injecting up to 5 years and over 5 years	5.299	1.545	18.179	.008	3.611	1.017	12.820	0.047*	
	Constant					.150			.000	
Note	R ² = 0.62 (Hosmer and Lemeshow), 0.118 (Cox and Snell), 0.207 (Nagelkerke)									
Model 2	Length of injecting career, age and groin injecting									
	Age under 35 or over 35 years	9.434	2.757	32.279	.000	6.686	1.897	23.557	0.003*	
	Injecting up to 5 years and over 5 years	5.299	1.545	18.179	.008	1.809	.465	7.039	.393	
	Groin injecting	.068	.016	.295	.000	9.235	2.014	42.345	0.004*	
	Constant					.005			.005	
Note	R ² = 0.99 (Hosmer and Lemeshow), 0.173 (Cox and Snell), 0.304 (Nagelkerke)									
Model 3	Groin injecting and hitting nerves and arteries									
	Groin injecting	.068	.016	.295	.000	6.170	1.180	32.160	0.03*	
	Ever hit a nerve	3.727	1.450	9.578	.000	1.760	.634	4.900	.280	
	Ever hit an artery	9.659	2.823	33.049	.000	3.190	.785	12.980	.100	
	Constant					.010			.000	
Note	R ² = 0.831 (Hosmer and Lemeshow), 0.138 (Cox and Snell), 0.243 (Nagelkerke)									

Table 31 Prediction of developing a leg ulcer 1

Model 4: *Age was a strong predictor of developing leg ulceration. As people get older and their injecting career lengthens they may be more likely to inject into the legs and / or groin.*

The model contained four independent variables (age, length of injecting career, injecting into the legs and injecting into the groin). The model was statistically significant ($X^2(4, n = 200) = 49.272$ $p \leq 0.001$) indicating that the model was able to distinguish between respondents who had and had not had a leg ulcer. As shown in Table 32 three of the independent variables (age group, groin injecting and leg

injecting) made a unique statistically significant contribution to the model. The strongest predictor was groin injecting at an odds ratio of 11.051. Leg injecting was also a predictor of developing a leg ulcer recording an odds ratio of 5.306. This indicated that participants who groin injected were over eleven times more likely to get a leg ulcer, and if leg injecting, more than five times as likely.

Logistic regression predicting the likelihood of developing a leg ulcer 2									
		Unadjusted Odds Ratio (95% CI)			p	Adjusted Odds Ratio (95% CI)			p
		Odds ratio	Lower	Upper		Odds ratio	Lower	Upper	
Model 4	Age, length of injecting career and injecting into the groin and legs								
	Age under 35 or over 35 years	9.434	2.757	32.279	.000	4.692	1.274	17.280	0.02*
	Injecting up to 5 years and over 5 years	5.299	1.545	18.179	.008	.948	.219	4.113	.943
	Groin injecting	.068	.016	.295	.000	11.051	2.363	51.678	0.002*
	Leg injecting	8.593	3.320	22.242	.000	5.306	1.854	15.182	0.002*
	Constant					.004			.000
Note	R ² = 1.179 (Hosmer and Lemeshow), 0.218 (Cox and Snell), 0.383 (Nagelkerke)								
Model 5	Age, injecting into the groin and legs, and using insulin syringes								
	Age under 35 or over 35 years	9.434	2.757	32.279	.000	4.720	1.275	17.469	0.02*
	Groin injecting	.068	.016	.295	.000	8.495	1.754	41.146	0.008*
	Leg injecting	8.593	3.320	22.242	.000	5.227	1.891	14.445	0.001*
	Insulin syringe used	4.000	1.782	8.977	.001	1.713	.659	4.456	.269
	Constant					.002			.000
Note	R ² = 2.046 (Hosmer and Lemeshow), 0.223 (Cox and Snell), 0.391 (Nagelkerke)								
Model 6	Age, injecting into the groin and legs, and inability to find a vein								
	Age under 35 or over 35 years	9.434	2.757	32.279	.000	4.406	1.128	17.208	0.033*
	Groin injecting	.068	.016	.295	.000	14.551	2.967	71.368	0.001*
	Leg injecting	8.593	3.320	22.242	.000	7.445	2.467	22.464	0.000*
	Inability to find a vein	.234	.101	.542	.001	.190	.068	.533	0.002*
	Constant					.005			.000
Note	R ² = 2.168 (Hosmer and Lemeshow), 0.261 (Cox and Snell), 0.485 (Nagelkerke)								

Table 32 Logistic regression predicting the likelihood of developing leg ulceration 2

Earlier the non-use of 1ml insulin syringes was found to be associated with the development of leg ulceration.

Model 5: *The older the drug injector, the more likely they are to develop a leg ulcer. Is the leg ulcer a consequence of age or of risky injecting practices such as non-use of small (insulin) syringes, leg and groin injecting?*

The model contained four independent variables (age, injecting into the legs and injecting into the groin and use of insulin syringes). The model was statistically significant ($X^2(4, n = 200) = 50.494 p \leq 0.001$) indicating that the model was able to

distinguish between respondents who had and had not had a leg ulcer. As shown in Table 32 three of the independent variables (age group, groin injecting and leg injecting) made a unique statistically significant contribution to the model. The strongest predictor was groin injecting at an odds ratio of 8.495. Leg injecting was also a predictor of developing a leg ulcer recording an odds ratio of 5.227. Use of insulin syringes was not significant, so the next model will examine whether with the known predictors, (controlling for age, groin and leg injecting) poor technique and inability to find a vein is significant.

Model 6: *The older the drug injector, the more likely they are to develop a leg ulcer. Is the leg ulcer a consequence of age, or of leg and groin injecting or inability to find a vein?*

The model contained the four independent variables and was statistically significant ($X^2(4, n = 200) = 60.620 p \leq 0.001$) indicating that the model was able to distinguish between respondents who had and had not had a leg ulcer. As shown in Table 32 three of the independent variables (age group, groin injecting and leg injecting) as before made a unique statistically significant contribution to the model. The strongest predictor was groin injecting at an odds ratio of 14.551. Leg injecting was also a predictor of developing a leg ulcer recording an odds ratio of 7.445. Inability to find a vein was significant but the odds ratio was low.

As DVT was significant in the development of leg ulceration the next two models examined its role along with leg and groin injecting.

Model 7: *Many leg injectors develop DVT. Therefore this test was to establish whether leg injecting or DVT was more significant in the development of a leg ulcer.*

The model contained two independent variables, leg injecting and DVT and was statistically significant ($X^2(2, n = 200) = 76.826 p \leq 0.001$) indicating that the model was able to distinguish between respondents who had and had not had a leg ulcer.

As shown in Table 33, both leg injecting and DVT made statistically significant contributions to the model. Participants who had a leg ulcer were over 80 times more likely to have had a DVT, and nearly 5 times as likely to have leg injected. DVT was the most significant indicator.

Logistic regression predicting the likelihood of developing a leg ulcer (DVT) 3									
		Unadjusted Odds Ratio (95% CI)			p	Adjusted Odds Ratio (95% CI)			p
		Odds ratio	Lower	Upper		Odds ratio	Lower	Upper	
Model 7	Leg injecting and DVT								
	Leg injecting	8.593	3.320	22.242	.000	4.803	1.617	14.266	0.005*
	Deep vein thrombosis (DVT)	107.944	14.218	819.551	.000	80.601	10.473	620.289	≤ 0.001*
	Constant					.004			.000
Note	R ² = 0.584 (Hosmer and Lemeshow), 0.319 (Cox and Snell), 0.559 (Nagelkerke)								
Model 8	Groin injecting and DVT								
	Groin injecting	.068	.016	.295	.000	1.436	.225	9.160	.702
	Deep vein thrombosis (DVT)	107.944	14.218	819.551	.000	89.189	9.705	819.679	≤ 0.001*
	Constant					.006			.000
Note	R ² = 0.464 (Hosmer and Lemeshow), 0.288 (Cox and Snell), 0.506 (Nagelkerke)								
Model 9	Leg injecting, groin injecting and DVT								
	Leg injecting	8.593	3.320	22.242	.000	4.884	1.638	14.560	0.004*
	Groin injecting	.068	.016	.295	.000	1.691	.252	11.349	.589
	Deep vein thrombosis (DVT)	107.944	14.218	819.551	.000	63.144	7.134	558.893	≤ 0.001*
	Constant					.003			.000
Note	R ² = 1.698 (Hosmer and Lemeshow), 0.320 (Cox and Snell), 0.561 (Nagelkerke)								
									*p < .05

Table 33 Logistic regression predicting the likelihood of developing a leg ulcer (DVT)

3

Model 8: *Many groin injectors develop DVT. Therefore this test was to establish whether groin injecting or DVT was more significant in the development of a leg ulcer.* The model contained two independent variables, groin injecting and DVT. The model containing both predictors was statistically significant ($X^2(2, n = 200) = 68.076$ $p \leq 0.001$) indicating that the model was able to distinguish between respondents who had and had not had a leg ulcer.

As shown in Table 33, only DVT made a statistically significant contribution to the model. This indicated that participants who had a leg ulcer were over 89 times more likely to have had a DVT.

Model 9: From the above, *three predictors have appeared most strongly indicative of developing leg ulceration. Therefore this test was to establish whether groin injecting or leg injecting or DVT was more significant in the development of a leg ulcer.*

The model contained three independent variables, and was statistically significant ($X^2(2, n = 200) = 77.123$ $p \leq 0.001$) indicating that the model was able to distinguish between respondents who had and had not had a leg ulcer.

As shown in Table 33, only DVT made the most statistically significant contribution to the model. This indicated that participants who had a leg ulcer were over 63 times more likely to have had a DVT. Leg injecting was also predictive of leg ulceration with an odds ratio of almost 5. Interestingly, in this model groin injecting was not significant.

Summary of statistical testing

The earlier tests of association yielded a number of variables of significance in the development of leg ulceration which were tested using regression. These were:

- Increasing length of injecting career
- Groin injecting
- Injecting in the legs
- Difficulty finding a vein
- DVT

As PWID get older they were more likely to have age-related problems and change habits in response. The regression testing showed that DVT was the greatest predictor of leg ulceration followed by injecting in the leg and groin injecting.

Some other variables were also significant – BBVs, heart problems and claudication, mobility issues (joint and arthritic problems) however, each of these was not specific and the questions were not precise enough to be truly useful. Also, varicose veins and cellulitis were statistically significant in the development of ulceration however, as these often precede ulceration, they were known to be part of the progress of venous

disease towards the endpoint of ulceration and suggesting that these were causative factors would be inappropriate.

4.13 Participants' views on the cause of leg ulcers

Participants who had experienced leg wounds

The participants (n = 35) who had a wound on their leg were asked what they thought caused it. Four participants answered 'don't know' and the remaining answers were grouped into emergent themes (Burns and Grove, 2005, p553).

Hygiene

The predominant theme related to hygiene – whether it was *'sleeping rough and not able to get clean'*, or *'not taking care of yourself'*, or something within the drugs – sometimes described as a *'dirty hit'* - *'injecting the wrong way – under skin turned to poison and went septic, maybe a dirty hit'*, *'dirty needle something on it'* *'injecting in leg ?dirty hit'*.

Two participants described poison travelling down their leg: *'injecting into groin – poison going down the way because I had a DVT and the poison had to get out somewhere....'* *'poison travelled down the leg'*.

Abscess

Some participants talked about the ulcer starting as an abscess: *'through injecting, became a lump and then started breaking up'* *'an abscess –started as a red patch'*, *'abscess not healedgot antibiotics but not healed up'*, *'ulcers appeared from abscesses sometimes would appear overnight 3 or 4 at a time at different sites from where injected – caused scarring'*.

Injecting technique

Injecting technique was also implicated : *'desperation – withdrawal and not taking usual care'*, *'way I was injecting'*, *'hitting in wrong place, continuously using the same place'*.

Some of the participants related the leg wound to what they injected – two related this to injecting 'jellies', and four participants mentioned using cocaine, as well as MST and temazepam (or mixing as a speedball). Four participants put the ulceration down to injecting in the groin or injecting in the leg.

Treatment

Some mentioned forms of treatment- *'a midwife pulled off the scab and it never healed up'*, and *'formaldehyde treatment for a DVT'*. One self-treated with problematic results: *'bad hit – blood blister and took a Stanley knife to them to clean it out and then abscess formed – and then got worse'*.

Delayed presentation

Some reported the leg ulcer appearing later, sometimes a long time after the event *'don't know – happened years after injecting'*; *'used to inject into leg years ago, knocked it against the car door and then an abscess formed- it's been a year now'*, *'hitting jellies and MST – wounds appeared four weeks later'*.

Of those that actually had a wound on their leg there was no overarching theme to the responses. There was no true agreement between the participants.

All participants' views on causation

The final question, asked of all participants, was *'Why do you think some injectors get wounds on their legs and others don't?'*

The answers were grouped into themes. Some answers comprised data that matched several themes, and responses were copied into more than one theme if appropriate. Some of the participants elaborated on their earlier opinions but essentially the responses were similarly diverse. Only fourteen (7%) answered 'don't know'.

Technique

The majority of responses related to technique. Some of these responses related to sites – reusing the same site, or injecting into sites where there was already a problem, letting others inject (and possibly sharing equipment) or a lack of knowledge about technique:

'Hygiene, still injecting into same area when already damaged'

'people just give up and don't care - keep going in the same places, not keeping clean'

'careless injecting, possibly hygiene'

'don't know what they are doing and think they know what they are doing'

'people not being clean not injecting using proper procedure'

'not taking their time and doing it right'

'don't know what they are doing'

'good hygiene, injecting bits of filters, injecting jellies in the past'

'not doing it right, letting others give them a hit - after they have given themselves'

Some participants talked about being careless and injecting in a rush, sometimes when desperate for a hit:

'too much of a rush, can't do it right - don't care just want the hit'

'carelessness - being careful helps and hygiene - finding veins help'

don't know what they are doing, don't care when choking for a hit

'people rushing - not taking time'

'can't get it in - keep going into the same site - can't get it especially when full of it'

'Don't take care how they inject - jab in - impatience - too rushed'

'a lot to do with looking after themselves, don't care how they get it into them'

'desperate - trying to get it in - too full of it and not being able to see what they are doing'

Injecting sites

Others talked about choosing injecting sites without due care:

'sticking it in anywhere - blowing veins - not caring - makes a mess'

'using the same sites'

'keep going into same bits all the time'

'injecting too much in the same place - muscle popping'

'starting to inject in the groin first'

'putting it in anywhere, not caring about themselves'

'missing veins, vein blows and still using in, using the same place repeatedly'

'muscle popping, not getting in right vein'

'don't take care - people picking scabs on legs causing it to get worse - mainly women'

'multiple popping, bang in anywhere'

'Injecting when high and missing – scratching'

'injecting - going in the fine veins all the time - using surface veins'

'injecting technique, missing or reusing same veins - using same place'

'not doing it right, dinnae know what way to put needle in – flushing'

'surface veins - injecting into surface veins, raising veins till they blow up'

Hygiene

Also rating highly were issues relating to hygiene:

'not looking after themselves, not enough cleanliness'

'groin injecting- filthy hands and nails, poor facilities in hostels'

'not taking care not cleaning themselves enough'

'scratching the site, not washing hands'

'Don't take care - using too many swabs too often- touching it all the time instead of washing hands - not keeping clean'

'dirty people, dirty clothes and not washing'

'dirty - hygiene - living in squalor and don't clean themselves (can't)'

'hygiene, not washing - morals go down the drain a lot of folk are homeless and can't wash'

Self-neglect

There was some emphasis placed on self-neglect which linked to hygiene, with comments about injectors not looking after themselves and not caring about themselves:

'not looking after themselves, not enough cleanliness'

'looking after themselves, cleanliness, rushed to have a hit and don't take care'

'don't look after themselves- cleanliness - you become lazy when strung out on heroin'

'not looking after themselves, letting others do their hits'

'the way they look after themselves – hygiene'

'homeless and being dirty, not living in clean environment - neglect themselves'

'putting it in anywhere, not caring about themselves'

'people just give up and don't care - keep going in the same places, not keeping clean'

Drugs injected

Types of drug injected were mentioned by some – in particular cocaine and temazepam (previously available as 'jellies'), and the risk associated with the anaesthetic effects of cocaine:

'Cocaine - don't feel when veins are missed - keep injecting into wounds persisting'

'people who are mixing their drugs and do it a lot, out of control'

'hitting MSTs and street jellies for a long time - also the stuff coke is cut with'

'constant drug use - vein abuse, what they inject especially temazepam'

'cocaine caused this - no-one had problems with just heroin - with coke you are injecting much more often - people aren't using filters with cocaine but still a lot of problems with legs'

'Cocaine, amateurs missing veins'

'when people mix heroin and cocaine together - miss a vein and then an abscess comes and that's it after it pops'

'missing veins - depends on what its been cut with - people in Glasgow inject crushed temazepam - more chaotic users - no vit C to use - use a lot more in Glasgow and purer'

Injecting in the groin or leg

Whilst a small number of participants linked the leg problems to groin injecting, none were absolutely clear about the problems to the venous system. Injecting in the groin or leg area was suggested by smaller numbers:

'going in the groin, using the same hole every time, running out of veins and long standing users - over 20 years'

'Injecting in legs, groin injecting'

'don't know but injecting into groins might be it'

'injecting too often, injecting into leg'

'groin injecting, nicking femoral artery when injecting and citric - building up and working out through skin - livelihood - if not eating well or taking medication for wounds'

'Using groin'

'use legs more than other sites'

'injecting into legs when something is wrong'

'persistent jaggging in legs and body is rundown - scratching from the kit causes skin breaks down and gets infected then'

'injecting in legs- don't keep it clean -don't get treatment'

'not using groin would help – DVT'

Injecting equipment

Equipment was an issue for some, and some admitted to sharing:

'not taking their time to look for veins, might go through vein, that much of a hurry to get a hit. Not cleaning it right and using other people's tools'

'cleanliness using old needles and reusing dirty needles, not looking after themselves'

'using dirty needles - not using the right stuff'

'using dirty syringes / equipment'

'Using old tools / not cleaning tools'

'Sharing others needles, dirty surfaces, reusing filters, not using a vein, reusing needles, not cleaning the skin'

'Reusing tools, sharing, going into the same place all the time, popping if can't find a vein. If rattling will do anything to get it in'

'not taking care of their equipment, sharing equipment, doing it on dirty surfaces, not being hygienic'

'Not cleaning needles or the heroin- where putting the needle in'

Physical health

Other raised suggestions related to a poor immune system or nutritional status:

'Depends on immune system run down, not enough nutrition in system'

'how rundown someone is - how healthy they are'

'rundown, not looking after themselves not eating properly reusing same bit'

'how they look after themselves - if they have eating problems- pot luck'

'part diet / part laziness - not bothering to seek treatment and injecting in legs or groin'

'own genetics, everyone is different'

'not looking after themselves should get multivitamins when getting methadone at chemist'

Infection

Only two participants thought ulceration may relate only to an infection:

'Flesh eating bug'

'infection'

Vascular system

A few participants suggested that the vascular system may be affected:

'poor circulation'

'Clots - blown a hit - vein too small and blown when injecting'

'depends on individuals veins'

'varicose veins, ?had a knock on leg'

'injecting when young, DVT restricting blood flow'

A few remarks were difficult to classify some relating to age:

'Age - older users - using for a long time'

'when stuff goes wrong and don't go for medical help'

'Older generation get it, not younger people, Been using too long, injecting in silly places taking /reusing tools in desperation, when they start hitting the surface veins, people who don't wash and used to be in hospitals allow themselves to get so dirty that they'd get more money when begging'

There was no overarching theme within these free text answers, and no participant clearly identified risk factors of groin injecting and thrombosis so it was difficult to conclude anything from the qualitative data that was different from the statistical conclusions.

4.14 Phase 1 Results: Discussion

This section discusses the key results obtained from Phase 1.

4.15 Sample characteristics

The opportunistic quota sampling approach aimed to recruit a cross-section of the Glasgow injecting community, and whilst wide geographical spread was achieved, it was impossible to determine if the participants provided a cross-section of the injecting community, as the true representation of the population of PWID within a transient and mobile population was unknown.

However, the sample characteristics were comparable to the NESI study sample (Table 34) which recruited injectors from across Scotland in 2010 and is possibly the most recent and similar study to match against (University of the West of Scotland, Health Protection Scotland, University of Strathclyde and the West of Scotland Specialist Virology Centre, 2012) .

	Study sample	NESI Sample 2010
Male / female	74% / 26%	72% / 28%
Mean age	35 years	35 years
Mean age to start injecting	22 years	23 years
Homeless in last 6 months	41.5%	22%

Table 34 Comparison between sample and NESI study sample

74% of the participants were male and 26% female. This was similar to the NESI study and other Glasgow studies for example, Hay and Gannon (2004) estimated a proportion of approximately 70% males to 30% females and Shewan and Dalgarno (2005) used purposive chain referral sampling methods to recruit heroin users (75% male, 25% female).

Glasgow may have a different drug culture from other cities and comparative studies of both injecting habits and skin problems have not previously been published.

Sampling aimed to recruit participants between the ages of 16 and 44 years, however no participant recruited was under the age of 21 years. The data indicate that almost three quarters of participants started injecting before they were 25 years of age, with 17.5 % starting before they were 16 years. 46% were injecting before they were 20 years old. All potential participants were approached within each area and none was excluded on the basis of being too young, although a number were excluded as they were too old (aged over 44 years). It would appear that young injectors are not engaging with the drugs services used as recruitment sources within this study. This may be due to a

number of factors: services may not be attractive to younger people; it may be that new injectors are not approaching and using services, or it may be that the recruitment areas chosen for this study were not those that were used by young people. Dates of birth were possibly given incorrectly or perhaps younger people were not using these drugs to the same extent as previously, or some other unknown factor.

The number of participants who reported leg ulceration and /or skin problems was a small proportion of the total sample population. In the case of leg ulceration this meant that although a higher proportion was found than expected, the actual quantification of participants was small (15% of the sample, n = 30) and therefore some planned analysis such as comparing groups of current and former injectors was difficult to do with meaningful statistics and ran the risk of error. Comparing groups within the sample such as those people who have diabetes and leg ulceration with those that do not have diabetes but have leg ulcers, when the number of participants with known diabetes was only four, would not have been worthwhile as the numbers were simply too small. Future larger studies could address this.

4.16 Prevalence of leg ulceration

The findings indicate an unexpectedly high prevalence of leg ulceration in the sample of young PWID. 15% of the sample population had experienced a chronic leg ulcer, whilst 7% had an active ulcer at the time of interview. Comparatively, 1% of the general adult populations within Western countries are likely to have a chronic leg ulcer at some time (Dale et al, 1983). Later studies have agreed with this seminal study (Cornwall et al, 1986; Nelzen et al, 1991), and therefore the prevalence within this injecting population is worryingly high. This figure verifies the anecdotal claims from community nursing practitioners who were seeing rising numbers of young people with leg ulceration in their clinical practice (Male et al, 2006; Devey, 2007; SIGN, 2010). As those with leg ulceration seek treatment, the increasing numbers of PWID will impact on leg ulcer services.

Ulceration often outlasted the injecting career. In this sample, thirteen participants who had leg ulceration were no longer injecting, and all had stopped over three months before, some many years before. Of those with active ulceration at the time of interview, all had stopped injecting at least six months previously. Six current injectors had never healed up and of these, three had a Doppler test and compression, and three had not.

With correct treatment some authors have indicated that pure venous ulceration could heal within three months (Blair et al, 1988; Moffatt et al, 1992). This was not evident in this sample but treatment was not discussed in depth.

Nineteen participants had a leg assessment using a Doppler test, which is a pre-requisite to compression therapy (SIGN, 2010) and nineteen individuals reported then having compression therapy. This means eleven individuals who had a leg ulcer did not have a Doppler test or compression therapy.

It was not within the scope of the questionnaire to investigate why this did not happen. It may have been individuals failing to access services, services being unavailable, or health professionals simply not following guidelines. Anecdotal reports indicate that some health professionals will treat PWID differently and actively withhold treatment as it is not perceived as worthwhile (Finnie and Nicolson, 2003; Ford et al, 2008). Also, leg ulcer treatment traditionally commences with compression bandaging applied weekly. If PWID are finding it difficult to engage and to keep weekly appointments for treatment, then they are likely to have treatment withheld as there may be a perceived risk in applying compression bandages to a patient who fails to return for re-assessment, re-application or review. It is possible they were unsuitable for compression, but this is unlikely as the main reason for that would be an arterial deficit which could only be determined by Doppler testing.

Ulcer recurrence

As was noted in the results session, of the 24 that had a healed ulcer, 13 (54%) subsequently recurred. For seven people the ulcer recurred three or more times. Three participants with recurrence had never had a Doppler test or treatment with compression.

Slightly over half experienced a recurrence which is not unexpected with a failure to treat appropriately nor actively prevent recurrence (SIGN, 2010). Although small in number, the recurrence rate underlines the chronic nature of leg ulceration and the importance of early treatment.

Prevalence of skin problems

60% of participants had a skin problem at some stage in their injecting careers.

There was a particularly high prevalence of abscesses, and a number of other wound types which do not appear to have been previously defined or explored within the literature. For example the 'Shooting Up' report of 2013 states '28% reported that they had experienced an abscess, sore or open wound during the last year', all of which may be completely different types of wound (Public Health Groups, 2014).

Similarly Hope et al (2008) explored the frequency, factors and costs associated with 'injection site infections' and again defined these as 'either an abscess (pus filled swelling) or an open wound / sore at an injection site as these symptoms are most likely to be due to bacterial infection'. Differentiation between wound types had not occurred. The 'open wounds' described in these studies may have included acid burns, leg ulcers, abscesses, and other open wounds – and none, or all, or a proportion of them, might have been infected or there may have been infection during some of the time the wound was 'open'. Venous ulcers which are also 'open sores/ wounds' can occur away from the site of injection and also might never be infected. This is an area that requires further work to address the definition of the soft tissue infections in PWID, and to stop

all open wounds being assumed to be infected which could lead to consequences of inappropriate prescribing of antibiotics for wounds that are not infected (Leaper, 1998). PWID will often use A & E departments or their GP for advice on injecting injuries, and will commonly receive antibiotics for redness, swelling and tenderness, abscess, or a sore / open wound (Hope et al, 2014). Unfortunately it is unclear in Hope's study whether any of these wounds were truly clinically infected.

The inappropriate use of antibiotics is of concern. Novick and Ness (1984) identified that a number of PWID were able to obtain antibiotics without prescription either from friends, or by using old prescriptions or by purchasing on the street. They interviewed 197 patients admitted to a New York Hospital, USA, about their recent antibiotic usage and identified 13 patients who had recently abused antibiotics. No patient identified as abusing antibiotics had taken either the correct drug or the correct dose. Five patients cultured methicillin-resistant staphylococcus aureus from cutaneous ulcers. The authors also warned that PWID may present with apparent infection, but bacterial cultures may yield negative results as growth may be suppressed by the illicit use of antibiotics. On the other hand, injectors may have positive cultures but no clinical signs of infection and antibiotics are given because the open wound is assumed and misunderstood to be infected.

As this was 1984, long before the current global anxiety about multi-resistant organisms, and known over-prescribing of antimicrobials, this was an interesting finding. Subsequently, Binswanger et al (2000) reported similar antibiotic access and Roose et al (2009) in a survey investigating self-management of wounds in PWID also found a small number who had acquired antibiotics without prescription. Callahan et al (1998) similarly acknowledged that some PWID will self-medicate with antibiotics. It would appear that PWID have access to a wide range of pharmaceutical preparations without prescription and the ease of access to antibiotics in this group is concerning.

