

Development, implementation and evaluation of harm reduction techniques for drug users.

SCOTT, J.

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Development, Implementation and Evaluation of Harm Reduction Techniques for Drug Users.

A thesis submitted in partial fulfilment of the requirements of
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In collaboration with
Drugs Action, Aberdeen.

**To my parents, Evaline and Ronnie Scott for their unconditional love
and the late Jean Morison for her continued inspiration.**

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Jenny Scott, May 2000

Abstract

Recent strategies within health and social care state policies and interventions should be selected on the basis of evidence available to demonstrate their benefits. The provision of services for drug users is no exception to this. Harm reduction is a broad term used to describe drug policies and interventions that aim to reduce the risks to the individual and society, recognising that drug use is an inevitable part of society. Arguably, attention has largely focused on establishing the evidence of the benefits of harm reduction interventions that affect society, with little attention paid to those that are for the benefit of the individual alone. The work presented here explores two aspects of harm reduction interventions, using a combination of pharmaceutical science and social science. The first is a laboratory-based study that gathered evidence to establish the role of filters and acidifiers in the injection preparation processes. No previous work had been done in this field, yet anecdotal evidence shows that such materials are being provided by some UK drugs services. The illegal nature of drug use means that the results from this work cannot be taken as absolutes. Instead, they are indicators of the consequence that will result from using such paraphernalia. The results suggest that providing syringe filters to injecting drug users could reduce the incidence of health problems caused by the injection of insoluble materials, because the filters were found to greatly reduce the content of insoluble particles in injections prepared with street drugs and tablets, simulating techniques established from information collected from injecting drug users, drugs workers and published materials. Makeshift filters were also tested. These were cigarette filters, hand rolling cigarette filters and cotton bud tips. They caused some reduction in particle content, to a lesser extent than that seen with the syringe filters. There is concern regarding their use due to them not being designed for this purpose and the potential risk of fibre shedding from their fibrous materials. The work also illustrated the need for acidifiers to promote the solubility of street heroin obtained in the base form. However, this also raises questions around their use and safety, indicating the pathway of future work.

The second aspect of this work was a case study to explore the provision of a pharmacist-led information and advice service at a voluntary sector drugs agency. This work was done because much emphasis is placed on the importance of multidisciplinary teamwork within drugs services. However, the benefit of including an expert on drugs, namely the pharmacist, has been previously overlooked. This work was undertaken as a field study, monitoring and evaluating the role of a pharmacist within a voluntary sector drugs service. The environment in which the work was conducted and the combination of

factors and people involved will have influenced the work of the pharmacist and the findings. Therefore the results can be interpreted to show that it is possible to implement such a service and future study should expand on such service provision to investigate this matter further in a multi-centred study. Further work should also pay more attention to establishing the benefits or otherwise of such services to the team and clients. Overall, this work has provided foundation evidence to support the provision of certain harm reduction interventions that have previously been unexplored. It also illustrates how the knowledge and skills of pharmacists can be used to conduct unique research in this field.

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Chapter One

Introduction

1.1 Why do people use psychoactive drugs despite the risks of harm?

Beginning a thesis with a question that requires an answer outwith the remit of the work is not usually considered prudent. However, the purpose of posing this question is not to generate an all-encompassing answer through detailed analysis of human behaviour. Instead, it serves as a prompt to allow a summary to be given of the rationale behind the use of harm reduction interventions in response to drug (mis)use, a concept that at first glance may seem irrational. After all, if drug use has the potential to cause harm, why do people choose to do it? Why do those who experience harm not always stop doing it? It is only once these issues have been addressed that it can be understood why harm reduction practices and consequently harm reduction research, are necessary.

1.1.1 The benefits of using psychoactive drugs

As a crude summary, people who use psychoactive drugs (PDs) do so because they expect to benefit. The expected or perceived benefits may include the attainment of pleasurable feelings (i.e. fun), increased social interaction (i.e. reduced inhibitions), alteration of the person's psychological condition to a more desirable state (i.e. escapism) or avoidance of withdrawal symptoms (Gossop, 1993). Benefits from some PD use extend into the community and society at large. For example, the opening of a distillery brings the benefits of new jobs and revenue from the sale of the alcoholic products produced.