It would be interesting to explore the drug-related death data to see whether there are deaths from multi-resistant organisms given the reporting of frequent prescribing of

antibiotics, the street trade in antibiotics and the inappropriate taking of street antibiotics and likely non-adherence to completing full courses of antibiotics. At the moment these data do not appear to be known (ISD, 2011).

In this study, identification of true infection would have been difficult without clinical assessment and unlikely to be accurate. However, given the emphasis on soft tissue infection in the literature and the apparent difficulty with definition, this would be interesting to explore in future.

4.17 Risk Factors for Ulceration

The logistic regression tests showed strongly that the greatest risk for leg ulceration in this sample was DVT. However, this was strongly associated with injecting in the groin and also injecting in the legs. Participants were more likely to proceed to groin injecting or lower limb injecting the longer their injecting career lasted. The length of injecting career rather than simply age was also significant in developing ulceration. The tests for significance revealed other factors that were significant although none quite as important as thrombosis linked to groin and leg injecting. This is a key finding in the development of new knowledge surrounding the cause of leg ulceration in young PWID.

Deep vein thrombosis (DVT)

The statistical data are clear. A third of participants had been diagnosed with a DVT, which is the most significant risk factor for leg ulceration in this sample. DVT was also associated with leg injecting and groin injecting. Following a DVT, post-thrombotic syndrome can develop which is characterised by poor blood flow and which can lead to swelling, pain and ulceration and long-term implications for quality of life. Participants experienced DVT in both upper legs (thighs) and lower legs, both of which could precede post-thrombotic ulceration. It was not clear whether the ulcer occurred overlying an area where the DVT occurred.

DVT was explored further in Phase 2.

Leg injecting

Leg injecting was strongly associated with the development of a DVT and with subsequent leg ulceration. The questionnaire was not sensitive enough to identify whether those that injected at specific points on their leg went onto develop ulceration at the same site, or indeed whether DVT occurred at the same site as injecting. However, it would not be surprising if injecting damage at a particular site should then lead to ulceration at some point in time.

Groin injecting

Approximately one third of all participants injected in their groin and used the groin most commonly. Six people started injecting in the groin as a first access point. Groin injecting is culturally acceptable and common in Glasgow, and it can be assumed that knowledge of the technique is shared and perhaps recommended and perpetuated between injecting groups.

Groin injecting, with the persistent trauma of needle puncture creating an inflammatory reaction and clotting, leads to scarring, and narrowing of the femoral vein can lead to thrombosis (Senbanjo et al, 2012). The presence of a DVT in the femoral vein or any vein above the lower leg is likely to cause a venous back pressure, hypertension and damage which can lead to ulceration (Moffatt et al, 2007, p76).

Around half of the participants reported hitting arteries or nerves, which was significantly associated with development of leg ulceration. Those who reported this were also more likely to be groin injectors as the femoral vein lies close to the femoral artery and nerve in the groin. Injecting in an artery can have limb- and life-threatening implications. The impact of damaging the arterial system can be long-term, and possibly have implications for the development of ischaemic ulcers in the lower legs (Milburn and Brittenden, 2006). The high percentage of reported injuries to nerves and

arteries does indicate that injecting technique could be improved and that groin injecting is not necessarily as complication-free as some injectors suggest.

Injectors sometimes regard the groin as the answer to their injecting difficulties. It is a site they can access frequently and can be hidden from view. The femoral vein is large and thick-walled and can tolerate frequent puncturing, so from an injector's point of view it is a good result. However, medically there are huge risks such as pseudoaneurysms, DVT, femoral bleeds, abscesses and infection as well as vascular problems distally in the venous, arterial and cutaneous systems (Roszler et al, 1989; Welch et al, 1990; Woodburn and Murie, 1996; Mackenzie et al, 2000).

Susceptibility to abscesses and pseudoaneurysms in the groin that impinge on blood supply to the lower limbs is a serious risk and may need surgical intervention affecting arterial supply to limbs, which could ultimately cause arterial ulceration. There is also a risk of amputation (Maliphant and Scott, 2005; Georgiadis et al, 2005). It is unclear why the groin is such a favoured site, given these risks and so this was considered worthy of further exploration in Phase 2.

Injecting career

The length of injecting career - the longest in this study was 31 years - was statistically significant in the development of leg ulceration, and also in the development of skin problems generally. Concurrently with injecting for a long time, the individuals also became older. With age comes disease processes, but even controlling for age, the length of injecting career was significant in the development of leg ulceration. Despite injecting for a long time, and the prolonged opportunities to engage with harm reduction, participants still did not link risky activities to leg ulceration.

Injecting habits

Whilst some individual habits had changed over time in some ways, these were difficult to draw any significance from, as the questionnaire lacked time specificities. Almost all the participants claimed to make up their drugs and inject in the same way every time.

The ritualistic practices associated with their habits seemed important and some expressed this as part of the attraction. They actually enjoyed the process and the anticipation (McBride et al, 2001). Clearly if the ritual included risky or unsafe practices then these would be perpetuated. This would need to be considered when planning harm reduction as habits and ritualistic practices may be particularly challenging to change.

Some questions related to activities that occurred over many years, such as injecting technique. What some participants did at the beginning of their injecting career such as the type of acidifier used, was different from the end. It unlikely that all activities would be remembered, and the questionnaire was not sensitive enough to reflect changes over time or what was done on a day-to-day basis, if it varied at all, limiting some of the analysis relating to cause and effect. Practices did change over time as evidenced by the long-term injectors' discussions around what they used to do and what they do now and it was clear that there had been some element of reduction of risk such as the advent of freely available paraphernalia which reduced the need to clean, share, steal and re-use.

The questionnaire focused on asking what was 'normal' or 'usual' for the participant in terms of injecting behaviours but it may not have been the 'usual' practices that caused the skin problems. It may well be that it was the occasions when the participant was 'rattled', desperate, injected by others or unable to remember that caused the problems.

Drugs injected

Most of the participants (87.5%) injected heroin. Cocaine and 'jellies'(temazepam) were both mentioned by participants as possible causative factors in leg ulceration though numbers were too small to reach significance. Cocaine is a known anaesthetic and the normal signs of warning pain when a needle has been inserted badly may not be felt due to the anaesthetic effect (Lloyd-Smith et al, 2008). It is rare for 'jellies' to be

injected now however, those that injected a long time ago may have ongoing problems as a result of solidification in the veins (Forsyth et al, 1993).

Interestingly, the recruitment phase coincided with an apparent ‘heroin drought’. This was reported widely by service users, and was presumed to be due to successful police operations. There appeared to be a concurrent reduced demand for injecting equipment at needle exchanges. In Dundee, a similar heroin drought was reported within the media and drugs services were noting an increase in abscesses and injecting injuries, possibly due to the existing heroin becoming contaminated. This could have been due to the necessity of increasing bulk (and therefore apparent supply), with users also accepting poorer quality heroin and / or seeking alternative dealers or alternative drugs in response to the reduced availability of their usual drug (BBC Radio Scotland Newsdrive 30/07/08).

The heroin drought had potential implications for this study but there are difficulties in obtaining information around supplies of illicit drugs, and what they are adulterated with. It was not possible to identify sources and dealers. Similarly it is not possible, without acquiring supplies of heroin and conducting laboratory tests, to know what is within the compound that may potentially cause skin problems.

Injecting sites

When the injecting sites were investigated, participants were asked where they started injecting, where they inject currently and where they had injected most often. Most started injecting in their upper body, usually arms and hands.

Initially, when the questionnaire was being developed, it was considered that possible causes of skin breakdown may include poor injecting technique and it may be that in order to reach certain parts of the body the non-dominant hand might be required to hold the injecting equipment, therefore being less skillful (Maliphant and Scott, 2005). However, the complexity of linking sites of breakdown with dominance retrospectively

was difficult, as the large number and variety of injecting sites were not anticipated prior to data collection.

Participants also reported that ulcers appeared at different sites to the injecting site, often on the pretibial aspect of the leg which is unusual, and were not apparently associated with trauma or arterial disease. Pretibial ulceration has been previously reported in drug injectors (Williams and Southern, 2005).

Although uncommon, injecting into wounds is known to occur and in this study 7 of the 35 participants who had a leg wound used it as an access point for drugs to be absorbed (Phillips et al, 2013). This is likely to prevent healing.

Difficulty in finding a vein and ‘popping’

Just fewer than half the participants had at some time failed to find a vein and had ‘missed’ or injected into tissue or muscle, with over a third knowingly skin or muscle ‘popping’. When the ‘popping’ occurred, and the timing of ulceration is unclear. More of the long-term injectors ‘popped’, suggesting that as injecting careers progressed ‘popping’ became more prevalent as the veins collapsed and become useless for injecting into. This ‘popping’ is significant in the development of ulceration and is worthy of further exploration.

Fresh needles and syringes

Many long-term injectors had little or no access to clean needles and syringes when they began their injecting careers. Some reported that a local medical supplier sold injecting equipment, but when it closed they had no option other than to steal from hospitals and medical centres. The participants not only reported stealing sterile equipment but also a trade in sharps disposal bins which they broke open to extract used injecting equipment. This appeared to be usual practice in the late 1970’s and early 1980’s when heroin use became more commonplace, prior to IEP in Glasgow. Despite harm reduction attempts to persuade PWID to use a new needle and syringe for every injection, it appears this is not widespread and standard practice. Nonetheless, in

this study, participants who used a fresh needle and syringe every time were less likely to develop leg ulceration, although those who had been injecting more recently would have easier access to clean injecting equipment.

The nomenclature change of ‘needle exchange’ to ‘injecting equipment provision’ with the emphasis on *provision* should have helped with the distribution of fresh equipment. However, during data collection within pharmacies which provided IEP, the researcher frequently witnessed staff members demanding returns and stating that IEP would be withdrawn if returns were not given. Whilst ‘exchange’ has been a long held argument in terms of public health related to disposal of equipment, there has been a stronger argument put forward for freely available equipment which may prevent sharing and thus the transfer of BBVs (Scottish Government, 2010).

Insulin syringes

Unsurprisingly those who were using insulin syringes appeared less likely to develop leg ulceration. This may be because the needles are smaller, and are pre-packed with an attached syringe. Hence there is less touching and contamination in preparing the drugs. Harm reduction initiatives already recommend using the smallest needle possible.

Filters

Filters are used by heroin users during the preparation of their injection to remove the insoluble adulterants from their drugs but using a fresh filter every time was not significant. Filters are available within some needle exchanges, though at the time of the questionnaire these were not routinely available in Glasgow. Participants in this study used a variety of filter materials, most commonly cigarette filters, but also socks, pillows, cushions, cotton wool, and it is possible that fibres or particulate matter from the filters are injected. Some injectors save up used filters for a time when they have no drugs, and cook up the filters in an attempt to yield another hit of heroin. The filters may also serve to blunt a needle, making injecting more traumatic for the vein and leading to potential problems. Statistically it was impossible to tell from the small

numbers whether different types of filter would be significant. However, filtering drugs before injection is part of safer injecting advice.

New syringes which incorporate a filter within the syringe have been marketed since the data were collected and these may help prevent skin problems.

Licking needles

Licking needles is rarely addressed in harm reduction literature in the UK although a recent study had found that over 30% of subjects in a small sample of PWID licked their needles prior to injecting (Deutscher and Perlman, 2008). Results of this survey suggest that this seems to be a practice that is not unusual.

Licking needles was not statistically significant in terms of development of leg ulceration. However, more people who licked their needle had leg ulcers than those who did not. From the literature (Orangio et al, 1984; Henriksen et al, 1994; Summanen et al, 1995; Binswanger et al, 2000), bacterial culture of wounds and abscesses in PWID reveals growth of oro-pharyngeal organisms. This suggests a transfer of saliva or oral fluids into wounds by some mechanism. Only one participant reported licking their skin to clean it prior to injecting, whereas much greater numbers reported licking needles. No participant reported using saliva to mix up their drugs. This could be given greater attention when discussing harm reduction.

Acidifier

The role of acidifiers in the breakdown of skin is unclear. Almost all participants used an acidifier to break down the heroin and this was usually citric acid provided by drugs services. Surprisingly, despite the availability of sterile 'citric', other unsterile substances were also being used such as vinegar, lemon juice, and non-pharmaceutical vitamin C which can cause harm (Albini et al, 2007). Although pharmaceutical citric acid has only been available in recent years, the use of alternative acidifiers appeared to be more widespread with frequent mention of using lemon juice and / or vinegar, and

there were comments from participants about using any acidifier they could get their hands on, including effervescent vitamin C tablets.

The quantity of acid may be important and much less than is contained within the commercial sachets is needed to dissolve the average heroin 'score' (Scott et al, 2000). It would be useful to explore further the role of injected acid in skin breakdown, and whether harm occurs within the vein or only when hits are missed.

Gender

Interestingly, there was no link between gender and leg ulceration in this sample, despite females being known to be more prone to leg ulceration due to having finer and smaller veins (Topp et al, 2008; Human et al, 2009). A slightly greater percentage of females (17%, n = 9) than males (14%, n = 21) had ulceration but this was not statistically significant. This difference may be due to sampling bias. Males may be more likely to attend exchanges and collect equipment for their female partners (Barnard, 1993).

Housing

A surprisingly high number of participants (over 80%) had been homeless at some time in their lives, and at the time of interview 50% were homeless. The impact of homelessness on health (Stratigos et al, 1999; Badiaga et al, 2005; Keaney et al, 2011) cannot be underestimated and will impact on all aspects of a person's life. However, this does not appear to be significant in the development of either skin problems or specifically leg ulceration in the sample population. A study by Stratigos et al (1999) in Boston (US) investigating skin disease in a homeless shelter found a range of relatively minor dermatological conditions, but similarly no leg ulcers and no abscesses.

In this study, when the leg ulcer was experienced, almost half of participants were living in their own home. Being unable to maintain good hygiene was thought by many of the participants to be a factor in the development of leg ulceration, and good hygiene

practices may be difficult to achieve when a person is homeless and unable to wash hands, clean skin, prepare drugs in a clean environment, or wash themselves properly. Injecting outside and in public places, through necessity and lack of a safe place to go, also impaired an ability to wash hands and keep clean. Although numbers were too small to test for significance in leg ulceration, those who had poorer hygiene practices had a greater proportion of leg ulceration, and perhaps with a larger study this might have been more meaningful. However, it is quite possible that some participants despite stable housing did not maintain their own personal hygiene or take care of their legs.

Part of harm reduction advice relates to hand washing and skin cleansing. Some studies have argued for the importance of skin cleansing prior to injecting but there is little empirical data to support this, although it makes good sense (Vlahov et al, 1992; Murphy et al, 2001; Mercure et al, 2008; Dwyer et al, 2009; Phillips et al, 2013). Mercure et al (2008) describe a Canadian educational activity to reduce injecting-related infection by skin cleansing, with drug injectors who were then able to pass information on to peers. Practical workshops on infection transmission and skin care as well as identification of skin problems enabled positive behavioural changes and may be something to explore as part of harm reduction.

4.18 General health and co-morbidity

Smoking and vascular disease

Almost all participants were tobacco smokers (99%) and almost half were heavy smokers, smoking over 20 cigarettes or 1/2oz of tobacco a day. It is possible that the impact of smoking on peripheral vascular disease and subsequent leg ulceration may become apparent much later in life, and beyond the age-group within this study. Although smoking was not significant in this study, it is known to have a long-term impact on health, and is closely linked to heart disease and peripheral vascular disease (PVD) (SIGN, 2006). Heart problems, and claudication, which is a sign of ischaemia in the lower limb and an indicator of PVD, were both significantly linked to leg ulceration indicating that a level of arterial vascular disease was already being experienced by

these young PWID. This suggests that all leg ulcers in injectors cannot be assumed to be venous, and underlines the importance of identifying an arterial deficit through a Doppler test.

Venous signs

Venous leg ulceration is regarded as end-stage venous disease and there are signs that usually precede its development. It was not possible to undertake a clinical assessment at this stage in the study, but questions about venous disease indicators were asked instead (Eklof et al, 2004; SIGN, 2010). Unsurprisingly, classic venous disease indicators such as DVT, cellulitis, and varicose veins were associated with the development of ulceration. Other indicators such as family history, parity and obesity, were too few in number to reach significance in this sample. However, the questionnaire was also not sufficiently specific to determine whether these signs preceded ulceration or were present following ulceration or indeed were associated with the active ulceration.

Mobility

Those diagnosed with mobility difficulties, joint problems, or arthritis were more at risk from leg ulceration however, it is unclear whether the mobility and joint problems preceded or were a result of the ulceration (Moffatt et al, 2007, p54). Fractured lower limbs were not statistically significant in the development of leg ulceration in this sample, though it is known that fractures are linked to the development of venous disease. Fractures may have more of an implication in later life.

Standing

Occupations or hobbies that involve standing for long periods of time are associated with the development of varicose veins and venous disease (Tuchsen et al, 2000). In this sample, standing was not associated with the development of leg ulceration but it is likely that the interview schedule was not specific enough. Many of the participants

focused their answers on the job aspect rather than anything else, although the researcher did emphasise that hobbies were also of interest. Many had never been employed but may have sold the 'Big Issue' magazine, often standing on street corners or other pitches, or been begging, or had a hobby such as fishing or watching football that may have involved standing for long periods. A proportion said they were painters and decorators, which did involve standing, but the researcher later learnt that this was a trade often acquired within prison services and may not be anything that the individual had undertaken for any length of time. The length of time for which an individual stands for in order to acquire venous disease is unknown and this variable may have been significant in an older group.

Blood-borne viruses

Those diagnosed with a BBV were more likely to have had leg ulceration. This was surprising as BBV are not commonly associated with skin breakdown. HIV and Hepatitis are prevalent amongst Glaswegian injectors and can be asymptomatic (Hutchinson et al, 2004; Hutchinson et al, 2006; Nambiar et al, 2015). The figures for this study may have been under-represented as the question asked if participants had been diagnosed, and of course there may have been many who had not engaged with health services and were potentially positive, but had never been tested.

This may apply to other questions asked about health. There may have been pre-existing conditions that the participant was unaware of. If they are unable to talk to a health-care practitioner, then they would probably not be comfortable when presenting for well-person checks or similar appointments to identify disease.

Nutrition

It was difficult to assess the nutritional significance for those with leg ulceration as numbers were too small. A small number of participants were overweight (17% of the sample) but some said this was due to the high sugar content of methadone (Preston, 2008). A third considered themselves to be underweight. Being either underweight or overweight may impact on venous disease and on healing and some of the participants

felt their ulceration could be linked to their eating habits. Certainly insufficient intake of food links with a number of harms and not simply poor wound healing (Anema et al, 2010). Nutritional supplements may be worth considering in those with ulceration but there is school of thought that PWID obtain nutritional supplements in order to avoid having to buy food and thus divert money to service the addiction (Sillars, 2013).

Medication

For a young population, all under 44 years old, it was surprising that 97% took medications other than that which they injected. This sample includes a high number of ‘dual diagnosis’ participants who were prescribed medications for co-occurring mental illness and substance misuse. Almost half were taking medication acting on the central nervous system (CNS), whether this was antidepressants, antipsychotics or anti-manic medication or combinations of these. Of these, 89 (43.5% of sample) were also taking an opiate substitute in combination with a CNS active drug.

The co-occurrence of substance use and mental disorders have been well-documented in the literature, the most prevalent appears to be anxiety disorders, major depression and personality disorders (Mackesy-Amiri et al, 2012) and up to 85% of patients in drug and alcohol treatment have a concurrent mental health problem (Hamilton, 2009). Mental ill-health may impact on a participant’s ability to engage with services.

91% (n = 182) were taking an opiate substitute (methadone or buprenorphine), and of the 99 injectors, only 12 were not taking an opiate substitute. So, most PWID were injecting whilst taking a prescribed opiate substitute. Clearly the substitute prescribing is not replacing illicit substance use, or injecting, in this sample. Also if PWID are receiving substitute prescriptions and continuing to inject, this may be against a prescriber’s wishes or knowledge (Shewen, 1992). If the injecting behaviour is hidden, then it is probable that injectors will not seek help readily when they have injecting harm or injury, potentially leading to chronic or deteriorating wounds, increased harm and infection, and possibly crisis presentation at hospital (Morrison et al, 1997).

Parity

Pregnancy can lead to venous problems in the legs due to raised abdominal pressure, similar to obesity (Evans et al, 1999). However in this sample, 42 of the 52 women participating had had a baby, (81% of the female sample) and neither having a baby, nor having more than one baby, was statistically significant in the development of leg ulceration, but numbers were very small. It may have been more accurate to ask more specific questions about abdominal size and pregnancies that went to term however, as many PWID have children taken into care, this is a highly sensitive area and could possibly be explored in a different study (Chandler et al, 2013).

Access to care

The majority of participants (99%) had access to a health care professional such as a GP or Practice Nurse, but only 79% (n = 158) felt they could talk to that professional and the reason for this could be varied and not always clear. However, the majority of participants (n = 133) would consult the healthcare professional about a skin problem related to their drug use. Although the majority of participants (60%) would go to a GP if they needed advice for a skin problem related to injecting, it is possible that the GP will deal with the problem presented in front of them, such as an abscess requiring an antibiotic.

However, GPs may not have time, knowledge or training to discuss injecting techniques in order to reduce the incidence of further infections or injecting complications. It is notable that more participants would attend a GP than a drugs service and only 16% would attend a needle exchange or drugs worker for advice. This merits further exploration. Given that wound care services are not generally available in these places, it would indicate that a reasonable proportion of PWID do not have access to specialist skin or wound care advice and indeed may consider that drug services are not places to seek advice around physical health (Scottish Government, 2010). If skin problems are not addressed early and appropriately, then wounds are more likely to be chronic or problematic later. Problems may manifest themselves long after injecting and drug misuse has ceased (Pieper, 1996b; Lawson, 2010) and so care providers may

not understand that wounds were related to past activities. Opportunities for health promotion and harm reduction in relation to injecting may then be missed and hence costs of treatment will be unnecessarily increased.

4.19 Participant views on risk and causation

Those who had a wound on their leg were asked what they felt had caused it. The answers were extremely varied and there was no common and consistent theme and no conclusion could be drawn. This was surprising and unexpected. In clinical practice the researcher had found that most patients with a leg ulcer did suggest a theory of causation, and these were often similar, such as a traumatic event resulting in a non-healing wound.

The wider sample also did not identify links with leg ulceration. This suggests that the participants did not know that developing chronic wounds was a possibility, nor did they understand the link between the risks of leg and groin injecting and consequences of venous disease and ulceration.

The main themes emerging from participants' opinions were injecting technique, hygiene, self-neglect, abscesses, infection, treatment, and injecting site. More specifically, there was little consensus from participants who had experienced ulceration as to what had caused the wound.

Interestingly, the responses were very diverse but all of the responses had in some way been mentioned earlier during the interview relating to possible risk factors such as homelessness, skin cleansing and injecting equipment. This could be viewed as validation of the questionnaire which appropriately covered all relevant topics related to injecting and leg ulceration, or simply because the participants had been given 'ideas' earlier that they merely repeated, as many started off their answers with '*I don't know, but it could be*'.

Chapter summary

The first phase was designed to answer the first research question '*What is the extent of skin problems and chronic leg ulceration in young people who inject drugs?*' A high prevalence of leg ulceration and skin problems was identified within the sample of young PWID.

The second question, '*What causes chronic leg ulceration in young PWID?*' has been answered in part. A number of important factors have been explored. Statistical significance was found specifically for groin injecting, leg injecting, and DVT.

However these risks were perceived of little importance to participants as most could not identify them as causes of leg ulcers. Potential causal / risk factors, based on these findings, required further investigation especially with young PWID who had experienced leg ulceration. Questions specifically about the ulceration and what might be done to prevent it, were needed. This would help to begin to answer the third research question: '*What are appropriate harm reduction measures for leg ulceration in young PWID?*'

Within the next chapter, the findings of Phase 2 sought to clarify perceived causal and risk factors for leg ulceration based on the results of Phase 1, exploring from the participant's perspective what caused the ulcers and then examining what might be done to reduce harm and prevent ulceration.

Chapter 5

Phase 2: Findings

Introduction

The quantitative study in Phase 1 was conducted to gather empirical data which answered the preliminary research question of the prevalence of skin problems and leg ulceration in young people who inject drugs. The second question, '*what causes chronic leg ulceration in young PWID?*' was also answered, in part, by this first phase. Risk factors for causation were identified but lacked detail and full explanation.

A more probing qualitative second phase explored the findings of the first phase and helped to provide a better understanding than a single 'stand-alone' approach (Creswell, 2014, p4). The participants were able to discuss their injecting habits and lifestyles which may have contributed to the leg ulceration, and most significantly, to discuss what might contribute to successful harm reduction, and answer the third question: '*What are appropriate harm reduction measures for leg ulceration in young PWID?*'.

The postpositivist critical realist approach to developing the aims and research questions was helpful in executing the 'epidemiological' first phase. In that, it was acknowledged, there was no absolute certainty and the researcher and her views were not wholly detached from enquiry so results could not be universally generalisable and applicable to all situations (Clark, 1998). However, as the second stage lent itself more appropriately to exploration and a qualitative approach, the philosophical stance of postpositivist critical realism proved to be more reflexive and problem-centred (Weaver and Olson, 2006).

Semi-structured interviews (Appendix 8) explored injection history and behaviours, how the ulceration started and what the participants attributed it to. Risk factors that emerged from Phase 1 such as injecting in the groin or leg and presence of a DVT were

also probed in more depth. Participants provided detail on the experience of leg ulceration, behaviours that may have contributed to the disease process, and potential methods of harm reduction. The interviews lasted between thirty and sixty minutes, with some participants very willing to volunteer information and elaborate on issues, whilst others were much less keen to divulge information. Consequently the interview transcripts varied in length depending on how well the interview developed, as some responses were very brief. This was because the researcher felt unwillingness from some participants to be allowed to probe too deeply even though the approach was empathetic and reflexive. However, this was not unexpected given the illicit nature of drug use and the personal questions being asked about topics that were at times unpleasant to discuss.

5.1 Analysis

The data analysis sought to find associations, seek explanations for ulceration, examine the impact of ulceration on participant's lives and develop new ideas about the causation and possibilities for prevention.

Framework analysis was used and described in detail in Chapter 3. Key themes that arose were:

- 1) the causes of leg ulceration
- 2) the impact of leg ulceration
- 3) harm reduction

Within each of these themes were sub-themes (listed in Tables 6, 7 and 8, Chapter 3). These thematic 'scaffolds' allowed the data to be refined and interpreted. Figure 1 illustrates the thematic interpretation developed from the themes and sub-themes.

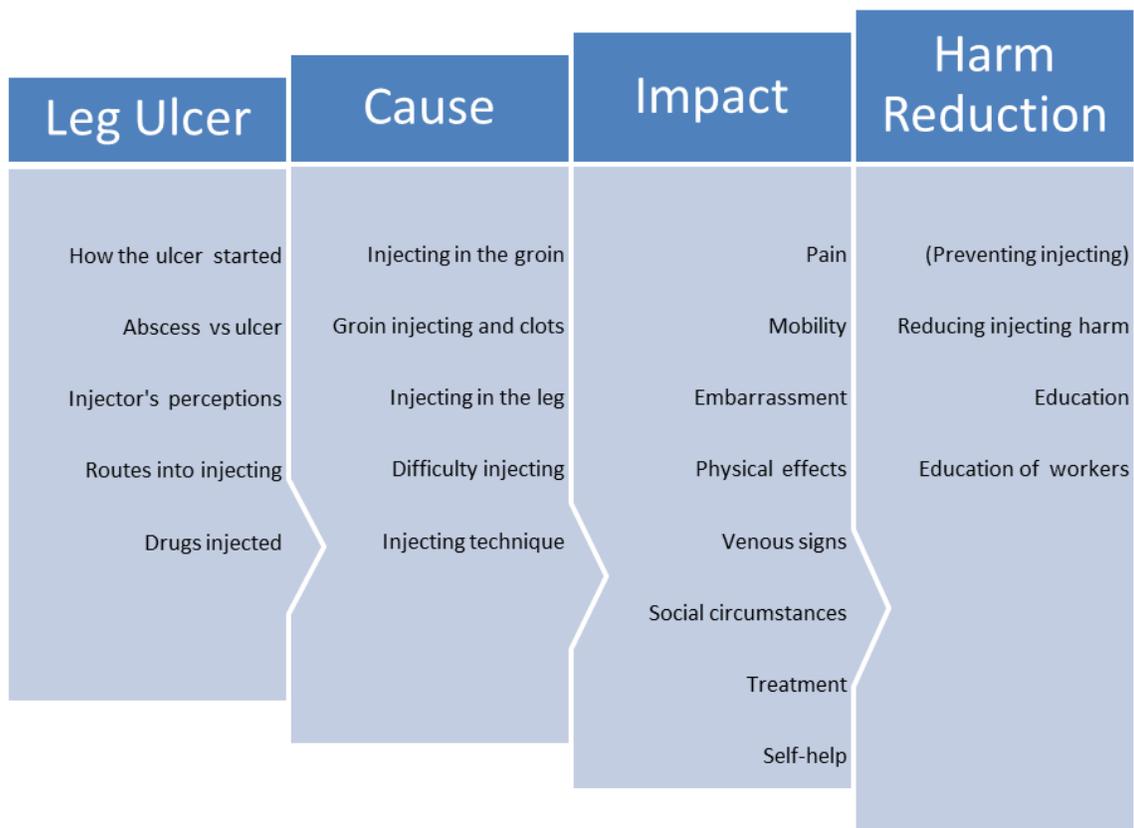


Figure 1 Thematic interpretation

5.2 Findings

Fifteen participants, four females and eleven males, were interviewed with an age range of 29 to 43 years. Postcodes demonstrated that participants had been recruited from across the city. All participants had been injectors and all had open ulceration at the time of interview. Six of the participants had a recurrent ulcer.

Seven participants were current injectors, and eight had not injected for 6 months or more. Five had developed leg ulceration within the last 6 months, 'recent ulceration', whilst 10 participants had experienced ulceration for longer than 6 months, 'old ulceration' (Table 35).

Participant code number	Gender	Age	Area of city	Former/ current injector	Recent / old ulceration
2	m	36	NFA	<i>Current</i>	Old
3	m	42	Centre	<i>Current</i>	Old
4	m	40	North	<i>Former</i>	Old
5	f	41	East	<i>Current</i>	Old
6	m	42	Centre	<i>Former</i>	Old
8	m	41	Northwest	<i>Former</i>	Old
9	f	29	NFA	<i>Current</i>	Recent
10	m	37	East	<i>Former</i>	Old
11	m	40	Southwest	<i>Current</i>	Recent
12	m	43	West	<i>Former</i>	Old
13	m	38	Southeast	<i>Former</i>	Recent
14	f	29	North	<i>Former</i>	Old
15	m	43	Centre	<i>Current</i>	Recent
16	f	39	East	<i>Former</i>	Old
17	m	34	South	<i>Current</i>	Recent

Table 35 Phase 2 sample characteristics

As all the participants were asked similar questions it was possible to further tabulate the ulcer history and injecting behaviours of the sample in Tables 36 and 37.

All of the participants had injected heroin and most had also injected cocaine. Over half had injected benzodiazepines – with most specifically stating they had injected the gel form of temazepam. Most had injected other substances as well such as dextromoramide, buprenorphine, and amphetamines. To mix with the heroin, all except

one had used an acidifier other than citric acid – commonly lemon-juice. Very few had used clean sharp needles every time and most had shared their equipment (Table 37).

All Phase 2 participants had injected for five years or more and most had injected for over ten years. All except one participant developed their leg ulceration more than ten years after starting injecting and all except one continued to inject once the ulcer had occurred.

All had injected in their groin although one participant said he had only done this once. All but one had also injected in their lower legs and ten participants had ulcers at a site of injection. Almost all had experienced ulceration in their left leg. Five had experienced ulceration in both legs and they had all injected in both groins. Eleven participants had experienced ulceration after DVT. All participants had had a DVT.

Table 36 Ulcer history

Participant	When ulcer started?	Where was ulcer?	How long injecting for	When started	What injected	Injected in lower legs	Injected in groin	DVT after groin injecting?	Ulcer at injecting site
2	2000	both	13 years	1998	Heroin, cocaine	yes	yes both, before ulceration	DVT after ulcers	yes
3	2004	L then R	26 years	1986	Jellies, heroin, cocaine	yes	yes both	DVT after groin injecting then ulcer	yes
4	2002	right leg	10 – 12 years	1992	Jellies, heroin, cocaine	yes	yes	yes in both thighs	yes
5	2008	one leg only	19 years	1991	Cocaine, heroin , temgesic, jellies	yes	yes	yes both	no
6	2011	left leg	Not for years	1991	Jellies, heroin, crack, cocaine	yes	yes both	yes – left leg	no
8	2000	L then R	20 years	1986	Temgesics, temazepam/jellies, heroin, speed	yes	yes both	DVT in right leg only	yes
9	6 wks ago	left leg	11 years	2001	Heroin, cocaine, valium	yes	yes both	DVT left leg	yes
10	2001	L then R	13 years	1991	Heroin, temazepam/ jellies	yes	yes	yes	yes
11	5 mths ago	L then R	24 years	1988	Temgesics, speed, heroin, cocaine	yes	yes both	right leg	yes
12	1999	R then L	22 years	1981	Heroin, temgesics, peach palfium, white palfium, 'everything and anything', valium, speed, coke	yes	yes both	yes	yes
13	18 mths ago	left leg	5 years	2001	Heroin	no	yes	yes	no
14	2007	left leg	11 years	1999	Heroin, cocaine, valium	yes	yes	yes	yes
15	2012	left leg	20 years	Not known	Heroin, cocaine, peach palfium, diconal, temgesics, temazepam	yes	yes	yes	yes
16	2005	left leg	20 years	1991	Temgesics, heroin, temazepam, cocaine	yes	yes	yes	yes
17	2012	right leg	14 years	1998	Heroin, crack, cocaine	yes	yes	yes	no

Table 37 Ulcer history and injecting habits

Participant	How ulcer started	What caused it?	Clean new needles every time	Shared	Acidifier used	Ulcer after DVT?
2	Scabs that broke out	Groin injecting	Not always	No	Abdine, citric, lemon juice	no
3	Scratch on R shin, burst open	Cocaine. Groin injecting, homelessness / cleanliness	Not always	No	Vinegar, citric	yes
4	Purple marks	Jagging jellies in groin	yes	Shared spoons and filters	Citric ?abdine	yes
5	Cleg bite	Not eating, homelessness	yes	?no	Citric, abdine	yes
6	Painful crack in skin	Bad circulation	no	yes	Citric, lemon juice	yes
8	Scab from a hit turned black and ulcerated	injecting	no	yes	Citric, abdine	No
9	A wee kind of hole – thinks had a fall	Hygiene, blood clot	no	yes	<i>Not asked</i>	yes
10	After the clot, a bang, got tingly then a smidge of pus	Homelessness, hygiene	<i>Not asked</i>	<i>Not asked</i>	Abdine, citric, vinegar	yes
11	Wee blisters after a hit	Hygiene / homelessness/ citric	yes	no	Citric, abdine	Yes
12	Banged them, a wee scab then an indentation	Dirty kit Bad bit of acid	no	yes	Vinegar , irn bru, tiser, cola, oranges, diluting orange, fresh orange juice	yes
13	Wee spots, that weeped	It's a dirty thing	no	yes	Citric	yes
14	Black spot	injecting	no	yes	Citric, vinegar	yes
15	Cellulitis	The phlebotomist not changing the needle after trying the arm	no	yes	Citric , lemon juice, wine, irn bru	yes
16	Cleg bite	No healing process in leg due to drug abuse damaging the veins	no	yes	Abdine, lemon juice, citric acid	yes
17	Not sure – 3 little spots and spread	Possibly injecting or a knock	mostly	yes	Lemon juice, citric	yes

5.3 Theme 1: Cause of Leg Ulceration

How the ulcer started

All participants were asked how the ulcer had started and although the answers varied, all described a hindered healing process:

'I woke up the next morning in some guys house and I didn't even know how I got there and I woke up and my leg was like, well it just started off like as kind of like a wee kind of mark. A wee kind of hole sort of thing, like I'd had a fall or something like that and as the days went on it progressed bigger and bigger' (Participant 9).

'It started in 2005 I was on my lunch, I was out on a prison workplace and I was sitting having my lunch and a cleg bit me and with me being an intravenous user for years, for like twenty years, there is no healing process in my left leg. And I scratched it and it went into a cut and it ended up ulcerating and I had that on and off, from 2006 it's cleared up - I've lapsed, it's opened up' (Participant 16).

Some were unsure of how it started but they were aware of some pain or discomfort and scratching the area:

'It was just my skin, see the likes of a normal bit of skin, it was, there was nothing going on there or nothing. It just got dead itchy and I was scratching and dead painful. There was nothing really, it was a tiny, tiny, just like a wee crack in my skin. But the pain was just unbelievable. Then as the weeks went on it started getting bigger and bigger' (Participant 6).

Others were injecting in the area – all but one had injected in their lower legs:

'I had a hit on my leg one day do you know what I mean there, you know what I mean and then the next minute there was wee blister things do you know what I mean, they were bursting and I ended up getting big holes in my leg everywhere in this leg' (Participant 11).

Abscess vs ulcer

Participants were asked about their history of abscess and this was explored to ensure that meaning was consistent between cases. Two participants thought their ulcer had

started as an abscess. Most were very clear that there was a difference between ulceration and abscess and most, but not all, had experienced an abscess at some time in their injecting career:

'I know exactly what an abscess is and an ulcer, I could actually tell somebody, a lot of people ask me, you know for advice what do you think is that an abscess and if it's an abscess I'll say it's an abscess and get it checked and if it's an ulcer I'll say it's an ulcer, a lot of people ask me that' (Participant 12).

'It's definitely, definitely ulcers that is the problem it's not abscesses, the ulcers, the abscesses are sore and all but it's the ulcers. The abscess it's short-term the ulcers it's long, long term' (Participant 2).

Participant perception of cause

All participants were asked what they thought was the cause of their ulceration.

Two participants said their diagnosis was a surprise:

'I got a hit on my leg and I went to my doctor when I came back and I said I've got an abscess and they went that's not an abscess that's an ulcer. I says what? Telling me I've got an ulcer, you don't get ulcers in your legs, right that's how daft I was. You don't get ulcers in your legs; you get ulcers in your stomach or your tongue whatever. But he says it's an ulcer and from there it progressed from that size to that size and ended up having them all over the place' (Participant 8).

'Doctor Smith² came and he says you've got leg ulcers you are in a bad way and he gave me a methadone script there and then that was how bad I was because I couldn't even walk to go and get a methadone script because of the leg ulcers, I didn't even know I had ulcers at this time I thought it was just scabs that had broke out and that was just the start of the leg ulcers' (Participant 2).

Some participants denied that the ulcer was related to injecting habits for various reasons:

'So I know it's nothing to do with injecting do you know what I mean because I've not touched my groin for years' (Participant 12).

² All names changed for confidentiality purposes

'it was a shock so it was when I got that. I don't have an ulcer, I don't inject in there' (Participant 9).

'No, no, I got a, nothing hen, nothing sparked them off, I am like that to myself, why is this happening to me?

I don't know hen because I don't know what causes them, I am wondering to myself, why after seven years of not touching anything am I getting this on my leg' (Participant 13).

Many were unsure, and didn't necessarily relate their ulceration to injecting – one felt it was due to trauma not associated with drug use:

'I don't think it's to do with anything with injecting no I don't think so but probably if you go back years and years, yes to do with the blood clot, I got that through injecting but I don't know. I think it was just a bad fall that made it erupt I don't know because I don't go in that leg so that's why I am still kind of puzzled. But em no I don't think it was the injecting, I think it was just that blood clot that's made it come, come up that way' (Participant 9).

Another thought it was just luck:

'Just pot luck with you, do you know what I mean. Get an ulcer do you know what I mean and pot luck that you are not getting an ulcer or a blood clot do you know what I mean' (Participant 11).

Participant 12 related it to injecting but had various thoughts on the specific cause:

'don't know maybe it was dirty kit, maybe it was a bad bit of acid, maybe because I am using all sorts of different stuff, like because a lot of my mates they would use brand new needles, they had to be brand new, the citric had to be brand new, nobody used to be able to take the first bit out the packet, we used to be able to buy a box of citric, they would take the first bit out and then as soon as everybody else put their hands in they wouldn't touch it after that' (Participant 12).

Another related it unequivocally to injecting but considered many options a possibility:

'it could be something off that hairs in your vein or, do you know what I mean it could be anything, it could be something in the smack it could be something in the citric, something in the water that I am using, something in the filter, do you know what I mean because I've not used clean filters and all that I've not used clean water before I've used water out of a puddle to inject, I've used wine I've used 'irn bru' do you know what I mean to actually inject. So who's to say what it is really' (Participant 15).

Only two participants related it to clots. Participant 6 noted that an ulcer appeared years after injecting had ceased, but appeared to make the link between drug use, clots and ulceration.

'I've no even thought about it that much but because of my clot, you usually find it's people with clots because that boy I was telling you, Andy, he had a blood clot, and I know another guy who told us, his name is George as well the same as mine, he had a blood clot and he also had an ulcer, so I think a lot of it is to do with that. That place I was telling you Green Street, my wee pal worked there, wee Jimmy Brown he was a worker and he ended up having to take time off because an ulcer just appeared in his leg do you know what I mean and he'd been off it for three or four years, it just appeared. So it doesn't, it's quite hard to make sense of why they appear' (Participant 6).

Participant 10 was more definite:

'it caused the clot and the clot caused the ulcer' (Participant 10).

Most had experienced homelessness and some felt this was related to poor hygiene as a result:

'See eighty five percent of the people that I know with ulcers they are skippered' (slept rough) (Participant 3).

'Hygiene, I think so definitely it's a lot to do with hygiene because like you say there is a lot of people sleeping, skippering, sleeping rough, they don't have the means to, I don't know, there is plenty places you can go and get needles but at the time they are just wanting their hit and it doesn't matter if the tools, they've had the tools for a while' (Participant 9).

Another made the link between keeping the ulcers clean when housed but not when homeless:

'They weren't as bad as that do you know what I mean, you know what I mean, because I had a house to stay in do you know what I mean and I was cleaning it all the time. Aye, aye, because I was sleeping outside out by Springburn under bridges, anywhere do you know what I mean, the dirt was getting into it do you know what I mean' (Participant 11).

However, one participant was adamant that personal hygiene could be maintained whilst homeless:

'But see the places they stay in, they've got soap and there are razor blades in it. I only takes five minutes of your time to go and wash yourself because there is soap and showers provided for them - like this place. Now if I was homeless I would use them because I stayed in London on the run for, when I was done for a murder, I had to get out of Glasgow, went to London because it wasn't me that done the murder, they were trying to frame me with it. I went to London for two years and survived two years in London and then I came back up here so I know if I wanted to get a wash or a shave all's I would do is walk into one of them and do it. They can walk round the corner and they choose not to do it' (Participant 13).

There was a realisation that diet was important to some:

'I think it's because I never ate and all that as well, due to my health' (Participant 5).

'Your diet I think it's to do with your food, your diet, whatever, what they give you to live on is atrocious and when you are unfit for work what are you meant to do' (Participant 16).

Being homeless also affected dietary intake:

'I think it's all down to that. no eating right and all that.

In they hostels you are not having your three square meals you know, you are not doing everything you would do in your house do you know what I mean.

No your body is kind of run down as well do you know what I mean.

It's cleanliness and vitamins and irons and all that in your body. Eighty five percent of people that are in there are run down do you know what I mean' (Participant 3).

So whilst participants had various suggestions as to causation, they were not united in a common view and no hints or broad themes emerged.

Routes into injecting

If ulceration is related to injecting then the route into injecting is of interest. All participants had injected before the age of 21 years and one as young as 12.

Most were introduced to injecting by their peers:

'I was hanging about with people that were older than me and I just, at that time that's what everybody was doing. Well not the ones that were my age but the ones that I were going about with they were sniffing tems (buprenorphine) and stuff like that you know....

Aye so, I don't know just the progress from there, we were all sitting one night and we were sniffing the tems and we didn't, after a couple of months we were like that these aren't working anymore and somebody pulled a needle out and said listen we'll get a charge out of this do you know what I mean. I just can remember getting somebody to give me a hit because the next again day my arm blew up like a big balloon and I was like that, is that the way it's supposed to go and all that and I didn't end up taking it then but I smoked it, I started heavily into it when I turned nineteen, twenty or something like that' (Participant 12).

Most had smoked illicit drugs before they injected:

'I was sitting smoking four or five bags and my pals were sitting injecting.....

Oh I don't know, just curiosity basically I think because I had the best of jobs and all that, but as I say injecting was, watching my pals sitting, having a fiver bag, hitting it or a tenner bag and sitting there.... smashed and I am still sitting like that burning, burning, burning, bag after bag. But they only needed a fiver or a tenner and they were gone. But I was sitting there like that still burning that's why I started injecting to be honest' (Participant 15).

Some grew up in areas where drug use was prevalent:

'The Calton has got the highest epidemic for heroin abuse right. See when I was a boy I used to see my uncles and things and they were all doing good and big motors and all that and I never seen my family going out and doing brick laying jobs or anything like that. I seen all my families going out and driving big BMWs and that and I was like what kind of job is that to myself as a young boy and then as I got older I started doing it myself. So when you are born into something like that you just carry on doing it and through doing that I had the stuff about me so I started abusing myself a bit' (Participant 13).

One was introduced to injecting by her mother:

'I knew what it was, like I used to see my ma injecting in front of me when I was three years old. I used to protect my wee sister, I used to have to protect my wee sister from no seeing it when I was four or five years old because I knew what was happening and Laura didnae. So I said to her who does that belong

to - she said it's your uncle Neil's do you want to try it - and that her exact words to me and I thought ma ma's not going to do anything, she's not going to give me anything that's going to harm me is she so I accepted and she gave me two lines and they two lines made me run into the bathroom and I was being sick for a day and a half, I missed an exam.

Did she inject you?

Not that time, she injected me six months later, but that time she made me miss an exam and a half.

So six months later - you were still fourteen or fifteen by then?

No I was sixteen by then' (Participant 14).

A family history of leg ulceration was cited by two participants – one had a sister and one a mother who were injecting drug users and both had leg ulceration.

'So you didn't know about ulcers at all?

I didn't know anything about them – but my mum had ulcers – she had them for years and years.

What do you think caused your mum's ulcers? '

It was drugs' (Participant 14).

Most participants were introduced to drugs at an early age and within their own local culture. Friends and family taught them to inject and one was aware that ulceration in her mother had been caused by injecting drugs.

Drugs injected

Not only were participants starting their injecting career at a young age, they were also using a variety of drugs:

'my mum and dad split up when I was thirteen and I got into the smoking hash and that, drinking and then when I was sixteen I started injecting temgesics then from temgesics, speed and that and then heroin. When I was eighteen I had heroin and then from then on from heroin right on then cocaine and all that, injecting' (Participant 11).

'Aye them, valium, I injected speed, coke, I injected the lot, anything you could dissolve into a set of two mls I've done it' (Participant 12).

The heroin injectors also used acidifiers, commonly citric acid, and previously a substance called 'abdine', which participants described as no longer available. It was an indigestion powder which was available over the counter. Lemon juice was also used but there was concern about the side effect of blindness that it could cause:

'There is a few things you can use we knew we could go into the Chinese shop but lemon juice was the main one but that was making people blind so that was a no go but if you didn't have anything you would use lemon juice because you could go into a shop and just buy it.

Yeah like a wee jiff lemon?

Aye, you could just buy that but you had to use, well not plenty but a lot of it, so you did.

Do you think that did any harm?

Aye, I would say aye, as I say I know people who have went blind with it do you know what I mean, it was, you could actually smell it and taste it after a day or two or maybe when you were injecting it like you know when you can taste the heroin you know what I mean you could taste this do you know what I mean and that's not right it should be the heroin you are tasting but you were tasting the lemon juice you know in your throat and things like that. When you have a hit you taste the heroin and you know you've had a hit like you've not popped' (Participant 15).

The varieties of drugs injected are also listed in Table 36.

Injecting sites: groin

Phase 1 identified a link between injecting in the groin and the legs with ulceration. All but one of the participants reported using a multitude of sites for injections but all of the participants injected in their groin. Almost half had hit arteries during the process:

'Yeah I have had problems, sometimes, you know if I get myself into a flap or whatever or if there is people around and I am trying to do it quickly, I don't know, sometimes I've hit like an artery before and whereas the needle will kind of pop out and the blood just comes spurting out do you know what I mean because you've hit that artery. Or sometimes it's not done that and I've pushed it in and I've shot to the floor in like pain because I don't know it must be very close to the vein or something. I need to read up

because I am rubbish at this stuff and I should be clued up on it. But it must be close to the vein or whatever do you know what I mean and you are just going right next to it and it's just coming popping out. Or if I am too busy yapping away I'll just start pushing it in and the pain is unbelievable. It's horrible pain so it is' (Participant 9).

'So when I've been drawing back when it's been going into it I've not been realising it's been artery blood and when I am injecting it the cocaine is numbing it so instead of, if it had been just heroin I would have hit the roof, the tools would have flew out my legs and whatever but because it was cocaine and it was numbing it so I was just hitting it' (Participant 15).

'I started on the left for some reason, I don't know if it was true or not, but apparently the vein is slightly bigger on the left because your heart is on the left side. That's probably rubbish but that's just something I heard. But I started on the left but then for some - I think the vein and the artery are a wee bit closer together on the left and I was hitting the artery a few times and there is not any pains like hitting the artery - the needle flies out - you scream at the top of your voice it's like, it is like having electrodes wired to your brain' (Participant 17).

Participants were asked about their groin injecting in more detail, particularly why they used their groin. Some talked about it being a better 'hit', a better 'buzz':

'Some people have really, really good veins and some folk don't have like really good veins. But a lot of people I don't know if this is a myth, it probably is a myth, but people either go in the neck or the groin because it's like having their first hit again, they say. So that's what people are doing, they are just chasing it after that first hit, that they get that first buzz and they say going in their groin and their neck gives them that because I don't know it just seems to go to their brain quicker, I don't know, it's probably a myth, a load of rubbish like, but that's what they say anyway. So a lot of people, when you say you are going in the groin, folk kind of, oh I wouldn't do that, do you know what I mean, if I had to go the groin that would be the day that I would have to stop. But I don't know, I am in the groin now and I never thought I'd go there but I have so' (Participant 9).

Some talked about it being a site that could be hidden:

'Yes, I done that and my neck, they were the first places I really done so I could try and hide it' (Participant 5).

'I find that you are better off in your groin then people look at your arms and you don't see any needle marks do you know what I mean. When you hit your groin nobody can see anything do you know what I mean you get the people now they are homeless now they are begging, 'aye you are a drug user', 'no I'm no', 'well let's see your arms' you know you pull it up what I mean no needle marks, no marks at all because they don't know about your groin' (Participant 11).

'some people go for it straight away to hide it so nobody can see any track marks on them and that'(Participant 6).

The simplicity of accessing the femoral vein was repeatedly mentioned:

'Ah well because it was better you know what I mean, because you were getting yourself right away instead of mucking about with your arms or your leg or your feet all the time do you know what I mean but in your groin you were in right away and then in and out do you know what I mean' (Participant 11).

'It's just quickness I think it's just canny be bothered farting about for ages they just want a quick, and that is quick, shoot and get it right away' (Participant 2).

'I started on the left for some reason, I don't know if it was true or not, but apparently the vein is slightly bigger on the left because your heart is on the left side. That's probably rubbish but that's just something I heard. But I started on the left but then for some - I think the vein and the artery are a wee bit closer together on the left and I was hitting the artery a few times and there is not any pains like hitting the artery – the needle flies out – you scream at the top of your voice it's like, it is like having electrodes wired to your brain' (Participant 17).

Whilst access was initially reported to be easier in the groin, participants also experienced scarring and sinus formation:

'So I was like that, well I'll go for my groin because everybody said oh put it in, two seconds and that's you its done and dusted and all that. Little did I know that I'd end up with a big hole that size and a big hole that size in each end do you know what I mean, I've had all sorts of infections in them and everything. But that one there has got, it's got a good bit where you can just put your pinkie in it now, you used to be able to get your two fingers right in and that side and that one actually, that's kind of disappearing you still get the hole but it's a lot wee'er. So I am kind of healing do you know what I mean I am actually healing for a change' (Participant 12).

Bigger needles were required for femoral access:

'As it got harder and harder to get to the groin, I used to use 1mls in the groin at first and then it would be the wee blue spike and then you would go onto the big blue spike and then before you knew it you'd pushed it back that far you needed the big green goddess' (Participant 4).

Some participants talked about the groin being the site of last resort:

'I was actually using veins in my legs before I went to my groin because I, I kind of thought the groin was the last resort you know. Which is, any vein is the last resort if you like but a drug addicts point of view that was the last place I would have wanted to went to so' (Participant 10).

'And some people like, it took all my veins to collapse before I went to my groin because I didn't fancy going towards my groin at all, that's how I ended up using my arms and my legs and even my fingers and my neck before I went to my groin, I just didn't want to go there at all. As the need arises I ended up going there' (Participant 6).

Some participants made the link between groin injecting and the downward spiral of addiction describing it as the worst thing they had done or expressing regret because of the consequences:

'Somebody put a marker in my groin, put like, they felt for the vein and put like a wee dot so I was able to go in that myself. So after that, that's where I've just went ever since. Either side of my groin. But I wish I'd never started going there do you know what I mean it's the worst thing I've ever done. Injecting altogether is the worst thing I've ever done. It's left really big scars at either side of my groin, do you know what I mean, you can actually put your finger kind of, not right in, it's not as bad as some peoples but there is a big mark there and the same with the other side. But the other side is kind of swollen as well sort of there. I need to get that looked at, it's not sore or anything to touch it but it's just, that side is flat down but that side kind of goes into a swollen lump and you can feel it down the leg there' (Participant 9).

Another participant was less clear about the link to ulceration but nevertheless linked groin injecting to the potential loss of her limb, which would be due to non-healing ulceration:

'I think that was the main reason it never started to heal, it never started to heal because I was still using drugs intravenously and on that leg near where the ulcer was. it was from my ankle upwards and

then I started in my groin and once my groin was buggered I never went anywhere else.....

I never thought for one second that I'd end up the way I am just now I never thought that it would come to the conclusion where my leg might need to be amputated or else I would have tried my best to stop' (Participant 14).

Groin injecting and clots

A consistent feature was groin injecting and deep vein thrombosis. All the participants had injected in their groin and all had developed a DVT after this practice had started. As already mentioned, one explicitly made the link:

'it caused the clot and the clot caused the ulcer' (Participant 10).

Another participant made the link but not so explicitly:

'They've just ended up being lucky and they've not went to their groin, they've not injected into their groin, they've not got blood clots, they haven't got blood clots, I am saying that the now but some people, the likes of mine just appeared and people could experience it further down the road'(Participant 6).

On asking what caused the clot:

'Well injecting in your groin, sometimes if you are getting full of it and then you are maybe gouching for fifteen minutes, twenty minutes and then you'll maybe pull some blood back and then push the rest of it then and that blood has been lying there in the barrel for ages you know and it just gets put back in so I don't know if it breaks down' (Participant 10).

'I got this, this leg got a blood clot in it in 1996, I was in the hospital.....Aye, left leg and that was about eighteen weeks in the hospital because I had a groin infection as well. And then I was injecting in the groin. So it's never been the same. So this leg has always had bad circulation my left leg. And just what I take for that is, that's why I've got the ulcer, I don't know....' (Participant 6).

Others thought there may be a link between the drugs injected and a clot – all had injected more than one drug – commonly heroin, but also cocaine and in particular some expressed concern about injecting temazepam, known as 'jellies':

'Well I was injecting in my groin, left and right and it was getting nae hassle whatsoever and I started about 1987, 1988 jellies were going about -temazepam liquid and I started injecting them and that's when my troubles, my problems started. It caused me to get DVT on my right leg and I started using my other side a lot more because my left side, my right side was swollen up all the time. Apparently, I found out maybe five or six years later it was the gel fix in the capsules when I was injecting them, when they cooled down they were solidifying in my body so it was causing the veins to clog' (Participant 3).

'when I started injecting myself with kit was in my left groin. I think that's how I ended up getting a blood clot at the start, was the jellies' (Participant 6).

'I had read a book, actually it was by the guitarist from Guns and Roses and he was saying he was addicted to injecting OxyContin so I thought well I will give it a shot. But it's just the way it was available that day. I don't know if that caused this, I know injecting Subutex is a no, no, you know I phoned a few people who, let's say they are very experienced drug users and they all said do not do it. And, sorry for the benefit of the tape, so I don't know if that caused that but the DVT started around that time'(Participant 17.)

Injecting sites: leg

All but one participant reported injecting in their legs, but no-one considered the leg or foot to be a problem:

'Well not in both legs just both feet because I didn't have any problems at the time' (Participant 17).

'I was actually using veins in my legs before I went to my groin' (Participant 10).

'Aye I injected in my legs, I still injected in that leg after I came out the hospital, you know into surface veins and things like that' (Participant 15).

One person started injecting in their leg as it was a 'hidden' area:

I started smoking heroin and it wasn't getting me anywhere after about a year and somebody suggested what about injecting it. I'll inject you in the leg and nobody will see it so I said aye that sounds brand new.....So I was spending maybe sixty, eighty pounds a day and it wasn't getting me up nor down so I let

my pal inject me at the side of the leg and all of a sudden I was spending eighty pounds a day and when he started injecting, I was only spending twenty pounds a day. I thought it was great, I am saving sixty pounds here, after a couple of weeks that never got me anywhere so I kept injecting there. In the same place so they veins eventually ran out and then I started using my hands, I'd big fat veins in my hands but obviously they are away now, both hands, they went away (Participant 2).

Difficulties with injecting

Although no-one reported resorting to injecting into their existing wounds / ulcer, most participants reported increasing difficulty accessing veins as their injecting career lengthened. One had researched this carefully:

'I used to go into charity shops and read Gray's Anatomy just to find out where the veins were I'd been injecting wherever I could but I was struggling, running out of veins to find I was losing hits even and at a tenner a go that's not very nice. See you get blood in it, but you lose the vein, it congeals and you've got to throw it away. Anyway then somebody showed me how to get me groin and I started using my right groin. So that was three or four years ago. So yeah and then about a year ago I started getting swelling down this leg' (Participant 17).

It was clear that there were progressive difficulties experienced with injecting over time resulting in the use of riskier sites such as the groin and the legs.

Injecting technique

Many described what would be considered poor injecting technique – using larger needles especially in the groin:

'Everywhere, everywhere in my body I've injected, both sides of my groin, my legs, my arms, my neck, my feet, the bottom of my feet, you name it I've used there. In the palms of my hands once I injected in the palms of my hands as well. In between my fingers I've injected. Sometimes I didn't even know I was that mad with it I didn't even know I'd wake up the next morning and I'd be lying, the needle would still be in my groin, I'd be lying with a big set of 5mls, a big giant needle' (Participant 12).

'I went from 1mls to 2mls and the blue spike, the big blue spike, the wee blue spike first and then the big blue spike. Nothing bigger than a big blue with 2mls, the 2mls always used to hold seven jellies exactly that would do you so you always knew that' (Participant 6).

or re-using needles:

'Maybe it's not always a blood clot that kind of brings it up it's maybe using dirty needles over and over again' (Participant 9).

or preparing the injection:

'I've used dirty water out of a car park puddle and along in the NCP in the town a few times I've done it but I've always been alright.

I go and buy a bottle of wine on my own and I buy a bag and then I go somewhere for a hit where I know the police aren't going to come to me in a car park or something say and I've no water, I've got everything else but I've no water, I am going to use the wine or I am going to use the ginger, I'll use it because I know it's wet' (Participant 15).

Most had shared and reused tools:

'any junkie that says they have never shared is lying. When it comes to sitting there rattling, you will maybe give it a flush out with boiling water, maybe go as far as a bit of bleach but nobody is going to knock back a hit just because somebody else has used the needle if you are feeling that way. They are talking shit if they say they have never shared, everybody has shared' (Participant 17).

'I shared with my girlfriend at the time. But I used the same tools, because it wasn't as feasible now as it is now to get tools at that time. So you would try and keep the same sets for as long as possible' (Participant 6).

Another tried hot baths to get a vein:

'I would try and get a vein to, do you know what I mean, I'm talking about jumping into hot baths and sitting in a pure big and roasting bath you know what I mean, and looking and then going oh look at the blue line there and trying to get myself in pure roasting water' (Participant 4).

Participants described a variety of risky injecting behaviours which may have contributed to skin breakdown but generally were not united in their views. This will be discussed later within this chapter.

5.4 Theme 2 Impact of Ulceration

Participants reported the impact of leg ulceration on their lives in quite dramatic terms:

'I was right embarrassed because I've got leg ulcers. I'm dead, dead self-conscious that way I don't tell anybody I've got leg ulcers I don't let anybody know, I'm dead self-conscious do you know what I mean, it's embarrassing, really embarrassing' (Participant 2).

'I'd been in hospital, I've lost like tenancies or places that I've been in due to being in hospital for a few weeks and that' (Participant 5).

'it makes me feel less of a man and I don't deserve that' (Participant 13).

'I've not really got a quality of life, it's wrecked my life completely, they are saying they are going to end up taking my leg off and if they take my leg off I've got nobody to look after me' (Participant 14).

The impact of the ulceration was then explored in more depth and both physical and social implications were described.

Pain

Pain was the most predominant feature complained about:

'My leg oh aye it's agony constantly. Absolute agony. When I am in the project I can walk about without crutches but when I am in like the street I always need to make sure I've got crutches with me.

I just need to get the pain away a wee bit that's all it is it's just the pain, the pain is absolutely excruciating.

I'd rather go through labour ten times than go through this pain every day definitely' (Participant 14).

'since then I am in constant agony see when I sit down I am in agony, see when I stand up I am in agony, see when I walk I am in agony, I am in pain twenty four hours a day. See the pain it's starting to get, it's starting to get into my head, I'm in that much pain I just want to attack' (Participant 13).

'I've sat with the pain that I've had, if there had been a saw I would have sawed my leg off, that's how bad I've got' (Participant 16).

'But the pain was just unbelievable. It's a pain that is with you constantly that you don't need. It's like a, if you think of somebody with a hot screw driver and they are jaggging into your ankle you know, it's murder, torture sometimes I can hardly put, well most times I will walk for about five minutes and then I'll stop.

Aye it's torture the pain, when you see it you think how can there be so much pain coming off this wee thing. But it's murder and you keep going on and on about it wherever you are staying but you get that sick of talking about it because it drives you pure crazy. It affects your sleep, it affects your mood you are constantly thinking about it, you know it affects you walking, it affects you taking part in any sports and all that stuff, so it really grinds you down. It's on your mind constantly all the time' (Participant 6).

One participant complained that the treatment (compression hosiery) made the pain worse:

'they gave me one of they stockings and they didn't like tell me much about it they just gave me it, they never told me to take it off at night and I was in, I was in fucking agony it was so painful I was sending my girlfriend out to buy pain killers and all that and my mate was bringing me around mogadon so I could sleep. I was in severe fucking pain with it and people were saying you are not meant to wear them at night you are meant to take them off you know' (Participant 17).

Participants also complained that their pain was not managed well:

'sometimes it's like fighting a losing battle when you explain to the nurse how much pain you are in trying to get painkillers, it's really, really, really sore, it's really sore. Anything just touches it that's it, it's excruciating, you can just imagine somebody opening your leg up and an open wound and then somebody touching it, it's really, really sore do you know what I mean' (Participant 2).

'the big thing my down there it burns all the time. I'm to see the doctor after I leave here you know what I mean, I need to get pain killers. I need pain killers now to get for the pain. They gave me pain killers paracetamol but they are no good paracetamol, I says I'll end up taking, you are only meant to take eight, I'll end up taking twenty of them. Last time when I got took to the hospital the last time I was in pain, they gave us painkillers they gave us co-codamol and they worked do you know what I mean, I had two of them and the pain was away. Five minutes and the pain was away; brilliant' (Participant 11).

One noted that once the effect of injecting wore off the pain was evident:

'after I stopped injecting, that's when I felt the full pain' (Participant 4).

One participant whose ulcer had healed had not forgotten the pain:

'oh the pain is, I used to cry for that way in the morning every time I got up but I elevate them every night, make sure they are up and I am alright, I can walk fine now. But I still get a wee bit of pain and I don't want to go and get, I was on tramadol, gabapentin, amitriptyline, and I don't want any tablets you know I'll just deal with the pain myself and I came off them all. Just run it down. I was on methadone as well I came off that like that. It was sore but, it was, it was really sore but I survived.

It's the most painful thing you can get, it's like somebody burning you with a hot iron and somebody putting a fag into your face, the pain is unbearable. I was, many times I've cried because of the pain, I couldn't handle it but I push through it and I am still here.

The worst pain, yes, definitely, a hundred per cent.

And I've said to people now, even in here and outside, they go my leg is sore, I've got a trapped nerve, I'm like you are fucking lucky because see if you had ulcers you know what pain is' (Participant 8).

Pain also impacted on sleep in one participant:

'the pain, I don't sleep with the pain do you know what I mean, I just lie there and read a book. Sometimes I will doze off for half an hour and I feel as if I've been sleeping for days but it's not it's half an hour sleep and it does it depresses us so it does and she kind of moans because she gets her full eight hours sleep no bother and she is like, you don't even sleep, you are up and you are doing things and you don't even get a sleep, see if that was me I'd go mental but I kind of think I am used to it now so once I get a doctor I am going to ask him, I need my pain killers back because I was getting the amitriptyline and the gabapentin for nerve pain and they were working cracking so they were don't get me wrong they only work they only work for about four, five hours and then the pain was back but see for that four or five hours I could relax and just sit and relax and it was cracking you know what I mean' (Participant 12).

Mobility

Others complained about pain on walking:

'The pain, it's as if the back of my calves are seizing up' (Participant 3).

'it was sore even when I was out walking you could feel it kind of throbbing do you know what I mean' (Participant 9).

'My ulcer has affected my quality of life big time, see trying to walk it's absolutely excruciating. Usually every morning I'd take my pain killers and I'd wait have a wee cup of tea after my painkillers that will dissolve them, they will kick in. I can get out my bed and start doing whatever I need to do and that's it. But if I didn't have those pain killers I wouldn't be able to do anything' (Participant 14).

'it's really embarrassing do you know what I mean you are struggling to walk and you are on crutches and that it's embarrassing' (Participant 2).

'I had to learn to walk again and things like that, I had a Zimmer for six months

I couldn't walk I was, every time I was trying to walk I was just collapsing because this leg just wouldn't take any weight or nothing.

when I walk anywhere I've got to either stop or sit down or go slow

It's like a half a leg, I canny play football, I can only run, I canny run, I can run twenty yards and I would collapse on that leg' (Participant 15).

Embarrassment

A number expressed embarrassment associated with the smell and the appearance of the ulceration:

'I can smell it, it's throbbing, it's constant pain really and uncomfortable, really, really uncomfortable and there is nothing worse if you are sitting in company or whatever and you can smell your leg and other people canny, you know you are sitting there and you are thinking this isn't right I shouldn't be sitting here it's really, really awkward. It's embarrassing' (Participant 15).

'at the start of it it was just horrible, oh and like I say I'd be next to somebody and you could smell it, I was embarrassed all the time, embarrassed about it' (Participant 9).

*'you could see it was kind of, pus and stuff like that, sorry it's disgusting.
all the pus and stuff like that and it was really kind of like a dark kind of brownie colour it was horrible the infection and obviously that was all the stuff trying to come out of it' (Participant 9).*

'I felt right embarrassed, I was right embarrassed because I've got leg ulcers. I'm dead, dead self-conscious that way I don't tell anybody I've got leg ulcers I don't let anybody know, I'm dead self-conscious do you know what I mean, it's embarrassing, really embarrassing' (Participant 2).

Physical Effects

Most participants described infections such as cellulitis or an abscess with some requiring surgical intervention for debridement or excision:

'in surgery, well obviously I was out but they just scrubbed the hell out of it because I think it was quite bad at the time. Really like furry and you know like, I don't know if you find a dead body in a marsh you know that's probably what you'd expect it to look like you know. So they gave it a really good scrub, dressed it up and sent me on my way telling me to come back and to get a hand, put me on antibiotics and telling me to come back and to keep appointments' (Participant 17).

Scars resulting from injecting were mentioned often:

'Injecting altogether is the worst thing I've ever done. It's left really big scars at either side of my groin, do you know what I mean, you can actually put your finger kind of, not right in, it's not as bad as some peoples but there is a big mark there and the same with the other side.

I am only twenty nine and I've got all these scars and marks all over me it's horrible. I am just that self-conscious about it especially the one in my arm you can see' (Participant 9).

Some participants reported an itch associated with the ulceration:

'my legs get right, right hot and itchy and I try not to scratch them you know what I mean and I was with a partner there for six years and she used to be like that, I'm sick of hearing myself going, gonnae stop scratching Bob gonnae stop scratching Bob, go on stop scratching Bob and sometimes she would burst in

the toilet and I would be standing there on the toilet pan like that pure scratching and the blood would actually be all over my hand dripping in the lavvy pan and she was like that, but I was like Fiona you don't know how good this is, this feels brilliant man. Don't get me wrong the blood would be pishing out of it and I'd be like that, this is fucking brilliant and if you ask anybody a good scratch man it's fucking great' (Participant 4).

One participant removed her dressings as the itch was so bad:

'But now it's not too bad it's just the itchiness, I think so that's why I took the plaster off.

So that's why I took that off the other night because it was fair itchy. But it's a lot better now I've let the air get at it so it is' (Participant 9).

Venous signs

All but one participant reported obvious signs of venous disease – varicose veins or skin staining, and most reported swelling or oedema in their legs – some resulting from thrombosis.

'Aye I've got varicose veins' (Participant 11).

'it's like brown and then it's like pink in the middle where the ulcers have been but it's all brown round round about them do you know what I mean' (Participant 2).

'the skin colour changed to black, it went black and very, very sensitive. It went black and it went purple and sometimes it would be red and sometimes it would be pink, there was all sorts of changes towards the colour' (Participant 14).

Social circumstances

One participant described the impact on social circumstances:

'Well in prison for a start you've got to hide in the cubicle and not get dressed outside the same as everybody else because you are embarrassed, if you are sharing a cell with somebody you don't even

want to get undressed because you are embarrassed. Same if you are outside you get a girlfriend you don't want to say oh how you are doing I'm.....and I've got leg ulcers. You don't want to show that side it's really embarrassing do you know what I mean you are struggling to walk and you are on crutches and that it's embarrassing, it's very, very embarrassing. It's no life to have man. I've got two sons they don't even know I've got leg ulcers and I am right self-conscious that way, right embarrassed about it' (Participant 2).

Another reported the impact of the ulceration in a confined space:

'you are sitting on a bus and you can actually smell your legs and it just smells like dead flesh ken what I mean, and it was really bad at one time and I wouldn't go out the house because it was that bad do you know what I mean and even when, when I used to get my legs dressed, I had to get them dressed if Helen was away see an hour later it would be back and they would put they big pads on with charcoal with the big pads that's supposed to stop the smell but it actually made it worse for me because my leg was sweating with four bandages on and I used to hate sitting on a bus because you could tell people would be like that, what's that smell and all that.

I wouldn't go on a bus I wouldn't get in a taxi do you know what I mean because it was embarrassing do you know what I mean.

...they smell, see when I had the dressings on they were bad, really bad, they actually made me feel sick with the smell do you know what I mean. But when I pull the dressings off you canny smell anything like now' (Participant 12).

The ulceration also caused problems for clothing and bedding because of the exudate from the wounds:

'I ruined my full bedding, I had to buy a new duvet, quilt, I had to buy mostly everything I slept in that weekend, to pyjamas all the way down to a brand new sheet, well because I bought a new duvet I bought two new pillows too. But aye it ruined everything because even that bandage I was putting around on the inadine, the orange was coming right through the bandages plus the liquid of the size of the holes that I've got on my leg, it's just constantly, as soon as you take the bandage off it its just constantly liquid dripping off my leg' (Participant 4).

'there is hundreds of yellow water keeps coming out of that for some reason it's brand new socks I've got on and every time I put socks on they turn yellow with the stuff that comes out it' (Participant 12).

Most described an impact on their social and family lives as result of the ulceration and how it prevented them doing normal activities such as walking or swimming:

'I wouldn't be able to take my baby in for the swimming for the first time. Aye the things I've missed out with my kids. every time the summer comes in I seem to have ulcers you know what I mean and I can't wear three quarter length trousers or that you know what I mean. I've always got to be in denim or tracksuit bottoms. Now I canny wear a pair of shorts and as I said I canny do things with my kids, I canny go down to the beach with a pair of shorts on or that if we go away, canny you know what I mean, when I am away in Spain and that, I've been in Spain and that and I'm down at the beach sitting with a pair of joggers on and people are like that looking at you and that you know what I mean and they must see because I wear sandals

you miss out on a lot of things you know what I mean, you canny, like see my pals have been when we've been abroad and that, been scuba diving, I canny do things like that, I canny do a bit of mountain climbing or that, go away see when I am with Phoenix, I canny go, participate well I can do a wee bit of canoeing and that but I've got to watch I canny go down rough waters or that you know what I mean, I can only play in the dry water, they will not let me go down anything at all because of my leg, but I can swim, but it's your leg' (Participant 4).

Treatment

Once the ulcer had developed participants had various treatments – some obviously understood the importance of seeking appropriate healthcare:

'They gave me like a black sock, that's what it was, just a sock and it was really tight, tight to get on but that was just to keep it all packed in nicely so it could heal' (Participant 9).

'the compression bandages are a lot of help because that helps your circulation and that' (Participant 2).

'well go to Hunter Street, you will get it changed every two days, they will clean it for you and they will put another bandage on it and they will tell you to come back every two days to get it changed. A month or two months down the line your legs will be all clean' (Participant 11).

Another participant was frustrated that nothing was explained to him once the ulcer did occur:

'I can sit and tell you about how Doppler shifts or I used to measure receding galaxies you know, I know about fucking astral-physics you know what I mean. They wouldn't explain why they were putting a bloody thing on my leg you know. at times when I've been in hospital they just seem to have this idea you are a drug addict you are probably not very bright you know they don't fucking explaining things very well they don't bother telling you what they are doing. Right maybe if I was a bit smarter I wouldn't be in this situation but I mean I read a lot and I would say I am a fairly intelligent person. I would say I can understand what they are telling me but sometimes I ask them a question and they just fob me off you know. I am not going to bother explaining this to a junkie you know' (Participant 17).

Other participants were clear that there was a link between their ulcer deteriorating and continuing to inject, but also of the necessity of treatment:

'if I was still using in that leg I would have probably have had to have had it cut off, I don't want my leg cut off, that's what she says, your leg is getting better John because you are coming in all the time and getting it changed all the time' (Participant 11).

Self-help

Some participants described denial and a reluctance to get treatment and improve their chances of healing, for example by self-help:

'I didn't want to go to a clinic to get dressings and all patched up and that so I used to just leave it and it started to smell, smell and a lot of discharge came out of it so, I had it about fourteen, fifteen months by this time and it was about the size of an orange by then. I went to my doctor then' (Participant 3).

'I can only speak for me, I can maybe speak for my brother but it wouldn't sink in for him either because he says his legs are brand new and he's still got leg ulcers like that. Well he might tell you a wee white lie now and again because he says his legs is alright but they are no. They are alright compared to what they were, he had a hole that size in his legs and they were leaking and everything, I had to give him dressings the other day, well the last time Barbara and Helen (nurses) came I had to give him dressings. You should have seen him putting them on he's like that. I'll not put them on I don't need them; I'm like you fucking do need them' (Participant 8).

I think it's like how your life is you know what I mean, where you are staying and if you are eating and things like that, I was running about but you are supposed to take the weight off it and all that. I didn't do that and I was out drinking.....

And then when I am inside like a hostel and I am doing well it seems to clear up with your health do you know what I mean if you are eating and the nurses are getting to you like twice a week' (Participant 5).

'If I was in a project where I was able to eat fresh food and have a decent diet then I think it would have helped' (Participant 14).

The predominant impact of ulceration was pain and embarrassment, but it also affected social circumstances.

5.5 Theme 3 Harm Reduction

Participants were asked what health professionals and others could do to help PWID reduce harm from injecting, and particularly groin injecting.

Preventing injecting

Some of the participants felt that preventing injecting in the first place should be a priority as once addiction took hold they would ignore health risks:

'...back then years ago if you were to show me pictures of what you could get and things like that doing it, it probably would have put me off. But likes when I've come in here and in Dumfries in the waiting area like when that anthrax was out, it just had pictures of what that could do to you and I was looking through them do you know what I mean, I wasn't really, I knew that it could do to you but I was still going out there buying it and doing it' (Participant 9).

'I've always said, see my mum, see my mum's legs, my mum's legs are ten times worse than mine and I've always said to myself, there is no danger that I will end up with legs like my mum has, no danger but,

I was too strung out and too busy running across the town to get squared up, do you know what I mean I didn't pay any attention to those things I just wanted squared up? It wasn't until I ended up half dead - that's when I started paying attention to all the leaflets and all the correspondence that is out there for all this kind of stuff.

Any information, any information at all would help because I'd read it, I would read every single leaflet. I think in pharmacies and chemists, see you get the wee booths where chemists send the methadone patients, I think in there if you were to put them in there people would lift them up.

Nobody is going to stop injecting until something really, really bad happens to them, until they have a bad experience' (Participant 14).

Some participants were clear that nothing would make much impact once the addiction was formed as the desire to obtain drugs was too strong, and overwhelmed other needs. Two female participants illustrated this by describing behaviours they were ashamed of that were driven by the addiction:

'you are just out there to get your money do you know what I mean and that's it. But I would, I've not got the guts to do what the lads, but like I said it's dangerous what I am doing, jumping into, I mean what kind of person jumps into a motor you don't even know the guy. Anything can happen because you've heard stories on the telly that girls get taken away and they are never brought back and I am linked into the Base 75, that's just down the road in the town and they help out working girls they're brilliant and they let you go in there for a shower and talk to you and help you. But she was telling me stories and stuff like that about some guys like they are wanting girls that are twelve, thirteen and dressed in school uniforms and I think to myself I must be sick in the head going to go out there and walk through here and jump into a motor do you know what I mean but like I say I need to keep my habit going' (Participant 9).

'You know what I mean I actually had a brick in my handbag when I was standing at a cash line machine and rob somebody, hit them with the brick in the bag, that's how, to the extent I went to' (Participant 5).

Reducing injecting harm

Another participant felt that assistance from professionals with injecting would make the habit safer, and suggested the insertion of a cannula:

'Maybe even if there was one vein so if they started off in their arm if they put something on to use that vein so if they are going to use, put something in like a bus or something, put in a vein so that they could be using and then come every so often and move it about. Like so you could be in control, so you could do it you could put a bit of water in and then you could put something in you know the way you get a drip' (Participant 5).

Another participant felt that alternative routes needed to be encouraged:

'Everything is getting done isn't it, just guiding people towards smoking, I would advise anybody to smoke it rather than inject it because you don't know what's in the kit nowadays, anybody I ever see I say you should just smoke that because there is brick dust and everything in the kit nowadays. I don't know how you could kind of promote just smoke it instead of inject it though, some people think it's a waste of time smoking it because you get a rush when you thingmy. So its, it's hard' (Participant 6).

Education

Most participants felt that education was important but at a much younger age than when they started using drugs – many suggesting within the middle years at primary school, but taught by those who had experience of drug use:

'Aye especially young ones and that you know what I mean who have just started taking drugs they see that on a picture they are going to be like 'oh I don't want my legs looking like that' do you know what I mean because once you've got that its a scar for life' (Participant 11).

'Aye at school level aye, I think aye, definitely, but no, like at this level just now. At school level you could get people to really frighten kids with showing them pictures of, like pictures of ulcers and pictures of wounds and all that kind of stuff. Showing them, showing them statistics and all that. Get a drug user in that's actually got an ulcer and ask the drug user to show the children the ulcer, let them see it close up, to realise, like this is what is going to happen to you if you start using drugs.

Aye I was fifteen when I started using but I was eight, seven or eight when I started trying to protect my wee sister.

No I would say about ten, about ten, ten years old.

Before secondary school or maybe if some teachers are not too happy with it first year at the earliest well at the latest I would say, first year at the very latest' (Participant 14).

Participant 16 felt that slightly older children should be shown pictures of injecting damage:

'I just think making intravenous users aware of the outcome of what can happen and then showing them the harsh reality like pictures of what it is like.

No I just think like what you are doing is good but I think showing younger people what the outcome of injecting would do and what's happened to people that's carried on doing it.

High school, high school I wouldn't think is too young because people are leaving high school and that's when they are starting to dabble in drugs.

About fourteen or something' (Participant 16).

A minority felt it would never happen to them and that very little could be done to prevent injecting starting:

'at that age I was daft and stupid and I always knew that I would do myself damage but at that time, once you are in, once you are trapped in that addiction you're shut off to all the consequences that are going to happen later do you know what I mean, so you are not really open, your mind is not really open to all the, if you are sitting rattling and somebody says to you in ten to fifteen years later this is going to happen to you, you would still take your charge' (Participant 6).

A direct approach was suggested by another participant:

'just spit it out and say look you will end up dying, that's it, it's simple that's how I stopped it'
(Participant 8).

Another felt that frightening people would put them off:

'Aye show people the real bad ulcers, take photos of them, show people, put posters of them. This is what happens if you use heroin in your legs.

Aye because if I had seen that as a young boy it would have put me off.

I don't know, it's up to yous, it's up to yous, I can't say my head is all over the place I can't tell you'd how about out there, right outside there, put it on the walls all along Gallowgate let people know, you need to spread the word.

What you need to do is frighten people and you need to show, you need to get photos of bad ulcers and put them about the place and say this is what happens when you inject in your legs and it will stop people.

Take pictures of bad ulcers and show them and don't say it's such and such's ulcer just put this is what can happen to you, you'll soon see a change. I know Glasgow' (Participant 13).

Many expressed concern about the visual appearance and suggested that images of ulceration and femoral sites could act as a deterrent for some:

'make a video to show a kid what way a leg goes with ulcers and that's what you get through injecting. See if you were to see my leg you would be like that, it would put anybody off, it would have put me off if I'd had seen it when I was younger. See the likes of, see the likes of somebody coming into the schools and showing you things, I think that would have put me right, right off the track' (Participant 4).

'Aye I think that would be a good idea, the effects of, the difference of smoking it and injecting it, if you smoke it this is the damage you can do and if you inject it this is the damage, this is the more damage you can do or something. Aye show people how horrible, groin infections are and things like that, because that's where most people end up going and just bad ulcers. Because I don't think you get ulcers with smoking, smoking kit for some reason I don't know why I say that, I could be totally wrong but I think it's more down to the injecting all the shite, sorry for the language, all the shite that is in the tools, in the kit. It's meant towards; it contributed to having ulcers.

Show them pictures of a bad groin infection, that would discourage them a lot. Because people don't like to hear about that area being used or anything it's kind of dodgy jaggging, I don't know how you can do that, I don't know how she can do that so it's just kind of tarnishing that a wee bit worse' (Participant 6).

'The pictures aye and whatever else do you know what I mean, pictures of people's groin and that you know the state they are in, I've seen people's groin in some state big holes like that do you know what I mean. You get somebody who will volunteer as long as you don't see their face you can say do you know what I mean, it will put young people off do you know what I mean. I'll not do that do you know what I mean, they've just started taking drugs do you know what I mean.

Aye you could put them in chemists now pictures and all that, chemists, health centres, homeless places and all, people who are in homeless places in there and all' (Participant 11).

'look at me - if I had to undress to show them what it's done to me I would show them because it's not nice to see the marks I've actually got on my body' (Participant 15).

One participant had put this idea into practice and had dissuaded family members from using drugs as a result of his experiences. The following long quote describes well his determination to use his experiences to limit the damage in others:

'I managed to put my wee nephew started smoking cannabis and so did my other nephew he's twenty three now and my other one is twenty and now they won't touch a thing do you know what I mean. Just showed them the state that my legs were in,..... If somebody would have showed me the way my legs were the now I would never have touched a needle. See if I'd had seen photos of that in a catalogue of people's legs, no faces or nothing just legs, some of the people that I've seen they've had big chunks took out of their legs do you know what I mean. So if I'd had seen something like that I'd be like that, I'd never do that do you know what I mean. Back at that time when I, you hardly knew anything about anything like that do you know what I mean, I never knew what a leg ulcer was until I was twenty nine, you know what I mean, twenty nine, thirty then I knew what a leg ulcer was.

Aye, aye, any health centres the likes of the health centres, where you go to get your methadone or even see the likes of going to schools before they start leaving school and that. See if you, if somebody had come into my school and showed me a big catalogue of people's legs through injecting drugs.

That's what I mean but see, to me it's just like a short, sharp shock do you know what I mean that would put the majority people off the now because people think they are all wee tickets and stuff like that and if you see it right, if you actually see them, like of I got asked to go to a couple of schools and actually show them my legs do you know what I mean and they said listen you can do it, you can cover yourself with a screen. I was like no, I'll do it I'll go to the school and I'll do it I'll show them.

I went to that school, I went to that school do you know what I mean. I went in and there wasn't there was about thirty eight people there it was, to me it was all the older ones that were ready to leave school and I was thinking maybe you could catch them, you've got to catch them around about twelve year old, thirteen because that's what age I was, catch them then. But see the people that I spoke to after I'd shown them my legs and what it does to you and stuff like that you could see that they were shocked because some of them had parents that were injectors but they didn't have the problems that I had do you know what I mean. So maybe they are like that he's just a one off but I told them, look my brothers had them, all my friends blah, blah got them, it's just sheer luck if you don't get any problems do you know what I mean it's luck. And a lot of them were thingmy but a couple of them, you could see a couple of them were like that, I'm no bothering my arse about him he's talking a lot of nonsense but even if I could get through to the likes of one or two people do you know what I mean and they didn't do it, then I've done what I set out to do do you know what I mean. we've got four under twenty fives here and they think it's all a joke, do a group, is it alright if we do a group on your legs and show them, I'll take a group You

can see they are kind of interested because I've been asked a couple of times go on ask Stevie to take the group tomorrow again because they are coming to see someone like me that's been there done it wore the T-shirt done the lot. And it is, to me if it gets through to some of them do you know what I mean, you are never going to get through to everybody but if I get through to just one or two people then I'll be happy with that' (Participant 12).

Most of the participants focussed heavily on interaction with young people as having the biggest impact:

'I think it's all about educating young ones you know, it's hard as it may seem, showing them horror stories about how they could end up, not everybody ends up like that because I know guys that have been injecting in the past for years and years, ten, fifteen years and they've not got a blemish you know. I might just be one of the unlucky ones.

Schools and even community centres.

Aye, aye because I don't know if you remember one of the magazines we done years ago when my legs were really bad you know I think that would shock a few people.

it's the next generation that we need to worry about really in terms of drug use because a lot of them are getting into it earlier and earlier and earlier, you know it's not a case of a specific group it's, I think it's getting earlier and earlier and earlier, thirteen, fourteens want to have a wee toot or they have a wee burn. Maybe, in some of the, I don't mean stupid but some of the naiver ones say give us a wee hit to see what it's like and then they get a good stone and they think this is brilliant and keep doing it and keep doing it and keep doing it.

Because lately a lot of primary school kids have been bringing hash into school and heroin as well you know and pills you know, that was never heard of when I was young you know, that was a no, no, so' (Participant 10).

Others also felt dissuasion by experienced users would work:

'there is that much information there but a lot of people aren't getting it, a lot of kids aren't getting it and if they do get the information at that age it'll just go over your head anyway you don't want to know about it. Unless you are going to listen or you know somebody in your family who's been using and you are seeing them do you know what I mean, you know what they are going through and you've watched them going through it' (Participant 15).

Education of health care workers

Some felt that healthcare workers needed better education also:

'Aye, they are actually asking you about them do you know what I mean I'm like you are a nurse or a doctor you should know about this but they don't you know what I mean, some of them, But there is a lot of them that hasn't got a clue, not got a clue' (Participant 12) .

Poor attitudes were reported by some of the participants:

'at times when I've been in hospital they just seem to have this idea you are a drug addict you are probably not very bright you know they don't fucking explaining things very well they don't bother telling you what they are doing. Right maybe if I was a bit smarter I wouldn't be in this situation but I mean I read a lot and I would say I am a fairly intelligent person. I would say I can understand what they are telling me but sometimes I ask them a question and they just fob me off you know. I am not going to bother explaining this to a junkie you know' (Participant 17).

'She (the Practice Nurse) did nothing for me, she wanted me out of the place as quick as possible because the sun was out and it was a Friday, she wanted home, she said they'll send you a letter for the ulcer clinic two months ago and I am still waiting on a letter, they don't care about you, see because you are on methadone they think you are a junkie. I ain't no junkie hen I can tell you that the now, I am a drug addict. I hate that, a junkie, a junkie is a person that is a bit smelly, doesn't wash himself and doesn't shave, keeps unkempt, doesn't eat. I ain't that hen' (Participant 13).

The participants had clearer views on reducing harm than they did on causation. These findings will now be discussed.

5.6 Discussion

The data from Phase 2 corroborated the risk factors of significance found in Phase 1 such as DVT, groin and leg injecting, which were common to the majority of Phase 2 participants.

5.7 Theme 1 Causes of leg ulceration

It was interesting that there was little agreement on the cause of ulceration, despite the ulcer having a major impact on the participants' lives. An eclectic mix of contributing factors was discussed such as homelessness, lack of hygiene, and diet and nutrition. In some cases the formation of an ulcer was a surprise and appeared to come out of the blue, whereas other injecting complications, such as abscesses and blood-borne viruses, were known and understood.

Site of injecting

All but one had injected in their lower legs. However, in those who had injected in the lower legs, an ulcer only developed subsequently at some of those sites, but for others the ulcer was at a site where no injecting had occurred. This may indicate that injecting in the legs causes venous damage, which can cause skin to breakdown in other sites, due more to the vascular problems than the breached integumentary system.

Groin injecting

In this sample some participants described getting a better 'hit' from using the groin site, whilst others discussed the advantage of an injecting site which was hidden under clothing and not a visible sign of injecting. This was beneficial for those in employment, including those working in the sex industry as there were no visible track marks or similar that would alert customers to a drug injector. Another benefit described was ease of long-term access – the development of a sinus could be seen as advantageous as there was no need to search for a vein – the visible 'hole' was the access point. A hit could be obtained quickly and participants described the ease of injecting in public places because they could access the femoral so fast with no need for a tourniquet and no time spent searching for venous access.

Some participants described the groin site as the site of ‘last resort’, somewhere they really wanted to avoid, whilst others expressed regret at using the groin once the consequences of scarring and leg ulceration had developed. Many described problems with the site related to infection and swelling and described increasing difficulties accessing the groin over time. The vein apparently became more difficult to access and larger needles needed to be used, potentially doing more harm.

Few participants linked leg or groin injecting and clots to ulceration, despite all participants having had a DVT and all had injected in the groin and all but one had injected in the lower legs. No participant linked thrombosis with ‘gouching’ – long periods of static movement due to drug intoxication. Some claimed they had not injected where the ulcer had developed and they therefore could not see any relationship between the two.

It was clear that there was significant gap in knowledge relating to long-term effects of injecting in the groin or the leg.

Substances injected

Some of the older injectors related problems with groin injecting to the injection of temazepam (‘jellies’) which was available in gel capsules. These tended to solidify in the vein causing damage.

However, all except one of the participants injected more than one type of substance. All had injected heroin, and most had injected cocaine, buprenorphine, diazepam, and crack. Some had injected both cocaine and heroin together. One significant disadvantage of this, in terms of vein damage, is that no pain is experienced if the needle misses the vein because of the anaesthetizing effect of cocaine.

All of the participants had added an acidifier to their heroin to create a solution for injection. Within the city, citric acid was readily available as part of IEP, and most of the participants had used this. Those injecting for longer reported the use of a substance called 'abdine', an indigestion remedy, which is no longer manufactured. Many had also used a mixture of other substances including lemon juice, vinegar, wine, orange juice, and other fizzy drinks such as 'Irn Bru' and cola. The impact of injecting these substances is unknown, but it is clear that, when desperate, participants would not be selective about their acidifier or their diluent but would use whatever was available. Differentiating between the damage caused by individual substances over a long period of time was close to impossible.

5.8 Theme 2 Impact of ulceration

The participants talked about the impact of the leg ulceration in strong language describing it, for example, '*as having wrecked their life completely*' (Participant 14). Psychosocial issues such as embarrassment about smell and appearance were prominent and unseen aspects such as pain and lack of sleep were also significant.

Pain

Pain was a predominant feature described by participants, even though most were prescribed an opiate substitute or were still using opiates which would be expected to reduce ulcer pain. This was interesting given that venous ulcers are reputed not to be significantly painful (e.g. compared to arterial ulcers) and it is often assumed that drug users should not experience pain due to the level of circulating opiates in their blood stream.

However, the physiology behind the experience of pain may be altered in long-standing opiate users, resulting in opiate-induced hyperalgesia which increases sensitivity to even minimal stimulus (McCreaddie et al, 2010). It would appear that some opiate users therefore will experience heightened pain from ulceration (Pieper et al, 1998).

This could partly explain why the participants described the pain as being the most significant impact of ulceration on their lives. It affected their sleep, their mobility, and had a psychological impact.

Pain is not something that can be seen or easily measured. It is difficult to convey to others who have not had similar experiences and it is often assumed that the opiate use will mask any pain. Describing the terrible pain experienced by those with ulceration may therefore be a difficult message to get across within harm reduction.

Embarrassment

Participants complained that the embarrassment surrounding the odour emanating from the ulcer affected their lives. Some felt they were unable to go out and they couldn't use public transport as they would be within a small space where the odour was most noticeable. They linked the odour to the exudate from the ulceration, and some preferred not to have dressings on, not to be treated, as the smell was less if the wound dried out. The quotes relating to embarrassment were powerful and could be utilised to describe the impact of ulceration as part of harm reduction.

Psycho-social

The ulceration affected many aspects of life – the ability to socialise even with close family was affected by the embarrassment of malodour. Similarly the exudate which was described as soaking through clothing and bedding impacted on participants' willingness to leave their homes, whether this was for appointments, shopping or visiting other people.

Close relationships also suffered due to the consequences of developing ulceration, as participants expressed worries about the '*liquid dripping off*', and the smell. Similarly, one participant described the itch from the leg as being so bad that he had to go into a separate room to relieve the irritation by scratching.

Scarring

Although leg ulceration is usually hidden under clothing, some participants were concerned about the scarring that drug use had caused. Repeated injection and particularly when using a poor technique, such as ‘digging’, can result in scarring. The potential for disfigurement may be something that could be given greater publicity in harm reduction messages.

Venous disease

Venous disease occurred in the majority of participants, mostly without a recognized family history but with visible signs such as staining, varicose veins, and oedema. These signs were not linked to injecting by participants and this could be a role for education. Whilst DVT was usually diagnosed by health professionals, it appeared that information was not given to participants of the benefits of ongoing compression or possible sequelae. There could also be a role for education of health professionals about this topic (Prandoni et al, 2004; Meeto, 2010).

Mobility

A frequent complaint from participants was the impact that their ulceration had on their ability to walk, and subsequently to take part in what they considered to be normal activities. They complained about pain from the ulceration and general pain within their legs affecting walking. Some needed mobility aids such as a Zimmer frame or crutches whilst another ended up in a wheelchair. The issues with walking were not solely confined to the consequences of ulceration, but also with the pain and swelling caused by thrombosis which was linked to this. All these were related to injecting.

Those who wanted to do more, such as playing football, hillwalking, or swimming with their family, reported being unable to do so because of the ulceration and pain in their

legs. The issues with mobility and of independence appeared to be a surprise to most participants. This could be of value to raise awareness in appropriate harm reduction programmes.

Desperation

Participants described dangerous behaviours in relation to their drug use, such as participating in criminal activity like robbery. Undertaking risky sex work in order to raise money featured in the responses from two female participants. Both had insight into their behaviour as something they were ashamed of, but the over-riding desire for money to fund their drug habit took precedence. Incarceration in prison seemed to be little deterrent and just something that went hand-in-hand with their habits. When discussing dissuasion from injecting, some participants admitted that nothing would make any difference. If they were desperate for that hit, any thoughts of consequences simply were not considered.

Routes into injecting remain a global issue which is beyond the scope of this study.

5.9 Theme 3 Harm reduction

Participants were asked what health professionals could do to reduce harms and to prevent leg ulceration occurring. The initial focus was on preventing injecting rather than harm reduction.

Routes into injecting

Most participants focused on preventing injecting in the first place, by informing and to some degree shocking others. A common theme was specifically focusing on children. All participants in Phase 2 had injected before the age of 21 years but most indicated that their awareness of drugs, and participation in a drug culture, started long before this age.

Many participants talked about the influence of their family and friends in relation to commencing drug use and injecting. Some grew up in an environment where drug use or dealing was commonplace and progression to their own use seemed a natural development:

'So when you are born into something like that you just carry on doing it' (Participant 13).

One participant's mother gave her the first injection. Her expectation was that her mother would do her no harm:

'I thought ma ma's not going to do anything, she's not going to give me anything that's going to harm me is she so I accepted' (Participant 14).

No-one referred to any education or guidance from family members or peers, in fact, the opposite applied. There appeared to have been no dissuasion away from the drug culture amongst the participants in this sample.

Early education

The majority of participants indicated that the time to start prevention would be during primary schooling. One participant had started injecting at the age of 12 years.

Secondary schooling usually begins around the age of 11 or 12 so the suggestion of drug education before the potential start date of drug use is viable. However, all participants in this phase were aged 29 years or older and there have been changes in the education of young people in relation to drugs that may not have been considered or implemented when they were at school.

Harm reduction related to leg ulceration

It would appear that there is little information or education about the development of ulceration in injecting drug users. Ulcers may have developed in areas or sites where the participant had not injected, or appeared long after injecting had ceased, so participants were puzzled by this. They were mostly unable to make a link between

previous behaviours, for example injecting in the groin linked to a wound in their lower leg. In fact, some participants denied that the ulcer was related to injecting habits, and so it would appear that education relating to the causes of ulceration is an identifiable gap in harm reduction provision.

One participant noted that healthcare staff were poor at explaining things about the ulcer to him and he felt that this was because he was a 'junkie'. Poor attitudes from healthcare staff in generalist settings were repeatedly reported by drug users, though, as most interviews took place within a setting familiar to drug users, they were complimentary about the staff directly treating them there.

Visual images

Many participants were concerned about the visual impact of their ulceration. A number of participants had ceased injecting and in desiring to participate in more mainstream activities such as sport, their appearance had become a major issue for them. As such, they felt that the appearance of their ulcerated leg would be an inhibitor for those considering injecting, and some had demonstrated this in their personal lives by showing others their legs. Others referred to infection and the appearance of an infected groin injecting site as something worth showing others. A predominant theme was that the use of visual images was strongly influential, such as the campaign which encouraged the use of fresh needles by using an image of a magnified blunt and barbed needle to demonstrate what happens when needles are re-used. Strong advertising images could also be useful for those not fully literate, which is not uncommon in the drug using population (Yates, 2006).

Injecting advice

A few participants felt that greater help should have been made available once injecting was established, such as help with locating veins and possibly establishing access using

a venous port of some kind. No participants mentioned injecting rooms or changes to legislation surrounding drug use. One was keen that education about alternative routes such as smoking would be useful.

It is interesting that, despite huge initiatives within harm reduction and the extensive provision of injecting equipment, many gaps still exist. Recommendations for harm reduction arising from this study will be discussed in Chapter 6.

Chapter Summary

This chapter examined the findings from interviews held during Phase 2. Risk factors that emerged in Phase 1 were explored further and the findings corroborated the results of the first phase, in that ulceration was linked to injecting in the legs or groin and followed a DVT.

The participants' thoughts on the cause of leg ulceration showed a variety of views, and most were unsure of causes. Few related it to injecting. However, all described the negative impact that ulceration had on their lives, in particular the pain, the embarrassment and the effect on their family and social lives.

The participants' views on harm prevention and reduction in relation to leg ulceration can be summarised in the following ways:

- 1) Try to stop injecting occurring in the first place - something participants felt could be done within school education, with potential for the use of images of the consequences of injecting.
- 2) Reduce harm to the lower limb by promoting topic-specific education that will target areas of risk, such as groin injecting and injecting in the lower limb.

Phase 2 helped to answer the final research questions '*What causes chronic leg ulceration in young PWID?*' and '*What are appropriate harm reduction measures in young PWID?*'. Chapter 6 will discuss the integration of the findings of both phases.

Chapter 6

Synthesis and Discussion

Introduction

In this sequential explanatory mixed methods study two distinct phases were completed with the earlier results informing the second stage of the study.

This chapter considers the extent to which the findings from both phases (Chapters 4 and 5) are convergent and complementary, and explores the answers to the original research questions. The subsequent discussion draws on literature, some of which emerged during the course of the study, and concludes with limitations on the study and subsequent reflections.

6.1 'What is the extent of skin problems and chronic leg ulceration in young people who inject drugs?'

This research question was addressed within the first phase. The high prevalence of leg ulceration at 15% of the sample compares poorly with a 1% prevalence of ulceration in the UK general population (Hall et al, 2014). The identification of a high prevalence of skin disease at 60% was less surprising as the skin has to be breached in order to inject and, with all of the risk factors discussed previously in Chapter 4, skin is the first organ to be affected.

6.2 What causes chronic leg ulceration in young people who inject drugs?

The statistical results from Phase 1 about causation linked well to the experiences described by Phase 2 participants.

Deep vein thrombosis (DVT)

The statistical results demonstrated primarily that DVT was the most significant predictor of leg ulceration as 97% of those with a leg ulcer in Phase 1 had also had a DVT. This was corroborated in Phase 2 where all of the participants, who all had leg ulceration, had sustained a DVT.

Injecting in the legs

Injecting in the lower legs was a strong predictor of developing leg ulceration in Phase 1, and these results were also corroborated as all but one of the Phase 2 participants had injected in their lower legs. Ten participants in Phase 2 had ulceration at the site of an injection.

In Phase 1 DVT was strongly associated with injecting in the lower legs.

Groin injecting

All of the Phase 2 participants had injected in their groin and had a DVT. In Phase 1 DVT was also strongly associated with injecting in the groin.

Leg and groin injecting is a strong predictor of damage to the venous system within the leg, and the limb is likely to deteriorate progressively, especially if a clot forms. These are the most likely causes of leg ulceration in young PWID.

6.3 ‘What are appropriate harm reduction measures in young people who inject drugs?’

Harm reduction was a topic raised specifically in Phase 2. However, participants in Phase 1 were unable to articulate a rationale behind the development of ulceration in

some injectors and not others. If harm reduction approaches had addressed the development of ulceration as a consequence of injecting no participant taking part in Phase 1 alluded to knowing it. A number of harm reduction suggestions were made by Phase 2 participants.

Existing knowledge

None of the Phase 1 participants were able to articulate that groin and leg injecting were major risks to the venous system within the leg. This was surprising because so many injectors were sufficiently knowledgeable to be able to describe both how blood flowed in the veins and articulate safer injecting techniques. There was a lack of understanding about the ‘bigger picture’, that injecting into an individual vein was injecting into part of a whole body system and that damage in one area, such as the groin, could impact further away in the body such as the lower leg. Only one participant in Phase 2 could categorically state what the link was to their leg ulceration – *‘injecting in the groin caused the clot and the clot caused the ulcer’ (Participant 10)*.

Existing knowledge about long-term consequences was therefore found to be very poor. Participants felt that harm reduction needed to address first of all the prevention of routes into injecting, which is largely beyond the scope of this study. Secondly, education should be targeted around the physical impact of the consequences of injecting to both people who inject drugs, and also to the staff who work within the services with which injectors interact.

School-based education

The majority of Phase 2 participants felt that education regarding drug-related harm should begin in school thereby preventing routes into drug use or injecting in the first place.

In Phase 1 there were no participants who were under the age of 21 years but nearly 20% were injecting before they were 16 years of age, and almost half before they were 20 years old. It appeared that younger people were not engaging with services that recruited to the study, and therefore were not in touch with harm reduction providers. Similarly, in Phase 2, all had injected before the age of 21 years and most had been introduced to illicit drugs before the age of 16 years.

It could be suggested that education needs to happen before people encounter drugs for the first time, with the aim of stopping drug use all together and preventing routes into injecting. The participants in Phase 2 suggested that education needs to be delivered in primary school partly because a number of participants reported being taught to use drugs by family members and had become second generation users.

Tactics were suggested where images of skin breakdown such as an infected groin, or leg ulceration, could be shown as a dissuasive visual tool, as something people would appreciate and remember. Images might also be more successful due to the lower levels of literacy amongst drug users as written pamphlets and wordy posters may be inappropriate (Treloar et al, 2011).

6.4 Discussion

This study has found that there is a very high prevalence of chronic leg ulceration in young PWID. This empirical finding comes as no surprise to healthcare professionals treating injectors with leg ulcers, but within the literature the definition of skin breakdown requires to be tightened in order to be clear about the ongoing extent of the consequences of injecting on the skin and venous system.

6.5 Definitions

The existing literature was discussed in Chapter 2 and it was frustrating to find a lack of definition by so many authors. It would appear that there is a general assumption that

all authors understand a common meaning when this is simply not the case (Topp et al, 2008). There is frequent reporting of ‘soft tissue infection’ which may have become a blanket definition for many types of injecting wounds including leg ulceration. As leg ulcers are open wounds, and can be chronic, they can be prone to infection, but predominantly they are caused by venous damage, not infection, and by improving venous return, the ulcer heals. Infection can occur, and should be treated concurrently to the venous damage, but if the infection alone is treated the ulcer would tend not to heal without addressing the underlying venous problem (Moffatt et al, 2007, p192).

Therefore categorising ‘sores’ or ‘open’ wounds as soft tissue infection (Public Health Groups, 2014; Public Health Groups, 2015) is incorrect and can be misleading, potentially leading to an over-reporting of infections and an under-reporting of chronic leg ulceration.

Over the course of this study, attempts to define skin problems in the literature have improved, but could be better. For example, an Australian study looked at lifetime prevalence of injecting-related injury (Topp et al, 2008). The authors gathered data on problems including abscess and injecting site infection by a self-report questionnaire and acknowledged the potential for significant debate on definition and categorisation of injecting-related injury and disease, but stated that these are commonly reported, although not necessarily understood, by injectors completing their survey. They stated that it was ‘not practicable to provide definitions or descriptions of conditions’ for their study. They reported a slightly lower abscess prevalence of 27% than other studies (Public Health Groups, 2015) but there was no mention of leg ulceration. Clearly, if there is misunderstanding about meanings, the data cannot be accurately compared.

Another Australian study examined injecting-related injuries in a sample of 393 PWID, and drew up a list of symptoms associated with particular injecting injuries (Dwyer et al, 2009). Respondents had to experience every symptom in a list to be classified by interviewers as having had that particular injury. The authors acknowledged that the

interviewers were not medically trained and therefore the findings were indicative, but not diagnostic, or definitive, of any given complication. Interestingly, they reported a lower abscess rate of 16% and separately reported venous ulcers (1%) though they acknowledged that they were relying on self-report and that a clinical assessment would have improved confidence in the prevalence identified.

An American study published in 2014 undertook a survey of injecting practices in a mobile needle exchange to identify self-care factors associated with chronic wounds (Smith et al, 2014). Chronic wounds were defined as ‘open areas on the skin that had been present and non-healing for 8 weeks or more’. 19.7% of participants had a chronic wound which was visually verified. Wound position was not reported, and ‘chronic wounds’ could have included leg ulceration or any other type of wound as there was no differentiation between wound types or appearances. Whilst the definition was technically correct for a chronic wound, it was too broad to provide any meaningful comparisons.

It would appear that many wounds might have been misreported within the literature and therefore it was difficult to compare other studies with this one which defined each skin problem carefully (Coull et al, 2014).

6.6 Risk factors for ulceration:

Leg injecting

This link between leg injecting and ulceration is similar to Pieper’s work which found that chronic venous disorders were more associated with injecting in the groin, legs and feet as compared with other sites (Pieper et al, 2009b).

In this study, injecting in the lower legs was strongly associated with DVT. Injecting in the legs is clearly dangerous, and the serious consequences of injecting peripherally needs to be made clear to injectors and those that provide care for them.

Groin injecting

Groin injecting is known to lead to scarring and narrowing of the femoral vein. The resulting inflammation may lead to distal clotting, and subsequent DVT in the vein distal to the injecting site (Senbanjo et al, 2010).

In Phase 2, most participants had ulceration in their left leg. As most people (certainly within Phase 1) had right-handed dominance they were more likely to inject in their left side and therefore the damage could mostly be on that side (Maliphant and Scott, 2005).

Unfortunately the use of the groin in Glasgow appears to have become normalised and six people in Phase 1 started their injecting careers by being taught to go straight into the femoral vein. Not everyone did this and some referred to the groin as the site of ‘last resort’, but everyone in Phase 2 used their groin site eventually. Many described progressive difficulties with the groin as the vein became thicker and deeper and needed larger needles to access it. Hitting nerves and arteries was also positively associated with the development of leg ulceration, presumably because this was a problem associated with groin injecting due to the close proximity of the femoral vein, nerve and artery.

There is much debate surrounding harm reduction relating to groin injecting with some authors concerned that teaching safer groin injecting techniques contradicts the opposing advice that groin injecting is dangerous and should not be undertaken at all (Rhodes et al, 2006a; Zador et al, 2008; Miller et al, 2009; Hope et al, 2015).

Concern has been expressed that, in attempting to reduce harm amongst users who femoral inject, service workers are crossing ethical boundaries by providing information to assist injectors and the message that this is a dangerous activity, rather than an acceptable activity, is not getting across. Not one participant in this study said groin injecting was dangerous which suggests that advice regarding the practice might have a place.

The commercial harm reduction leaflets may say ‘don’t do it’ but then provide detailed information about how to access the groin / femoral vein in the safest way possible (Preston and Derricott, 2007; Kemplay, 2015). Much of the ‘danger’ alluded to in the literature relates to aneurysm and groin infection and whilst ulceration is mentioned as a possibility there is a lack of emphasis on venous damage and the chronic recurring nature of ulceration caused by injecting (Gan et al, 2000).

Injectors seemed unaware that persistent difficulties with accessing the femoral vein might be a warning sign that they needed to stop. In Phase 1 the groin was a favoured injecting site for many and the popularity of the site continued through Phase 2 but there was an almost complete lack of awareness of any long-term consequences. A recent study indicated that groin injecting is becoming more prevalent nationally and internationally (Hope et al, 2015) and it is increasingly urgent that attention is drawn to the long-term consequences.

Whilst other countries use injecting rooms, the UK has yet to adopt this strategy (Rhodes et al, 2006b) and this has been a cause for argument for some time (Parkin and Coomber, 2011). Whilst no-one suggested injecting rooms within this study, one participant expressed a desire for professional assistance with injecting safely. A study by Harris and Rhodes (2012) has demonstrated that many injectors who experience increasing difficulty with venous access will eventually end up injecting in the groin. Harris and Rhodes (2012) recommend that intervention opportunities are not missed by service workers, and offering better injecting advice may reduce public health risks and slow the transition to groin injecting by preserving peripheral veins, and encouraging the use of sterile and sharp needles. In their study, participants were keen to obtain advice on safer injecting techniques and how to access veins safely as some of the harm reduction advice of ‘just say no’ or ‘smoke it’ was ridiculed as ‘just not getting it’.

Similarly, Maliphant and Scott (2005) considered the use of structured safer injecting training to improve injecting techniques and promote the use of available peripheral

sites on upper limbs to avoid the potentially high-risk groin site. They also suggest that this initiative could be based within safer injecting facilities. Drug users often inject rapidly, preparing their hit quickly and in a concealed fashion to avoid detection by the public and police, and the groin is a popular site; this can lead to risk taking and injecting in less safe places.

There is clearly room for further discussion on harms associated with the normalisation of groin injecting, and options to consider in terms of safer injecting advice facilities and education for both PWID and service providers

DVT and Post-thrombotic syndrome (PTS)

All of the Phase 2 participants had experienced a DVT, but only one linked this to ulceration.

Post-thrombotic syndrome (PTS) can follow DVT in 20 to 50% of cases (Pirard et al, 2008) and may be characterised by signs of chronic venous insufficiency with limb swelling, pain, skin changes, difficulty walking and venous ulceration (Kolbach et al, 2003). These were symptoms complained of by the majority of participants in Phase 2 and it is possible they had post-thrombotic venous ulceration as most developed their ulceration after they had been diagnosed with a DVT (Kahn and Ginsberg, 2004; Neglen, 2006).

PTS has been known about for many years (Linton, 1953) but is not well-researched. Ulceration may form as part of PTS (Kahn and Ginsberg, 2004) and if this is the case, although the evidence is weak and studies have not been conducted in drug injectors, it is possible that the sequelae that follow DVT could be prevented in up to 50% of thrombosis sufferers by the use of compression hosiery (Kahn and Ginsberg, 2004; Prandoni et al, 2004; Musani et al, 2010; Arumugaswamy and Tran, 2014).

Compression can have a dramatic effect on reducing painful symptoms (Ettridge, 2011), and pain was a key complaint of all but one of those participants within Phase 2 who had recurrent ulceration.

Whilst clinical assessment would be required to investigate whether the participants in this study with leg ulceration were suffering from PTS, it seems a likely hypothesis, and services to provide compression hosiery following a DVT should be considered. However, reducing the risk of DVT in the first place by avoiding leg and groin injecting would be good advice, and should a DVT occur, a clear message of likely sequelae should be given to those continuing to inject.

6.7 Harm Reduction

Harm reduction services alone are not enough to improve the circumstances of PWID. Recovering addicts also need to be able to develop a 'non-addict' identity and public health interventions must address social factors such as housing, imprisonment and low socio-economic status amongst PWID (McIntosh and McKeganey, 2000; Galea and Vlahov, 2002). Whilst these factors may be outwith the scope of this study, an ideal aim would be to stop all risky behaviours, including the total use of illicit drugs, but a realistic and pragmatic assessment would accept that a balanced approach enabling people to make informed choices.

Preventing drug use through school education

According to Stead et al (2007) drug education is now well-established within the early years of primary school; however, it does vary in topics delivered, and by whom. External teachers in schools often have greater credibility as they speak from personal experience (Stead et al, 2007). Some participants in this study had already provided education within schools.

Whilst effective drug education does now happen in schools (Stead et al, 2007; Scottish Government, 2008), it is possible participants in this study were not offered or missed such education when young, and the education they received would not have focused on outcomes of injecting such as venous disease. Phase 2 participants were all aged over 29 years and their school education would have been completed at least eleven years previously. The Scottish Government's Recovery strategy offers a number of recommendations around school-based education and following the findings of this study, there is potential for including some of the physical effects of injecting within that education (Scottish Government, 2008).

Existing harm reduction information

Smith et al (2014) readily acknowledged that whilst local and national harm reduction measures had focussed on risky behaviours, efforts had not been directed at raising awareness of long-term consequences of venous damage related to injecting by PWID which can lead to chronic venous insufficiency and ulceration. An earlier study by Williams and Abbey (2006) also found a lack of basic knowledge about the risks of DVT amongst injectors. Much of the knowledge about drug culture is shared between users so if there is a gap in knowledge about the causes of leg ulceration then this would be perpetuated – these older, experienced participants in this study who act as potential 'teachers' did not make the links between injecting and ulceration.

In Phase 1, all participants were asked what they thought caused wounds on legs but very few of the total sample had actually experienced wounds on their legs and the responses lacked any uniformity.

This included the thirty participants with leg ulceration in Phase 1 who were also asked this question, and no consistent theme emerged. In fact, almost every answer was different. Few participants with ulceration in Phase 2 seemed to have even a vague idea of what might have contributed to the ulceration, and there was some denial that it might be anything to do with drug use as one participant put it:

'So I know it's nothing to do with injecting do you know what I mean because I've not touched my groin for years' (Participant 12).

This is a gap which should be filled. PWID need to be better informed of the risks they take when injecting in the legs and groin.

The main focus in most harm reduction messages seemed to be on addressing blood-borne viruses (Preston and Derricott, 2013). Specific literature related to groin injecting exists, and pamphlets are explicit about the dangers and harms of groin injecting including ulceration, for example, 'In the Groin. Femoral Injecting' (Preston and Derricott, 2007) and 'Going in the Groin' (Kemplay, 2015), but these seem to have made little impact on the participants in this study. Whilst venous disease is mentioned it does not appear to have been emphasised enough, or that PWID have not seen these leaflets or taken on board their message.

Some web-based guidance for injectors (<http://helpingaddicts.net>; Hardacre et al, 2005) offers safer injecting advice and practical advice about injecting sites. It states that one of the risks of groin injecting is developing circulatory damage including deep vein thrombosis and 'varicose ulcer in the lower part of the legs'. Later on under 'long-term consequences of substantial vein damage' the authors state that 'one possible result of serious deterioration of circulation can be *'painful areas of broken skin known as ulcers'* and ulcers *'can take years to heal'*. Whilst this is one of the few publications for drug users that mention the formation of ulcers, it isn't an aspect that is highlighted or to which attention is drawn. It does however have the merit of differentiating between ulcers, abscesses, cellulitis, phlebitis and local infections. This was web-based information and would require users to access the information via the internet and to be literate enough to do so.

The main harm reduction theme arising from Phase 2 participants concerned visual deterrents and education, whilst addressing prevention through early school-based education.

Visual deterrent

Senbanjo et al (2012) instigated health checks for groin injectors and undertook ultrasound examination of the femoral area. They found that the images of damaged femoral veins were a useful resource for discussion about risk. The impact of a visual deterrent such as this may be very useful to consider, as damage to the femoral vein will likely precede the venous changes in the leg.

Ulceration is end-stage venous disease and the limb is likely to have progressive and visible changes as venous disease escalates (Eklof et al, 2004). If injectors were shown corresponding visible images of early signs of venous disease such as ankle flare, skin staining and varicose veins on themselves (Moffatt et al, 2007, p81), then they might begin better to understand the damage to their veins. Similarly, they may become able to identify signs of damage on their peers. An identification of early signs and the knowledge that these were part of a sequence of events leading to ulceration may well dissuade those from continuing with injecting. As one participant said:

'If somebody would have showed me the way my legs were the now I would never have touched a needle. See if I'd had seen photos of that in a catalogue of people's legs, no faces or nothing just legs, some of the people that I've seen they've had big chunks took out of their legs do you know what I mean. So if I'd had seen something like that I'd be like that, I'd never do that do you know what I mean'
(Participant 12).

Formal or informal peer-to-peer education amongst drug users is a common approach known to be successful (Treloar et al, 2011), and is worth considering as part of harm reduction approaches.

Impact of pain and reduced mobility

The impact of leg ulceration on the lives of drug users has not previously been used as part of harm reduction messages. People tend not to think about their legs until they are injured or in pain, and problems are easily hidden under clothing, (Pieper and Templin, 2001) yet leg changes with CVI may hamper mobility, quality of life and employment (Pieper and Templin, 2003). Participants were not asked about pain in Phase 1 yet it was of major significance in Phase 2 with one of the participants summing it up well: *'the most painful thing you can get, it's like somebody burning you with a hot iron and somebody putting a fag into your face, the pain is unbearable. I was, many times I've cried because of the pain, I couldn't handle it.....The worst pain, yes, definitely, a hundred per cent' (Participant 8).*

For participants to express such severe pain was a surprising finding because of the level of opiate use and also because venous ulceration is often considered not to be painful (Moffatt et al, 2007, p216). However, Pieper et al (2013) examined pain in PWID and considered that the pain from ulceration reduced mobility and found that inadequate pain management could cause former injectors to relapse into drug use or resort to alcohol use. Although pain management was not explored in this study, the severe pain experienced was something that participants wanted to be able to convey to less experienced users as a dissuasive measure.

Participants also described considerable embarrassment as a result of the appearance, the smell, and the experience of reduced mobility due to venous disease (Pieper et al, 1998; Pieper et al, 2008a; Pieper et al, 2010a; Pieper et al, 2010b). In Phase 1 the reduced mobility was statistically significant in leg ulceration but it was unclear how much this preceded the ulceration or was caused by ulceration. In Phase 2 it became clear that leg ulceration and the pain and swelling associated with it had a direct effect on the participants' ability to be independent and mobilise freely. In relatively young people, being unable to walk is important and a message worth communicating as significant risk.

Timing of harm reduction interventions

Focus groups with drug users led by Phillips et al (2013) to investigate risk reduction interventions found that withdrawal symptoms negated consideration of risk reduction strategies. So when a drug user is craving then that is not the time to intervene. When PWID collect their injecting equipment, this is usually after they have acquired the drug to use, and are therefore beginning to withdraw (McKeganey et al, 1989). This would suggest that this is not the time to intervene, but somehow to consider access to drug users either when drug use is finished or when they are not about to use. That may be challenging, but timing seems important.

Knowledge and education of service staff

It became increasingly clear throughout the study that there was a gap in the knowledge of drug injectors of the impact that injecting had on their legs, but also an apparent deficit in the knowledge of the healthcare workers who interacted with these injectors. Interestingly, the most recently published textbook on the topic ('Leg Ulcer Management' by Moffatt, Martin and Smithdale, 2007) and recent guideline ('Simplifying Venous Leg Ulcer Management' by Harding et al, 2015) fail completely to mention injecting drug use as part of the risk of CVI and leg ulceration.

Despite all Phase 2 participants having attended for treatment for a leg ulcer neither they, nor the healthcare professional treating them, appeared to have attributed the ulcer to a specific aspect of injecting habits, if indeed the link to injecting had been made at all.

For healthcare professionals, it would be usual practice to offer explanations for disease process when discussing conditions, for example, linking smoking to heart disease, but this explanatory link appeared to be missing. Even though a significant proportion of people do develop chronic venous ulceration before middle age, and thus it is not rare, the lack of explanation was surprising (MacKenzie et al, 2003).

Chronic venous insufficiency is a progressive disease and although signs and symptoms may develop long after a person has ceased injecting, usually there are visible signs of damage that could be pointed out to PWID such as varicose veins, ankle flare, lipodermatosclerosis or skin staining. These may all precede ulceration (Pieper et al, 2006a & b; Beynon et al, 2010). Service staff who interact with drug injectors could be trained to identify these signs. Raising awareness of the risk with drug users before ulceration occurs may be very helpful in preventing extension of disease, or treatment can be implemented earlier and create a better chance of healing (SIGN, 2010).

It is possible that wound care experts and those normally charged with tissue viability services do not have the knowledge or feel equipped with the necessary skills to work with substance misusers (Gilchrist et al, 2011). Training should be available to help them deal with the particular needs of substance misusers as well as identify physical problems specific to drug users, including signs and symptoms of chronic venous insufficiency.

Equally, addictions workers may be ill-equipped to deal with physical health problems, and training should also be available for identifying venous damage within limbs.

Many injecting drugs users in Scotland acquire their injecting equipment or methadone at pharmacies (Matheson et al, 2002) and pharmacy staff are key people who should be educated in both harm reduction information relating to groin and leg injecting, and also in encouraging help-seeking behaviour for those with chronic leg ulcers who require assessment and treatment (Scott and Mackridge, 2009; Mackridge et al, 2010).

A & E services often see drug users and the one-off opportunities for harm reduction related to skin and injecting, and also in reducing mortality, could be utilised (van Beek et al, 2001). Brief interventions can be effective even though they are often opportunistic or quick (Hamilton, 2009) and training in these should be considered for nurses, especially for interventions with drug users where there may only be one first

chance to make a difference. Those with psychiatric co-morbidity and substance use may be more likely to attend A & E more frequently (Curran et al, 2008), and this also creates a training need for staff, many of whom focus primarily on physical health needs (Jones et al, 2002).

Wound care services

More than a third of those with ulceration in Phase 1 had never been properly assessed or treated despite current guidelines (SIGN, 1998; SIGN, 2010). Thirteen participants with ulceration also reported recurrence and three of those people had never had any assessment or treatment for the ulceration. It is unclear why this did not happen, but early assessment and treatment improves healing rates. Of the eleven Phase 1 participants who were not assessed, six were living in their own homes, so even with stable domestic situations they did not receive appropriate care. This may be due to chaotic lifestyles, a lack of accessible services, a failure to treat, or a difficulty engaging with mainstream services. Devey (2010) described the problem of drug users as always being 'in a rush' and unwilling to remain long enough in a clinical service for an assessment using a Doppler test to be undertaken. Compression treatment should not be applied without a satisfactory ABPI result (SIGN, 2010).

Recent empirical work indicated that ABPI in young people may be normally elevated (Male et al, 2007; Niblo and Coull, 2013). Published case reports of young PWID with ulceration showed that most were venous in origin, and all were suitable for compression treatment (Butcher, 2000; Acton, 2008; Devey, 2010). For some time the leg ulcer protocol within Glasgow also stipulated specialist referral if an ABPI reading was above 1.3 as this could suggest calcification (Finnie, 2003). Patients who were referred to hospital for further assessment found it difficult, or were unwilling to attend, so a full assessment and subsequent treatment did not take place. This raises questions about access to appropriate healthcare provision (Meetoo, 2010). It is likely that elevated ABPI readings may be normal and as drug injectors are likely to have almost

wholly venous damage, then compression should be applicable and the treatment of choice, and specialist referral is unnecessary.

Targeted services provided through, for example, IEP facilities may address these issues (Hope et al, 2014). A bridging solution has been developed in Yorkshire (UK) with the creation of 'well-being' nursing posts to meet the needs of drug users. Specialists in mental health have had additional specialised training in wound management and leg ulcer management (Cook and Jordan, 2010). These authors consider that utilising community nursing teams or wound management specialists to deliver care for drug users creates a fragmented service. The 'well-being nurses' were not trained to apply compression bandages but instead were supported to become skilled in using leg ulcer compression hosiery kits. They worked in collaboration with the vascular nursing service who undertook initial assessments and reviews. Whilst this management would not suit highly exuding wounds, it appears to have been very effective, and could be considered more broadly for other services.

The earlier that leg ulceration is treated then the more successful the outcome is likely to be (SIGN, 1998). Sometimes drug injectors may feel forced to self-manage due to negative attitudes and mistreatment by healthcare workers, a lack of appropriate provision of wound care services, or a denial of the seriousness of the wound. PWID appear to be able to self-diagnose and treat, to a limited extent, their own wounds, and only seek medical care when absolutely necessary (Roose et al, 2009; Devey, 2010; Phillips et al, 2013).

Manipulation of their own wounds and acquiring antibiotics without prescription should be discouraged because of worsening infection and potential resistance to antibiotics (Roose et al, 2009) and perhaps earlier intervention by health care staff might prevent crisis management in A & E services.

In the Phase 2 interviews there appeared to be an element of disbelief or denial, as this participant described:

'I says what? Telling me I've got an ulcer, you don't get ulcers in your legs, right that's how daft I was. You don't get ulcers in your legs; you get ulcers in your stomach or our tongue whatever' (Participant 8).

Also, once the ulcer started an element of ignorance about the serious non-healing nature of leg ulceration could result. Participants also took time to seek professional help, as one put it:

'...I started scratching it and it finished it burst open. I thought it would just a scab on it, I picked the scab off it awright, right, but because I kept on using it, I don't know if it was the citric or whatever, drugs, it started getting bigger. But at that time I didn't want to go to a clinic to get dressings and all patched up and that so I used to just leave it and it started to smell, smell and a lot of discharge came out of it so, I had it about fourteen, fifteen months by this time and it was about the size of an orange by then. I went to my doctor then' (Participant 3).

Access to early specialist assessment and treatment needs to be improved; this may occur if there is better recognition of ulceration by PWID, and also if the importance of early assessment and intervention is understood.

Attitudes by services

Drug users will often delay seeking treatment until they reach a crisis point (Hope et al, 2014). However, it would appear that there are limited facilities for drug users to approach without fear of discrimination, and these delays may reflect a number of issues such as competing priorities of acquiring money and using drugs, non-compliance with prescribed medication as well as barriers to accessing care.

The suggestions made by participants in this study with regard to service provision for wounds related more to attitudes rather than the services themselves. In this study, almost all participants in Phase 1 had contact with a healthcare professional, but 20% of these felt they were unable to talk to them. There is stigma associated with PWID which affects not only the public view of them but also those of health professionals (Simmonds and Coomber, 2009; Whittaker et al, 2015). PWID have a reputation for

being difficult and demanding, and may exhibit unpredictable behaviour and poor compliance (Dunlop and Steedman, 1985; Carroll, 1996).

Health professionals have reported that the care they give to users of illicit drugs is often the most negative, unrewarding and unpleasant experiences of their careers (McLaughlin and Long, 1996). Patients presented ‘considerable problems for both medical and nursing staff’, citing blood-borne viral risk, withdrawal symptoms, and a lack of peripheral vascular access inhibiting induction of anaesthesia and administration of intravenous antibiotics. Poor compliance, including a high non-attendance rate at follow-up clinics, complicated all forms of treatment (Fullarton, 1983). Whilst these two studies are dated it would appear that little has changed over time, as a recent Scottish study, examining healthcare practitioners approaches to drug using patients, confirmed (Whittaker et al, 2015).

Harris and Young (2002) suggest that the assumption that PWID are irresponsible about their own health is incorrect, and that if treated appropriately in a user-friendly and non-judgemental environment, PWID will utilise services. This is similar to the comments made by Finnie and Nicolson (2002a) about a drop-in wound clinic set up in Glasgow for PWID where a non-authoritarian, non-judgemental approach was found to result in good attendance figures and return rates.

The importance of straight talking and engaging trust to ensure regular attendance for treatment, especially when ulcers are chronic, was reiterated amongst the sample within Phase 2 but staff should beware of judgment-based remarks that are inappropriate as healthcare professional behaviour can be very influential on drug users seeking help in future (Butcher, 2000; Greene, 2010; Fowler et al, 2014). Amongst health professionals there needs to be greater understanding of traumatic histories experienced by drug users, and services need to be more inclusive and welcoming (Stewart et al, 1998; Neale, 2004b; Schwartz et al, 2006; Shand et al, 2011).

Reduction of stigma may increase their own control and self-esteem of drug users and possibly reduce risky behaviour in a move towards recovery (Simmonds and Coomber, 2009). Mothers in particular have reported alienation from mainstream services due to negative attitudes by nurses and midwives (Raeside, 2003; Fowler et al, 2014). Having an injecting injury is a visible sign of illicit behaviour and this can make substance users defensive and keen to conceal their wound for fear of authoritarian approaches, particularly in relation to child protection. Aggressive policing of injecting behaviour is thought to contribute to moving injecting behaviour into more secluded locations, causing increased harm and risk of overdose (Fitzgerald et al, 2004). It is possible that an authoritarian approach by health professionals also may encourage drug users to hide the evidence of their drug use (e.g. track marks, injecting injuries and wounds), thereby preventing access to appropriate healthcare when required (McLaughlin and Long, 1996; Ritson, 1999).

Nevertheless, further skills training of service staff engaging with drug users would be useful and merit some consideration by managers and policy makers to ensure that services to assess and treat physical harms from injecting are available (Whittaker et al, 2015).

Service provision

A consensus statement on reducing injecting-related harm has stated clearly that IEP services should be made available in every area and provide, amongst other services, ‘wound care advice and treatment’ (Exchange Supplies, National Needle Exchange Forum, and UK Harm Reduction Alliance, 2007).

In 2010, The Scottish Government recommended that all IEP services should be able to either provide or refer to accessible services for primary healthcare, including dressings, and wound care (The Scottish Government, 2010).

Of course, even when provided with harm reduction information, if given a choice the drug user may choose pleasure over risk and the standard model of reducing harm by education of risk simply does not work (Dwyer, 2008). This was summed up well by Participant 15:

'You are not going to stop anybody injecting if they are going to inject they are going to inject it's your choice do you know what I mean. Whether you do it or not is a different matter. But trying to deter people I find it hard, I would find it hard to try and stop somebody it doesn't matter what you tell them. Look at the state of my legs, look at this, look at that, if they are going to do it they are going to do it it's simple' (Participant 15).

Only one participant thought they might lose a leg and although she was still using drugs, she had stopped injecting. There is a minority of drug users who have an ambivalent approach to disease and death, in which case little may be done to influence that trajectory (Miller, 2009). Other studies have shown a fatalistic approach by some drug users in that if they know, for example, that they have a blood-borne virus, their approach to risk worsens (Korthuis et al, 2012). It may be similar once an ulcer develops. Some individuals are thought to deliberately undertake risky practices and health promotion is likely to be ineffective for these individuals (Peretti-Watel and Moatti, 2006).

6.8 Limitations

The literature was searched repeatedly throughout the planning and execution of this study but there was very little empirical work to draw upon with which to compare the findings. Also the inconsistent terminology, lack of definition, and misinterpretation of skin problems meant that any existing evidence generally lacked clarity and made comparisons with the findings of this study very difficult. Although relevant work in the field has previously been done by Pieper and her team in the US (for example Pieper and Templin, 2003; Pieper et al, 2015) and whilst venous disease and leg ulceration is regarded by them as a major issue, the types of drugs injected are different (typically purer heroin with cocaine and methamphetamine) and are not mixed with

acidifier as in the UK. Also US health policy on harm reduction differs to some extent in that injecting equipment provision is inconsistent and often lacking (Phillips et al, 2013). These factors made international comparison difficult which is unfortunate since this author's work is most closely aligned to this study.

Sampling

Of particular concern at the beginning was the ethical review and subsequent recruitment to the study. PWID are notoriously difficult to engage with, but pre-existing clinical links had already been forged, and colleagues within the NHS were more than willing to help. Data collection was largely smooth due to the generous assistance of the Pharmacy Team of Glasgow Addiction Services and the staff of the Physical Health Team from NHS GGC. The opportunistic quota sampling used within the first phase ensured a pragmatic approach to recruitment and was similar to other studies with similar populations (Morrison et al, 1997; University of the West of Scotland, Health Protection Scotland, University of Strathclyde, and the West of Scotland Specialist Virology Centre, 2012).

However, recruitment to Phase 2, when a specific sample was needed, proved difficult and future studies would require to develop a less opportunistic recruitment plan. The initial plan was to include some Phase 1 participants within Phase 2, but due to various practical barriers, this did not happen. The inclusion of these Phase 1 participants (with leg ulceration) might have contributed to an earlier completion of the sample as a range of potential participants with leg ulceration had been identified who were willing to take part in Phase 2. The inclusion of participants who were not engaging with the Physical Health Team (where Phase 2 participants were recruited from) might have created a more heterogeneous sample.

The sampling frame devised for the second phase was a proportional match to those recruited within phase 1 – similar ratios of males to females. It was intended to recruit

equal numbers of people with recent leg ulceration and ‘old’ leg ulceration, and current and past injectors. However, this proved difficult and time-consuming. In the end the sample fell slightly short of that anticipated.

The sample for Phase 2 was drawn from a group of PWID who were attending one service for treatment of leg ulceration. Therefore all of those in Phase 2 were engaging with services in some way, and their perspectives may have been influenced by each other, and by those who were caring for them. The group may have been slightly homogenous in this regard and their views may have been different from a population who were not engaging, and not attending for care. It may be difficult to generalise from the study due to the homogenous nature of the sample, the potential difference with other groups of PWID, and therefore applicability to other cities in the UK and abroad is possibly limited.

Perceptions of cause

Within Phase 2, by the very nature of the questioning, leg ulceration was linked to injecting and the study title which included the words ‘injecting’, ‘drug use’ and ‘ulceration’ also drew attention to potential causation. This may have influenced some of the participants to consider links between behaviours where previously they may not have given it any thought.

Under-reporting or over-reporting

Given the nature of drug use, information is understandably hard to come by due to the reluctance of PWID to divulge illegal behaviour. Similarly not all PWID will readily disclose skin problems and admit potentially poor technique resulting in injuries as many take pride in their ritual (McBride et al, 2001; Lloyd-Smith et al, 2005). Punitive behaviour from health professionals can result in methadone prescriptions being withdrawn if visible signs of concurrent injecting are seen. There is therefore a possibility that the prevalence in this study is under-reported.

Similarly the prevalence may be over-reported. This sample was drawn from a drug-using population who were engaging with services, but a number of PWID do not engage with any services and may have problems arising from their injecting habits. The population is an unknown quantity and hence it may be difficult to generalise the reported prevalence to wider injecting groups.

Clinical examination

Some studies, for example Senbanjo et al (2010) and Pieper and Templin (2003) verified disease by clinical examination which may be of value when identifying prevalence of a visible skin disease. Whilst recall was found to be reliable, clinical examination could have provided more clarity of signs and symptoms experienced and an accurate assessment of venous disease. Future studies should explore the degree of congruence between self-reporting and clinical examination. Accurate reporting of skin breakdown would improve rigour and comparability between studies and could be considered for future work, although serial assessments might need to be considered in order to capture the true nature of evolving disease and also the incidence of infection.

Wound definition

Clearly clinical examination would have assisted in ensuring rigour around wound identification and confirmation of definition. It is possible that participants may have misunderstood or not remembered what their skin looked like over the course of their injecting careers. Whilst the researcher attempted to make sure there was clarity and explanation around definitions and appearances of skin and wounds, the potential for misunderstanding and failure to recall remained. Possibly the use of images may have assisted participants but this also would have been challenging as few wounds or skin problems are identical. Future studies might seek to combine accurate definition with examples of wound type in a visual form and so potentially reduce the risk of ambiguity or misunderstanding.

Substances injected

There was a lack of knowledge about the true chemical content of injected substances including the adulterants and acidifiers which are injected over long periods of time. This creates a further question about aetiology. Is it the injected substance that causes the clots or the skin to breakdown? This was not something that could be explored within this type of study but is worthy of consideration for future studies.

Interpretation of findings

The lack of pre-existing robust evidence about of leg ulceration in PWID leads to some difficulties in interpreting the study's findings. There are so many 'unknowns' within the field: the injecting population (Robinson et al, 2006), the substances injected (Coomber, 1997c), injecting techniques (Taylor et al, 2004a), where and why clots form (Williams and Abbey, 2006) together with systemic processes that impact on skin breakdown and wound healing (Moffatt et al, 2007). Utilising a pragmatic and practical mixed methods approach allowed clear statistical inferences to be drawn from the information gathered, and these were, to some extent, corroborated within Phase 2. However, due to the unknown factors around which data could not be gathered the findings from this study should perhaps be regarded as a first, small step towards increased knowledge for prevention, assessment and treatment of leg ulceration in PWID. Much more research requires to be done to understand the physical impact of injecting.

6.9 Reflections

Critical realism as a philosophical approach.

The use of critical realism as a methodological approach to the research was helpful. The use of two methods was a pragmatic and practical response to answering unique research questions within a challenging population. This study had three aims which were met by using both empirical and interpretivist approaches. Striving for rigour but

recognising within the fieldwork that the convergence of ‘idealism’ and ‘reality’ could conflict. In some ways critical realism is a ‘middle-ground’ between empiricism (a largely quantitative questionnaire survey) and interpretivism (using semi-structured interviews) and therefore can endorse a range of designs according to the study aims. The empirical questionnaire also included qualitative sections, and tabulation was used within the interpretation of the interview data so neither of the two phases were pure approaches to one quantitative or qualitative method or indeed a specific philosophical view. For that reason critical realism, which does not commit to one single type of research design was a good fit for this study. It allowed reflexivity and responsiveness to the research questions without being bound to a pure and rigid approach.

However, critical realism also regards all knowledge as potentially fallible in that a scientific account of a particular phenomenon, in this case the likely causative factors for leg ulceration, may only be a partial account. Indeed whilst deep vein thrombosis linked to groin and leg injecting are significant indicators for causation of leg ulceration in PWID in this sample, there may be a number of other factors occurring which could not be observed or explored. The constituent elements of the drugs injected are a case in point where the cutting agents, the diluents, the ph., the acidifier and the contextual circumstances surrounding injecting are all variables which in the main are unknown but could have influenced the findings.

The explanatory nature of the sequential design permitted triangulation which enabled the results inferred from Phase 1 to be confirmed within Phase 2 giving the entire study a better balance and perspective (McEvoy and Richards, 2006). The knowledge gained is meaningful for this applied health research but the critical realist accepts that further exploration would be worthwhile (Schiller, 2016). Therefore recommendations for further research are made within Chapter 7.

Use of mixed methods and the linkage between two studies

The explanatory and sequential nature of the research design meant that the data analysis had begun before all the data were collected, and this was necessary for Phase 1 to inform Phase 2. However, at the conclusion of both phases, the data from each were reviewed and links made retrospectively between the Phase 2 findings and the earlier Phase 1. One of the strengths of this mixed methods approach was that the data from two studies were brought together to allow a better understanding of the phenomena under investigation (Onwuegbuzie and Teddlie, 2003).

There were, albeit small, overlaps within each study where a qualitative element within Phase 1 asked participants views about what caused leg ulcers. Within Phase 2, there was a quantitative element where data from the participants was tabulated and counted to further validate the results from Phase 1- this was specifically related to the number of participants who had groin, and leg injected and those that had a DVT within the leg(s) that had ulcerated.

The 'triangulation' – the search for concurrent or convergent results by means of different methods (Erzberger and Kelle, 2003) - of the results of both phases allowed added depth and insight to the research questions that neither method alone could produce. Until the first phase was complete it was not apparent which aspects of risk and of the experience of ulceration by injectors should be explored in the second phase. The first phase therefore provided the basis for the subsequent interviews to allow the exploration of injecting habits and risks associated with leg ulceration in a more refined way than was revealed during the qualitative element of Phase 1. Hence the two phases were firmly connected (Creswell and Plano Clark, 2001, p234).

Each phase was analysed separately and independently of the other as is common for a sequential design (Creswell and Plano Clark, 2011, p232-4). The first phase was analysed using descriptive and inferential statistics and the second phase utilised framework analysis. Both methods of analysis are robust and widely accepted methods of analysis for the type of data collected (Creswell and Plano Clark, 2011, p203 - 50). The findings from both phases were brought together using a system of logical inference (Erzberger and Kelle, 2003) and whilst the qualitative findings helped to explain the quantitative results, they also added depth and another dimension to the study by exploring in more depth how the participants felt about having a leg ulceration and its' impact (Creswell and Plano Clark, 2011, p221). The convergence of the Phase 1 results and the Phase 2 findings allowed similarities, differences, and conflicts to be explored within the sequential explanatory design. Synthesising the two phases was challenging but the findings from the phases were integrated in such a way as to demonstrate the similarities between the findings of each phase, such as the presence of deep vein thrombosis in almost all participants with leg ulceration. Another example would be the lack of insight into the harms and risks associated with injecting in the groin for participants in each phase.

A separate element to Phase 2 allowed the participant's views about harm reduction, the third research question, to be explored in more depth than the direct questions raised in the first phase. In doing so, there was slightly more collegiality to the responses as all Phase 2 participants had leg ulceration, enabling themes to be identified more clearly.

There was a time gap between the two studies caused by extenuating circumstances unrelated to the research. However, it is doubtful that this significantly affected the findings. The second phase sought to explain and explore the findings from the first phase and there was limited change in the evidence base, or knowledge around the development of leg ulceration in PWID. During the gap between the two study phases,

the literature continued to be searched and no new developments within the specific field of research were found that would influence the second phase.

Undertaking a mixed methods approach was challenging, but developing two phases and linking them was worthwhile. The two phases allowed a deeper understanding around the research questions and for further exploration to be undertaken once the initial quantitative data were collected. However, given the opportunity to repeat the study again, it would be helpful to spend more time on creating, and piloting a specific questionnaire. The knowledge gained about risk, injecting sites and thrombosis, would enable a more exacting focus and for that to be explored robustly within another study. It would also be useful to incorporate some method of identifying changes in injecting practice and health outcomes over time.

However, the development of the questionnaire and the semi-structured interview schedule was part of the evolutionary research process and if further research were to be undertaken then the evidence from this study would be useful to inform future research designs and tools, together with any new emerging evidence from other sources.

Overall, the use of mixed methods with a sequential design was a good choice to allow the research questions to be explored, the two phases enhanced rigour, and the findings were more robust as a result of their integration.

Application of framework analysis to analyse and interpret data

Framework analysis is a now tested approach for analysing qualitative data (Ritchie and Spencer, 1994). This method appealed, because both the systematic and matrix approach was not aligned to any particular philosophical stance, so was suited for use with the critical realist approach.

As a novice qualitative researcher, framework analysis allowed a clear plan for organisation of a large amount of data derived from interview transcripts. The structured approach offered by the framework was a helpful learning tool to guide and manage a large amount of data using detailed summaries and proved effective for answering the research questions.

In early literature, which was drawn upon when planning the study, the method was heralded as useful where timescales were short (Pope et al, 2000). Yet later accounts of using framework analysis describe it as time-consuming and resource intensive (Smith and Firth, 2011; Gale et al, 2013). Indeed the method was time-consuming however, the approach allowed the efficient handling of quotes and ensured that checking and cross-checking back and forth from the raw data within NVivo was simple to manage. It was particularly helpful to use framework within NVivo as some participants were known to the researcher and their data became anonymised within the charting process. Similarly NVivo was helpful in allowing the simplified management of large amounts of data and helped aid retrieval and refinement.

Framework analysis allowed a transparent and rigorous approach to the analysis of the qualitative data. Using an inductive approach to the analysis worked well with the framework allowing themes to be generated from the data collected, and subsequent refining of those themes to form the basis of the narrative (Gale et al, 2013). It was a replicable method of analysis so transparency could be ensured if others wished to revisit the data, or indeed if further analysis or retrieval of data is required for future publications. Although the interpretation might have been viewed as rather individual, it could still be followed by others within the transparent frameworks or matrices created within NVivo. This benefit of transparency also lent itself to easy retrieval and revisiting of the data during the writing up and revision process.

Links to the Recovery Strategy

During the course of this study the Scottish Government published their strategy entitled ‘A Road to Recovery – a new approach to tackling Scotland’s drug problem’ (Scottish Government, 2008). Harm reduction may be seen to be set apart from Recovery *per se* but *every* small step that an individual takes towards health improvement forms part of their journey away from drug use harms.

Whilst this study is rooted within harm reduction, preventing leg ulceration from occurring by early intervention with groin or leg injectors would also form part of the process of recovery. There needs to be consideration within policy frameworks for addressing the physical harms of injecting as part of Recovery. PWID would benefit from better information in order that their choices to inject in the femoral vein or the lower leg may be fully informed regarding the associated risks, and this information currently appears to be absent from harm reduction material.

Reflexivity

Across both phases some of the participants may have known me as a nurse within a wound clinic. A few mentioned this during interview. This may have had advantages in that they may have been more willing to participate or divulge information, but alternatively it may have inhibited them. It was important to be aware of the different roles as a nurse and researcher, and that the participants also may hold other views. Whilst previous experiences had led to the research questions and could not be disregarded in entirety, prior knowledge needed to be set aside with the participants whilst remaining professionally compassionate and empathetic to each participant’s situation (Berger, 2015). My entire approach needed to be reflexive and I acknowledged the impact my personal experiences and views may have had on the interactions. Depersonalisation of the ensuing data by the utilisation of the Framework Approach to analysis and through the coding process helped reduce the reliance on the personal experiences and improve rigour and credibility in the research.

Clinical practice

Throughout the process of this PhD study, my own clinical practice has continued within a nurse-led wound clinic for PWID. The knowledge gained throughout the process has substantially influenced my own role. For example, when assessing patients with leg ulceration, or offering advice to groin injectors, the knowledge I have gained about risk factors and potential sequelae following DVT has resulted in improvements to my practice such as earlier prescribing of compression and more specific advice. This knowledge has also been passed to colleagues and others through publications and teaching (Coull et al, 2014; Coull, 2015).

Chapter summary

By using a mixed methods approach, all of the research questions have been addressed. Each phase contributed uniquely to the development of new knowledge about risk factors and harm reduction but it is clear that more work is required to raise awareness of venous disease amongst PWID and service providers. The final chapter follows to conclude with recommendations for clinical practice, research and policy.

Chapter 7

Conclusion and Recommendations

Introduction

The chapter summarises the findings of this applied health research study. Recommendations for practice, research and policy will be outlined and are sourced largely but not exclusively from the discussion within Chapter 6. The thesis closes by stating the study's original contribution to knowledge.

7.1 Prevalence

Within this study, the prevalence of leg ulceration in young people who inject drugs was found to be very high at 15%. This very high level of morbidity is notable and should be considered in planning services for PWID.

7.2 Risk factors

This study has shown empirically that leg ulceration is directly attributable to deep vein thrombosis with risk predominantly associated with leg injecting and groin injecting. This is new knowledge that services involved in preventing and reducing harm can utilise.

7.3 Harm reduction

The impact of leg ulceration on the lives of people who injected was substantial; pain, embarrassment, and reduced mobility were cited as particular problems. To date it seems that existing harm reduction is inadequate in relation to raising awareness about the sequelae of injecting below the waist in PWID.

7.4 Recommendations for practice

Education for PWID

It is clear that there is a lack of knowledge in relation to leg ulceration amongst PWID. Injectors need to be more aware of the risks of injecting below the waist, within the legs and the groin. Difficulties in accessing the femoral vein should not be regarded as standard but as a 'red flag' that the vein is damaged and that there will be consequences such as deep vein thrombosis, chronic venous insufficiency and ulceration. The presence of DVT should indicate to injectors that damage has occurred and that the likely sequela is post-thrombotic syndrome in up to half of all sufferers. Harm reduction services should consider providing education about the visible skin changes associated with venous disease and the wholly negative impact that the experience of living with a leg ulcer has on quality of life. Consideration should be given to the display of graphic images of venous insufficiency in the leg caused by injecting.

Education for service providers

Whilst the education and knowledge of service providers was not specifically explored as a research question in this study it is an important topic and worthy of further investigation.

A third of participants in Phase 1 reported a lack of appropriate leg ulcer assessment. There was an overall lack of knowledge about the aetiology of leg ulceration in injectors, which could or perhaps should, have been considered by healthcare providers and discussed with service users. The findings from this study should be disseminated amongst service providers to help address this gap in knowledge.

Consideration should be given to offering education to those working with PWID in any setting, including primary and secondary care encounters. Training should include raising awareness around groin injecting as this is often hidden, and may lead to venous insufficiency and ulceration. Health professionals need to be better informed about

deep vein thrombosis and post-thrombotic syndrome and the potential use of compression therapy to prevent progressive disease.

Service providers should consider improving injecting advice to prevent early transition to groin injecting.

7.5 Recommendations for research

Definitions

The literature describing injecting harm often mentions skin-related damage but generally the definitions used have been unclear or absent. A desirable outcome would be the adoption of a clearer reporting system for skin breakdown, with defining and differentiating of terms such as ‘soft tissue infection’ and ‘ulceration’. Future studies would benefit from clearly articulating the signs and symptoms of injecting injury and defining terms unambiguously.

Infections

In this study, identification of true infection would have been difficult without clinical assessment and unlikely to be accurate however, given the emphasis on soft tissue infection in the literature and the apparent difficulty with definition, this would be useful to explore in future.

It would be interesting to examine drug-related deaths and whether they relate to resistant organisms and, if so, if this is due to availability of ‘street’ antibiotics, or the failure to properly complete a course of antibiotics when appropriately prescribed, or the over-prescribing of antibiotics to PWID.

Many injectors had blood-borne viruses, and this was significantly linked to leg ulceration in Phase 1 but not explored in Phase 2. A useful study might investigate whether BBVs have an impact on skin breakdown and on healing.

Post-thrombotic syndrome

Further exploration of limb changes following DVT would be valuable, seeking to confirm or deny the presence of post-thrombotic syndrome.

It would also be useful to examine how and why a DVT forms so often in the thighs of PWID, and whether DVT in the thigh or the lower leg is most associated with leg ulceration, and whether ulceration occurs at the site of injection and if overlying the site of a DVT is of importance.

Harm reduction

The impact of harm reduction in relation to venous disease such as the use of images of the progressive disease of chronic venous insufficiency such as varicose veins, skin staining and ankle flare and the deterrent effect, if any, should be explored in a further study.

Similarly, research into the prevention of DVT in PWID through educational initiatives around injecting below the waist would be useful.

7.6 Recommendations for Policy

Local service delivery which is person-centred and responsive to changing patterns of drug use, such as tackling the increasing numbers of people groin injecting, forms part of the Recovery Strategy (Scottish Government, 2008). The Scottish Government recommends that treatment and rehabilitation services be available at local level and that should include appropriate provision of services for PWID with physical health needs and wounds, provided on a drop-in basis that are inclusive, welcoming, and non-judgmental, and this may reduce crisis attendance at hospitals.

Service providers need to have a better understanding of the situations that can lead to drug use. There could be better links between wound care / leg ulcer specialists and

addictions services in order to bridge gaps and focus on ensuring venous disease is detected early and treated appropriately.

The increase in femoral injecting and rising concerns around long-term damage require to be addressed more formally within health policy. Physical examination of the lower leg should be included within harm reduction interventions and form part of practice recommendations for services providing injecting equipment. Service provision should encompass safer injecting advice, assessment of venous and arterial damage below the waist and the provision of compression therapy following DVT.

Preventing drug use through school education

The Recovery strategy (Scottish Government, 2008) discusses approaches to preventing and tackling substance misuse amongst children and families. The education of children falls outwith the parameters of this research. Other experts within the field of health promotion and harm reduction may wish to consider the findings from this study and its relevance to localities where there is significant and early injecting occurring.

The study participants identified a need to tackle initiation into drug use early in life. Participants recommended that education regarding injecting of drugs should be delivered to primary school-age children before they are likely to come into contact with substance misuse. This intervention would be viewed by some as both controversial and very sensitive. Future educational initiatives might wish to consider the challenging participant views within this study and the issues involved in including information and discussion around physical harms caused by injecting within education programmes tackling substance misuse. Participants also felt that consideration might also be given to the use of images of injecting-related damage that may impact and be remembered.

7.7 Impact

This thesis focused on the exploration of leg ulceration in PWID and in so doing, tales of personal tragedy associated with drug use were uncovered. Stories such as the 14 year old girl who was given heroin by her mother as a reward for sitting an exam, and two years later was taught to inject by her mother; the 12 year old girl who was taught to inject by a babysitter as a reward for good behaviour; and the women who may have lost their homes, their children, and undertaken crimes that horrify them such as prostitution, assault, and theft, but who continue to be driven by their addiction.

Drug addiction can lead to desperate situations and there appears to be an inability within the civil system to offer real solutions. Frustration was repeatedly expressed by those on methadone - desperate to come off it, but held back by what they perceive as 'the system working against them'. Harm reduction services alone are not enough to improve the circumstances of drug users. Public health interventions must address social factors such as housing, imprisonment and low socio-economic status amongst drug users although these were areas not explored in this study.

The true impact of ulceration on lives was not immediately apparent. Failure to address wounds early can result in crisis admission to hospital. One participant described being hospitalised because of infected ulcers, and due to non-attendance then lost her methadone prescription, her tenancy and subsequently her children were taken into care. The knock-on impact of non-healing ulceration may be underestimated. Prevention, or appropriate, and early, assessment and treatment are essential.

7.8 Original contribution to knowledge

This thesis sought to ensure that the definition of skin problems is sound and reasoned and to set a precedent for others to follow and develop.

The original contribution to knowledge is three-fold:

1. Leg ulcers have been found to be highly prevalent in young people who inject drugs.
2. Ulceration is predominantly caused by venous thrombosis due to injecting in the legs or groin.
3. Harm reduction related to the development of venous disease has lacked impact and effect.

Untreated ulceration is likely to become chronic and recurrent, and will become a critical problem for the health-service in the future as the drug injectors of the 1980's and 1990's reach middle age. The impact of ulceration on people's lives should not be underestimated, as Participant 6 summed up:

'Aye it's torture the pain, when you see it you think how can there be so much pain coming off this wee thing. But it's murder and you keep going on and on about it wherever you are staying but you get that sick of talking about it because it drives you pure crazy. It affects your sleep, it affects your mood you are constantly thinking about it, you know it affects you walking, it affects you taking part in any sports and all that stuff, so it really grinds you down. It's on your mind constantly all the time.'

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Appendix 1 Glossary of terms and abbreviations

Abscess: pus-filled swelling

Abdine: An indigestion remedy used as an acid dissolver

ABPI: Ankle Brachial Pressure Index – a test undertaken using Doppler to assess arterial deficit within the legs

Ankle flare: dilatation of the arterioles around the ankle

BBV: Blood-borne virus

Benzos: slang for benzodiazepines the drug group includes diazepam and temazepam

Cannabis: marijuana ('dope', 'hash', 'joint', 'skunk')

Cellulitis: Infection of the soft tissue characterised by a spreading redness, with tenderness

Claudication: pain in the calf on walking due to ischaemia

Coke: cocaine

Cooker: container or receptacle used for heating drugs

Crack: also called freebase or rock

CVI: Chronic venous insufficiency

DVT: Deep vein thrombosis

Eggs: Temazepam in gel form capsules

Hit: injection

IEP: Injecting equipment provision

Induration: The hardening of a normally soft tissue or organ, especially the skin

Jellies: Temazepam usually in gel capsule format

Kit: heroin

Lipodermatosclerosis: a skin change of the lower legs usually appearing as a brown stain

Mainlining: injecting in a large vein such as the brachial

Methadone: Opiate substitute

Missed hit: injecting into subcutaneous tissues or extravascular space usually in error

Osteomyelitis: Infection of the bone

Pins: needles

PTS: post-thrombotic syndrome

PWID: people who inject drugs

Rattled: withdrawing characterised by sweating, shaking and malaise

Shooting galleries: areas where drug users will congregate to inject

Smack - heroin

Speedballing or snowballing the injection of mixed drugs commonly cocaine and heroin together but may include other drugs

Tenosynovitis: inflammatory injury to the sheath surrounding tendon

Thrombosis: clot

Tools: injecting equipment

Varicose veins: swollen and enlarged veins

Works: injecting equipment

(Source WHO, 2007)

Phase 1 Structured Interview using a Questionnaire

Research question: What is the extent of skin problems and chronic leg ulceration in young drug users?

(For researcher use only)

Preamble regarding research:

Explain who I am

Have you ever injected drugs? Yes / No – eligibility criteria Age 16 – 44?

Seek consent to proceed – sign two copies of consent form (one for file/ one for participant)

Ensure that participants have every opportunity to ask questions about the research prior to, during, and after, the data collection has occurred.

It will be explained to the participants that they are under absolutely no obligation to take part and that they may withdraw at any time, including after the data has been collected without any repercussions whatsoever to their script or services or benefits or care.

Explain that all information is confidential subject to legal requirements. All information will be anonymised and all written information will be kept locked away and not shared with anyone not involved in the research project.

Identify person / support following questionnaire completion.

Questions will be delivered in a friendly conversational way, seeking answers and won't appear as direct as noted here.)

A. First I am going to ask you some general questions about you

- 1. What are your initials?*
- 2. Note assumed gender M1 F2 Other3*
- 3. What is your date of birth?(translate to age for data entry) 4. age?*
- 5. Are you right or left handed (or ambidextrous)? 1R 2L 3Ambidextrous*
- 6. In which area are you living at the moment? Postcode if known? (first three letters eg G24)*
- 7. Have you ever lived in a) a hostel, b) been sleeping rough c) have no fixed abode d) been registered as homeless? Yes1 / No2*
- 8. Has this been in the last six months? Yes1 / No2*
- 9. Where are you living now? Own home (tenancy / rented / mortgage)1 / bed and breakfast2 / with friends or relatives3 / hostel 4/ sleeping rough 5 / no fixed abode6*

Appendix 2 Questionnaire Phase 1 p 3

5. *If no, who else injects you?* Dealer¹ / Friend² / Partner³ / Watching others⁴ / Other⁵
6. *When you inject do you always use a new and unused needle and syringe?*
For all injections¹ / for most injections² / half of the injections³ / some of the injections⁴ / never⁵
7. *What site do you normally usually use to inject?* Arm R L / Hands R L / Neck / Breast R L / Groin R L / Thigh R L / Lower leg R L / Foot R L / Buttock R / L (separate codes)
8. *What other sites have you used to inject?* Arm R L / Hands R L / Neck / Breast R L / Groin R L / Thigh R L / Lower leg R L / Foot R L / Buttock R / L (separate codes)
9. *Which site did you start injecting in first?* Arm R L / Hands R L / Neck / Breast R L / Groin R L / Thigh R L / Lower leg R L / Foot R L / Buttock R / L
10. *Which site have you injected in most often?* Arm R L / Hands R L / Neck / Breast R L / Groin R L / Thigh R L / Lower leg R L / Foot R L / Buttock R / L
11. *What kit do you normally use (circle)? insulin syringes? yes¹ no²*
12. *Pins? short brown (26g)¹ / oranges² / long oranges (25g)³ / blues⁴ / long blues (23g)⁵ / greens (21g)⁶*
13. *Barrels? 1ml ¹ / 2ml ² / 5ml ³ / 10ml ⁴ / 20ml ⁵*
14. *Other?*
15. *Do you wash your hands before you inject? Always ¹ / Most of the time² / Rarely³ / Never⁴ / Unsure⁵*
16. *Do you clean your skin before you inject? Always ¹ / Most of the time² / Rarely³ / Never⁴ / Unsure⁵*
17. *If Yes: What do you clean your skin with? Soap and Water¹ / water² / Alcohol swab³ / Saliva⁴ / Other⁵ (specify)*
18. *If alcohol swab do you let the alcohol dry before you inject? Always ¹ / Most of the time² / Rarely³ / Never⁴ / Unsure⁵*
19. *Do you use a filter? Always ¹ / Most of the time² / Rarely³ / Never⁴ / Unsure⁵*

Appendix 2 Questionnaire Phase 1 p 4

5. *If yes – what kind?* Cigarette filter¹ / rollup filter² /sterile filter from N Ex³ / home made (e.g. cotton wool) ⁴/ other⁵

6. *If yes – do you use a fresh filter each time you inject?* Always ¹/ Most of the time²/ Rarely³ / Never⁴ /Unsure⁵

7. *Do you inject in the same way each time?* Always ¹/ Most of the time²/ Rarely³ / Never⁴ /Unsure⁵

8. *If no – what differs?*

9. *and why?*

10. *Do you always find a vein?* Always ¹/ Most of the time²/ Rarely³ / Never⁴ /Unsure⁵

11. *Do you skin or muscle pop?* Always ¹/ Most of the time²/ Rarely³ / Never⁴ /Unsure⁵

12. *If yes, what sites do you use to pop?* Arm R L / Hands R L / Neck / Breast R L / Groin R L / Thigh R L / Lower leg R L / Foot R L / Buttock R / L

13. *Have you ever hit a nerve?* Yes / No *If so where and what happened*

14. *Have you ever hit an artery?* Yes / No *If so where and what happened*

15. *Do you ever lick your needle?* Always ¹/ Most of the time²/ Rarely³ / Never⁴ /Unsure⁵

- Go to Section E Q82 unless their practice was different in the past (then continue to F)*

- D For those who are no longer injecting / history of injecting more than 6 months ago:*

16. *What did you inject most often ?* Heroin¹ / Cocaine² / Speed³ / Crack⁴ / Benzodiazepines⁵ / body building drugs – steroids⁶ / HCG⁷ / other⁸
(specify).....

Appendix 2 Questionnaire Phase 1 p5

5. *Did you inject anything else?* Heroin¹ / Cocaine² / Speed³ / Crack⁴ / Benzodiazepines⁵ / body building drugs – steroids⁶ / HCG⁷ / other⁸
(specify).....
6. *What did you use to dissolve your heroin?* Lemon juice¹ / pharmaceutical (sterile) citric acid² / pharmaceutical (sterile) vitamin C³ / vinegar⁴ / other⁵
(specify).....
7. *What kind of water did you use to make up your drug solution?* Tap water¹ / bottled water² / sterile water³ / boiled water⁴ / other⁵ (specify).....
8. *When you injected, how frequently were you injecting on average?* less than every 2/3 days ¹ / every 2/3 days ² / once a day ³ / twice a day ⁴ / three times a day ⁵ / four times a day ⁶ / more than 4 times a day ⁷
9. *When you injected, how frequently were you injecting at most?*
less than every 2/3 days ¹ / every 2/3 days ² / once a day ³ / twice a day ⁴ / three times a day ⁵ / four times a day ⁶ / more than 4 times a day ⁷
10. *Who taught you to inject?* Dealer¹ / Friend² / Partner³ / Watching others⁴ / Other⁵
11. *Did you always inject yourself?* Yes¹ / No² / sometimes³
12. *If no who else injected you?* Dealer¹ / Friend² / Partner³ / Watching others⁴ / Other⁵
13. *When you injected did you always use a new and unused needle and syringe?*
For all injections¹ / for most injections² / half of the injections³ / some of the injections⁴ / never⁵
14. *What sites have you used to inject ever?* Arm R L / Hands R L / Neck / Breast R L / Groin R L / Thigh R L / Lower leg R L / Foot R L / Buttock R / L (separate codes)
15. *Which site did you start injecting in first?* Arm R L / Hands R L / Neck / Breast R L / Groin R L / Thigh R L / Lower leg R L / Foot R L / Buttock R / L
16. *Which site have you injected in most often?* Arm R L / Hands R L / Neck / Breast R L / Groin R L / Thigh R L / Lower leg R L / Foot R L / Buttock R / L
17. *What kit did you normally use? insulin syringes?* yes¹ no²
18. *Pins?* short brown (26g)¹ / oranges² / long oranges (25g)³ / blues⁴ / long blues (23g)⁵ / greens (21g)⁶

Appendix 2 Questionnaire Phase 1 p 6

5. *Barrels?* 1ml 1 / 2ml 2 / 5ml 3 / 10ml 4 / 20ml 5
6. *Other?*
7. *Did you wash your hands before you injected?* Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5
8. *Did you clean your skin before you injected?* Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5
9. *If Yes: What did you clean your skin with?* Soap and Water1/ water2 / Alcohol swab3 / Saliva4 / Other5 (specify)
10. *If alcohol swab did you let the alcohol dry before you inject?* Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5
11. *Did you use a filter?* Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5
12. *If yes – what kind?* Cigarette filter1 / rollup filter2 /sterile filter from N Ex3 / home made (e.g. cotton wool)4/ other5
13. *If yes – did you use a fresh filter each time you inject?* Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5
14. *Did you inject in the same way each time?* Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5
15. *If no – what differed?*
16. *and why?*
17. *Did you always find a vein?* Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5
18. *Did you skin or muscle pop?* Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5
19. *If yes, what sites did you use for popping?* Arm R L / Hands R L / Neck / Breast R L / Groin R L / Thigh R L / Lower leg R L / Foot R L / Buttock R / L (separate codes)
20. *Did you ever hit a nerve?* Yes1 / No2 *If so where and what happened?*
21. *Did you ever hit an artery?* Yes1 / No2 *If so where and when*
22. *Did you ever lick your needle?* Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5

Appendix 2 Questionnaire Phase 1 p 7

E I am now going to ask you some questions about your skin

5. *Have you ever had a problem with your skin since you started injecting (expand on what is meant by skin)?* Yes 1 / No 2
6. *Have you ever had a leg ulcer (a wound on the leg between the knee and the ankle that is present 4 weeks or more)* Yes1 / No 2 **if no to both go to Q108**

If yes, to skin problems what kind of problem? And how often do you get them? Tick all that apply.

7. *Lumps (not broken skin)* Several times a week1/ Weekly2 / monthly3 / less frequently4
8. *Track marks /scratches (heal within 2 weeks)* Several times a week1/ Weekly2 / monthly3 / less frequently4
9. *Abscesses* Several times a week1/ Weekly2 / monthly3 / less frequently4
10. *Acid Burns* Several times a week1/ Weekly2 / monthly3 / less frequently4
11. *Broken skin (heals within 4 weeks)* Several times a week1/ Weekly2 / monthly3 / less frequently4
12. *Chronic wounds (present over 4 weeks)* Several times a week1/ Weekly2 / monthly3 / less frequently4
13. *Rashes* Several times a week1/ Weekly2 / monthly3 / less frequently4
14. *Other skin problems* Several times a week1/ Weekly2 / monthly3 / less frequently4
15. *If so what kind.....*
16. *Did you inject at the wound site before it became a wound?* Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5 (which wounds?)
17. *Did any skin problem last 4 weeks or more?* Yes1 / No2
18. *Which?*
19. *Have you ever had a wound on your leg?* Yes1 / No2 **If no go to Q 108**

Appendix 2 Questionnaire Phase 1 p8

5. *If yes, did it heal up? Yes1 / No2*
6. *If yes, has it recurred / come back ever? Yes1 / No2*
7. *If yes, how often? Once1 / twice2 / three times 3/ four times 4 / more than 4 5*

8. *Did you inject at the leg wound site before it became a wound? Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5*

9. *Did you use the leg wound to inject into? Always 1/ Most of the time2/ Rarely3 / Never4 /Unsure5*

10. *If yes – when (dates) and where?*

11. *Have you ever had a Doppler test? Yes1 / No2*

12. *If yes when was that?.....*

13. *Have you had your legs treated with compression bandaging or compression socks? Yes1 / No2*

14. *When you had the wound on your leg, can you remember where you were living?
Own home (tenancy / rented / mortgage)1 / bed and breakfast2 / with friends or relatives3 / hostel 4/ sleeping rough 5 / no fixed abode6*

15. *What do you think caused the wound on your leg? (free text)*

F. I am now going to ask you some general questions about yourself and your health.

16. *Where do you go for advice if you have a skin problem? No-one1 / GP2 / A & E3 / Practice Nurse4 / Wound Clinic5 / Needle Exchange 6/ Drugs worker 7 / Other (specify) 8*

17. *Do you have any contact with health professionals such as practice nurses or GP? Yes1 / No2*

18. *If yes, are you able to talk to them about any health problem? Yes1 / No2*

Appendix 2 Questionnaire Phase 1 p9

5. *Have you ever smoked tobacco? Yes1 / No2*
6. *Do you still smoke? Yes1 / No2*
7. *How much a day? Light1 (less than 10 cigs/ 1/4oz tobacco) Medium 2 (10-20cigs, up to ½ oz) Heavy 3 (over 20 cigs, over1/2 oz)*
8. *Is this cigarettes1 / cigars2 / pipe3 / ounces tobacco4 / cannabis5 /crack6/ combination7?*
9. *In the past 6 months how often have you had a drink containing alcohol? Never1 / once a month or less2 / twice a month3 / once a week4 / 2 – 3 times a week5 / 4 – 5 times a week6 / 6- 7 times a week7*
10. *Have you ever been diagnosed with a BBV – such as HIV or Hepatitis? Yes1 / No2*
11. *Subjective assessment of current BMI (made by researcher)*
Underweight1 / normal 2/ overweight3 / obese4
12. *What is your normal eating pattern?*
3 meals a day1 / 2 meals a day 2/ 1 meal a day 3/ snacks all day4/ no fixed eating pattern5
13. *How often do you eat fruit? Several times a day1 / once a day2 / less than once a day3 / once a week 4/ less than once a week 5/ never6*
14. *Do you take any medicines prescribed or otherwise (apart from what you have already told me about)? Yes1 / No2*
15. *If so what?*
16. *Have you ever been diagnosed with heart problems? Yes1 / No2*
17. *diabetes? Yes1 / No2*
18. *joint / mobility problems or arthritis? Yes1 / No2*
19. *Do you get pain in your calf on walking (claudication) Yes1 / No2*
20. *Have you ever had a DVT or thrombosis or a leg clot Yes1 / No2*

Appendix 2 Questionnaire Phase 1 p10

5. Site L R arm
L R lower leg
L R upper leg (code as appear)
6. *Have you ever had varicose veins? Yes1 / No2*
7. *Is there a family history of varicose veins or leg ulcers? Yes1 / No2*
8. *Have you ever broken a leg? Yes1 / No2* L R lower leg
L R upper leg (femur)
9. *Have you ever had a red leg / cellulitis? Yes1 / No2* (L R lower leg ; L R upper leg)
10. *Have you ever had skin discolouration on your legs? (LDS or staining) Yes1 / No2*
11. *Have you ever had a hobby or a job or any other experiences that have involved you standing for long periods of time? Yes1 / No2* (specify)
12. *(For females)Have you ever had a baby? Yes1 / No2* If so how many 1 / 2/ 3/ 4/ 5/>5
13. *Finally :Why do you think some injectors get wounds on their legs and others don't?*
(free text)

If participant has had a leg ulcer, ask if willing to participate in phase 2. Complete preliminary consent form for phase 2, and provide phase 2 information sheet. Take contact details separately.

Thank you. That is all the questions I wanted to ask, is there anything you would like to ask me?

Give shopping voucher as acknowledgment of contribution

Thank you very much for taking part.

Appendix 3 Information sheet - health and social care services Phase 1

Health and Social Care Services in Glasgow

Individual Support for you:

NHS 24

24-hour health advice
08454 242424

Homelessness Persons Team

Social Work Department (24 hours)
Hamish Allan Centre
180 Centre Street
Glasgow G5 8EE
0141 287 1800 or Freephone 0800 838502

Physical Health Team for the Homeless and Homeless Addiction team (HAT)

55 Hunter Street
Glasgow G4 0UP
0141 553 2826 or 0141 553 2801

For Addictions (drop-in) at Hunter Street Health Centre

Monday – Friday 9- 5pm

Clinics (drop-in) for physical health with GP at Hunter Street Health Centre

Every day, 11 – 1230; and 2-330pm (Monday – Friday)

Glasgow Drug Crisis Centre, Nurses Clinic, West Street, Glasgow

Wednesdays (drop-in) 2 – 4pm

Salvation Army - Laurieston Centre, Nurses Clinic, 39 South Portland Street, Gorbals, Glasgow

Monday 130 – 230pm and Thursday 130 – 230pm

Lodging House Mission (Trotters), Nurses Clinic, 35 East Campbell Street, Glasgow

Fridays 12 – 2pm

Drug Crisis Centre

Glasgow Drugs Crisis Centre (GDCC)
123 West Street
Glasgow, G5 8BA
0141 420 6969
24 hour advice information and support
24 hour assessment
Detoxification and stabilisation
24 hour needle exchange

Sandyford Initiative (sexual health)

2-6 Sandyford Place Glasgow G3 7NB
0141 211 8130

Brownlee Centre (HIV and Hepatitis)

Gartnavel Hospital, 1053 Great Western Road,
Glasgow, G12 0YN
0141 211 1089

A nurse from the University of Stirling is investigating health problems of drug users and would like to talk to drug users using this pharmacy / needle exchange.

If you are aged 16 – 44 years and have been an injecting drug user or are still injecting, then please come along and answer some questions – this should take no more than 25 minutes of your time.

Interested? Contact me to arrange an appointment
Alison: 0759 169 5620
Or call in here. Alison will be here sometimes during October and November.

The research study is part of a postgraduate degree being undertaken by the researcher,

Alison Coull

at the University of Stirling.

Alison has been partly funded by a Smith and Nephew Foundation Doctoral Nursing Research Studentship, and a Department of Nursing and Midwifery Doctoral Research Studentship.

Stirling Campus:
Stirling
FK9 4LA
Tel: +44 (0) 1796 466340
Fax: +44 (0) 1796 466333

The University of Stirling is recognized as a Scottish Charity with number SC 011159

Research Study

Would you like to help us find out more about the health problems of people who inject drugs?

Appendix 4 Information leaflet Phase 1 p2

What is the research about?

The purpose of the study is to develop a greater understanding of skin problems in people who have injected drugs. The research is particularly interested in investigating long lasting skin problems or wounds on the legs of people aged between 16 and 44 years who have injected and how these might be prevented, perhaps by using harm reduction techniques.

What will happen to me if I take part?

You will be asked to read an information sheet, and sign a consent form to take part. If you have any questions before, during or after the study, the researcher will be happy to answer them.

The researcher will explain the purpose of the study and will then ask you a number of questions about your drug use and your health.

The researcher will write down your answers. This should take about 25 minutes and the questions will be asked in private.

What are the possible benefits of taking part?

Whilst there are no immediate benefits to you in taking part, it is hoped that this work will help nurses to understand more about skin problems caused by injecting and also identify ways to improve the treatment of drug users who have had skin problems.

Will my taking part in this project be kept confidential?

All information which is collected about you during the research study will be kept strictly confidential subject to legal requirements.

Any information about you will have your name removed so that you cannot be recognised from it.

Do I have to take part?

It is up to you to decide whether or not to take part. Refusal to take part will involve no penalty or loss of benefits and will not affect any of the services you currently get. If you decide to take part you are still free to withdraw at any time, without penalty or loss of benefits and services, and without giving

any reason.
**Interested? Contact me to arrange an appointment:
Alison 0759 1695 620 Or call in here.**

Research Study

Would you like to help us to find out more about the health problems of people who inject drugs?



- **A nurse from the University of Stirling is investigating health and skin problems, leg ulcers and wounds in drug users and would like to talk to drug users using this pharmacy / exchange.**
- **If you are aged 16 – 44 years and have been an injecting drug user or are still injecting, then please come along and answer some questions – this should take about 10 minutes of your time**
- **Any information you provide will be completely confidential**
- **Interested? Contact me to arrange an appointment Alison : 0759 169 5620 or Alison will be here sometime during October and November**



Information About the Research

An exploration of chronic leg ulceration in young injecting drug users.

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the project?

The purpose of the study is to develop a greater understanding of skin problems in people who have injected drugs. The research is particularly interested in investigating long lasting skin problems or wounds called ulcers, on the legs of people who have injected and how these might be prevented.

Why have I been chosen?

You have been asked to take part either because you have attended here for a methadone prescription or because you have come for needle exchange. We would like to talk to about 200 people in Glasgow who have been injectors.

Do I have to take part?

It is up to you to decide whether or not to take part. Refusal to take part will not affect any of the services, medical care or benefits you currently get. If you decide to take part you are still free to

Appendix 6 Patient information sheet Phase 1 p2

withdraw at any time, without any penalty or loss of benefits and services, and you do not have to give a reason.

What will happen to me if I take part?

You will be asked to read this information sheet, and sign a consent form to take part. If you have any questions before, during or after the study, the researcher will be happy to answer them.

The researcher will explain the purpose of the study and will then ask you a number of questions about your drug use and your health. The researcher will write down your answers. This should take around 25 minutes and the questions will be asked in private. You will be given this information sheet to keep and also a copy of your signed consent form.

What are the possible disadvantages and risks of taking part?

It is possible that the research questions may raise issues that you might find uncomfortable for whatever reason. At the start, the researcher will identify with you someone who will be able to offer you support should you wish to talk to someone about the issues raised during the questioning. Ideally this might be your own key worker or someone else will be found that you can talk to.

If at any time during the questions you wish to not proceed any further then you may withdraw without any repercussions to your services, benefits or treatment.

What are the possible benefits of taking part?

Whilst there are no immediate benefits to you in taking part, it is hoped that this work will help nurses to understand more about skin problems caused by injecting and also identify ways to improve the treatment of drug users who have had skin problems. The researcher may also be able to recommend services that can help you with either drugs problems or health problems.

Appendix 6 Patient information sheet Phase 1 p3

What if I have any comments or complaints?

If you have any comments or other questions about this research or wish to complain then you should contact the postgraduate tutor at the University of Stirling. Her name is Dr Ruth Jepson, and she may be contacted at the Department of Nursing and Midwifery, University of Stirling, Stirling FK9 4LA Telephone 01786 466402

Will my taking part in this project be kept confidential?

All information which is collected about you during the research study will be kept strictly confidential subject to legal requirements. Any information provided for the study will be confidential and anonymised and will not be passed onto a third party except where activities may be divulged that suggest serious harm to yourself or others such as child abuse. If you tell the researcher about something that may cause serious risk to yourself or someone else, then the researcher has a duty to pass that information onto the appropriate professional. Any information about you which is disseminated will have your name removed so that you cannot be recognised from it. Your consent form will be kept locked away till the study finishes in five years time. A copy of your completed questionnaire will be kept locked away for 10 years and only the researcher and her two supervisors will have access to it. The information you have provided will be destroyed in accordance with the Data Protection Act.

What will happen to the results of the research project?

The results will be written into a report as part of a postgraduate degree thesis. The information collected during the study might be used for additional or subsequent research. It is also hoped that the results will be published in professional journals and might be presented at conferences. You will not be identified in any report or publication about the study.

The study is not likely to finish before 2011, but after that time, if you wish to receive a copy of the results please contact the researcher.

Appendix 6 Patient information sheet Phase 1 p4

Who is organising and funding the research?

The research study is part of a postgraduate degree being undertaken by the researcher, Alison Coull. Alison has been partly funded by a Smith and Nephew Foundation Doctoral Nursing Research Studentship and the Department of Nursing and Midwifery at the University of Stirling.

Who has reviewed the project?

All research in the NHS is looked at by an independent group of people called a research ethics committee to protect your safety, rights, dignity and wellbeing. This study has been reviewed and given favourable opinion by the University of Stirling Departmental Research Ethics Committee and the NHS Glasgow West Research Ethics committee.

Contact for further information

Thank you for taking part in this research study. The information will be very useful and will help to develop a better understanding of skin problems in drug users.

If you have any questions about the study please contact:

Alison Coull	or	Andrew Watterson
Department of Nursing and Midwifery		Department of Nursing and Midwifery
University of Stirling		University of Stirling
Stirling FK9 4LA		Stirling FK9 4LA
Telephone 01786 466382		Telephone 01786 466283

Thank you very much for taking part!



CONSENT FORM FOR RESEARCH STUDY

Title: An Exploration of Chronic Leg Ulceration in Young Injecting Drug users

Name of Researcher: Alison Coull

Venue Initials of Participant

Venue	Initials of Participant	TICK ✓
I confirm that I have read and understand the information sheet dated 100608 (version 7) for the above study.		
I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
I understand that any information that I provide and will be stored in a locked drawer for the researcher's use only and will not be shared with anyone else. I understand that it will not be possible to identify me from the stored information.		
I understand that the information I provide will be kept confidential except where there is a legal requirement such as where there is a danger to myself or others.		
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care, benefits, services, drug agencies or legal rights being affected		
I agree to take part in the above research study.		

Initials of Participant Date Signature

Name of Researcher Date Signature

Complete 2 copies: 1 copy for participant; 1 copy for researcher file

Highland Campus:
Centre for Health Science
Old Perth Road
Inverness IV2 3JH
Tel: +44 (0) 1463 255655
Fax: +44 (0) 1463 255654

Stirling Campus:
Stirling
FK9 4LA
Tel: +44 (0) 1786 466340
Fax: +44 (0) 1786 466333

Western Isles Campus:
Western Isles Hospital
MacAulay Road
Stomoway Isle of Lewis HS1 2AF
Tel: +44 (0) 1851 708243
Fax: +44 (0) 1851 706070

The University of Stirling is recognised as a Scottish Charity with number SC 011159

Phase 2 semi-structured interview schedule

(Intro: For researcher use only)

Preamble regarding research:

Explain who I am

Check eligibility Have you ever injected drugs? Yes / No – Age 16 – 44 Have / had leg ulcer?

Seek consent to proceed – sign two copies of consent form (one for file/ one for participant) Seek consent to use digital recorder.

Ensure that participants have every opportunity to ask questions about the research prior to, during, and after, the data collection has occurred.

Explain to the participants that they are under absolutely no obligation to take part and that they may withdraw at any time, including after the data has been collected without any repercussions whatsoever to their script or services or benefits or care.

Explain that all information is confidential subject to legal requirements. All information will be anonymised and all information will be kept locked away or in password protected files and not shared with anyone not involved in the research project.

Identify person / support following questionnaire completion.

Questions will be delivered in a friendly conversational way, seeking answers and won't appear as direct as noted here.)

A First I would like to ask you some general questions about you

1. What are your initials?
2. Note assumed gender M1 F2 Other3
3. What is your date of birth? (translate to age for data entry) 4. age?
5. In which area are you living at the moment? Postcode if known? (first three letters eg G24)

B I am now going to talk with you about drugs and injecting and how your legs have been –(broad topics to cover)

Explore age when started injecting and initial access to services such as needle exchange – injecting habits initially?

Years injecting?

Are you still injecting?

If no – when was the last time you injected?

Appendix 8 Semi-structured interview schedule phase 2 p2

How long have you had / did you have a wound on your leg?

Ask about when ulcers appeared , where, and how often and what aspects of drug use they might have related to

(ensure matches with LU definition) Ask about healing / recurrence.

What do you think caused it?

Discuss medical history related to the ulcer such as DVT, varicose veins, cellulitis, abscesses, timing of signs and events

What has it been like, having the leg ulcer? How does it affect you?

Did you seek help for it?

Talk through typical injecting episode – explore risks / potential links to ulceration

Ask about injecting sites, hygiene, who injects you – why do some groin inject and others don't?

Explore healthcare delivery - Treatment of the leg ulcer – venues / professionals/ assessment / Doppler

What do you think might have prevented you from getting a leg ulcer?

Explore what health professionals role was and could be

Effective harm reduction – what would work for them?

To finish with:

What do you think would discourage people from injecting in legs / groin etc? /

doing whatever you think caused the ulcer?

Anything else you would like to comment on in relation to your leg ulcer?

(Thank participant – offer gratuity)

Research Study

Would you like to help us to find out more about the health problems of people who inject drugs?



- A nurse from the University of Stirling is investigating health and skin problems, leg ulcers and wounds in drug users and would like to talk to drug users using this clinic who have had an abscess, wound or ulcer on their leg.
- A nurse will be at this clinic on (dates) and may approach you and ask if you are willing to answer some questions.
- Any information you provide will be completely confidential.
- Interested? Would you like to take part? Contact me to arrange an appointment
Alison : 0759 169 5620



Information About the Research

An exploration of chronic leg ulceration in young injecting drug users.

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the project?

The purpose of the study is to develop a greater understanding of skin problems in people who have injected drugs. The research is particularly interested in investigating long lasting skin problems or wounds called ulcers, on the legs of people who have injected and how these might be prevented.

Why have I been chosen?

You have been asked to take part either because you have attended here for your leg to be treated or have had a wound on your leg in the past. We would like to talk to about 12 people in Glasgow who have been injectors and have had problems with their legs.

Do I have to take part?

It is up to you to decide whether or not to take part. Refusal to take part will not affect any of the services, medical care or benefits you currently get. If you decide to take part you are still free to withdraw at any time, without any penalty or loss of benefits and services, and you do not have to give a reason.

Appendix 10 Patient information sheet Phase 2 p2

What will happen to me if I take part?

You will be asked to read this information sheet, and sign a consent form to take part. If you have any questions before, during or after the study, the researcher will be happy to answer them.

The researcher will explain the purpose of the study and will then ask you a number of questions about your drug use and your health, and in particular about your legs. The researcher will record your answers on a digital tape recorder. This should take around one hour and the questions will be asked in private. You will be given this information sheet to keep and also a copy of your signed consent form.

What are the possible disadvantages and risks of taking part?

It is possible that the research questions may raise issues that you might find uncomfortable for whatever reason. The researcher will identify with you someone who will be able to offer you support should you wish to talk to someone about the issues raised during the questioning. Ideally this might be your own key worker or someone else will be found that you can talk to.

If at any time during the questions you wish to not proceed any further then you may withdraw without any repercussions to your services, benefits or treatment.

What are the possible benefits of taking part?

Whilst there are no immediate benefits to you in taking part, it is hoped that this work will help us to understand more about skin problems caused by injecting and also identify ways to improve the treatment of drug users who have had skin and leg problems. The researcher may also be able to recommend services that can help you with either drugs problems or health problems.

Appendix 10 Patient information sheet Phase 2 p3

What if I have any comments or complaints?

If you have any comments or other questions about this research or wish to complain then you should contact the Postgraduate Advisor at the University of Stirling. Her name is Dr Josie Evans, and she may be contacted at the Department of Nursing and Midwifery, University of Stirling, Stirling FK9 4LA Telephone 01786 466352.

Will my taking part in this project be kept confidential?

All information which is collected about you during the research study will be kept strictly confidential subject to legal requirements. Any information provided for the study will be confidential and anonymised and will not be passed onto a third party except where activities may be divulged that suggest serious harm to yourself or others such as child protection. If you tell the researcher about something that may cause serious risk to yourself or someone else, then the researcher has a duty to pass that information onto the appropriate professional. Any information about you which is disseminated will have your name removed so that you cannot be recognised from it. Your consent form will be kept locked away till the study finishes in three years time, and then it will be destroyed. A copy of the tape recording will be stored in a password protected file for 10 years and only the researcher and her supervisors will have access to it. The information you have provided will be destroyed in accordance with the Data Protection Act.

What will happen to the results of the research project?

The results will be written into a report as part of a postgraduate degree thesis. The information collected during the study might be used for additional or subsequent research. It is also hoped that the results will be published in professional journals and might be presented at conferences. You will not be identified in any report or publication about the study. The study is not likely to finish before 2011, but after that time, if you wish to receive a copy of the results please contact the researcher.

Appendix 10 Patient information sheet Phase 2 p4

Who is organising and funding the research?

The research study is part of a postgraduate degree being undertaken by the researcher, Alison Coull. Alison has been partly funded by a Smith and Nephew Foundation Doctoral Nursing Research Studentship and the Department of Nursing and Midwifery at the University of Stirling.

Who has reviewed the project?

All research in the NHS is looked at by an independent group of people called a research ethics committee to protect your safety, rights, dignity and wellbeing. This study has been reviewed and given favourable opinion by the University of Stirling Departmental Research Ethics Committee and the West of Scotland NHS Research Ethics 3 committee in Glasgow.

Contact for further information

We hope the information will be very useful and will help to develop a better understanding of leg ulcers in drug users.

If you have any questions about the study please contact:

Alison Coull	or	Andrew Watterson
Department of Nursing and Midwifery		Department of Nursing and Midwifery
University of Stirling		University of Stirling
Stirling FK9 4LA		Stirling FK9 4LA
Telephone 01786 466382		Telephone 01786 466283

Thank you very much for taking part!

Appendix 11 Consent form Phase 2



UNIVERSITY OF STIRLING

DEPARTMENT OF NURSING AND MIDWIFERY

CONSENT FORM FOR RESEARCH STUDY

Title: An Exploration of Chronic Leg Ulceration in Young Injecting Drug users (Phase 2)

Name of Researcher: Alison Coull

Initials of Participant

TICK ✓

I confirm that I have read and understand the information sheet dated 170910 (version 2) for the above study.	
I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I agree that the interview will be digitally recorded and that I will not be named on the recording.	
I understand that any information that I provide and will be stored in a locked drawer, or electronically in password protected files for the researcher's use only and will not be shared with anyone else other than those personnel authorised for audit purposes. I understand that it will not be possible to identify me from the stored information.	
I understand that the information I provide will be kept confidential except where there is a legal requirement such as when there is a danger to myself or others.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care, benefits, services, drug agencies or legal rights being affected	
I agree to take part in the above research study.	

Initials of Participant Date Signature

Name of Researcher Date Signature

Complete 2 copies: 1 copy for participant; 1 copy for researcher file

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