1.1.2 The harm from using psychoactive drugs

The harms from PDs are not equivalent. Their incidence and nature vary with the drug and individual concerned and their circumstances. Examples of such variables include the drug substance, presence of impurities, the dose, the frequency of use, the route of

administration, the legal status of the drug, related social and financial circumstances, the personality of the individual drug user and its interaction between their drug use and lifestyle. Some harm associated with PD use can occur at any point, whereas some tends to increase with the extent of use. Harms from some PD use also extend into communities and society, for example, the financial and social costs to the community of drug related crime and the cost to society of criminal justice proceedings (Gossop, *ibid.*). Such harms are often associated with dependent drug use, which is described in section 1.1.5.

1.1.3 The balance of benefits vs. harms

If the benefits from PD use are experienced before the harm, or to a greater extent than the harm, positive endorsement of drug taking occurs (Tober, 1989). If the person perceives the benefits to outweigh the harms or risk of harms, use of the drug may continue. The level of control the person has over their drug use will be a consequence of the interaction between the drug, the individual and their circumstances. The level of control will influence the balance between the benefits and harms. For example, with controlled use harms can be prevented or contained. In uncontrolled use, harms can escalate (Zinberg, 1984). Uncontrolled use is a characteristic of dependence on PDs.

1.1.4 Examples of harm

The complex nature of drug use means that many varied harms can result, relating, for example, to health, welfare and social well-being. Not all drug users are at the same risk, so do not require the same interventions. It is impossible and unnecessary to list all potential risks. This work relates to health related risks, so a few examples of this nature will now be given.

1.1.4.1 Harm experienced by the individual

General health may deteriorate in dependent people if lifestyle factors such as diet and self-care are poor. Drug users who inject are at risk of HIV, hepatitis B and C and other blood borne infections if they share injecting equipment. Injecting can also result in damage to tissue and the circulatory system. This is largely due to the unintentional injection of solid materials and bacteria and frequent vascular access. Some people may

sell sex to gain money for drugs or in exchange for drugs, which can result in physical and psychological damage. Dependency and the behaviours it may drive can cause psychological distress.

1.1.4.2 Harm experienced by communities and society

Drug related crime impacts on communities by causing economic harm and compromises community safety. The families and friends of drug users may experience psychological distress. Society suffers economic harm from the expense caused by drug related crime (e.g. police and criminal justice costs and raised insurance premiums). Dependence on illegal drugs (e.g. heroin) tends to cause greater harm at community and societal level than dependence on legal drugs (e.g. alcohol and nicotine). At this level, legal drugs tend to be perceived to produce greater benefits, such as revenue from sales and employment in production.

1.1.4.3 The prevalence of drug use in the UK

Drug taking is a difficult activity to quantify. By nature, it is not a static activity, so the numbers of people using drugs will vary. Additionally, not all drug use causes problems, either for the individual or society, so figures that describe factors such as the number of young people who have ever taken an illegal drug in a particular survey do not equate with the number of people experiencing drug related harm. Additionally not all drug users who are experiencing harm necessarily also harm their communities, or conversely some may harm their communities but experience little harm themselves. However, statistics collected over several years suggest that drug use, and within this, problem drug use, is increasing within Scotland and elsewhere in the UK. In the literature review for the second part of this thesis, further information and illustration is given to show the extent of known problem drug use in the UK (7.2.1).

1.1.5 Drug dependence

Drug dependence is defined by the World Health Organisation (WHO) as:

'a cluster of psychological, behavioural and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or drugs) takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug seeking behavior'.

(WHO, 1993)

Although the creation of a dependent state will be influenced by the pharmacology, dose, and frequency of use of the PD(s) concerned, factors related to the person and their environment have also been shown to influence the level of control an individual has over his or her drug use (Zinberg, 1984). This was demonstrated to apply even to drugs considered to be highly physically addictive such as opiates. Dependency is however, often associated with opiate use. Factors that motivate drug use in dependent individuals include the avoidance of physiological and/or psychological withdrawal effects. Dependence on a drug prevents the individual who is unable or unwilling to endure the withdrawal effects, from stopping their drug use and hence avoiding drug related harm.

1.1.6 The stages of change in dependent behaviour.

It is recognised that there are six stages involved in changing dependent behaviour. It is important to be aware of these stages as they show how harm reduction interventions are more realistic than only enforcing all drug users to become abstinent. These stages were first characterised by Prochaska and DiClemente (1983) in their cycle of change model in relation to nicotine dependence. This model was later modified and shown to apply to dependence on other psychoactive drugs (Prochaska et al, 1992). The model is illustrated in appendix 1. The stages can be briefly described as follows:

The pre-contemplation stage: People at this stage perceive the benefits from their drug use to outweigh any harm. They may experience harm but often remote from their drug use, so it has lesser immediate importance. It may be that others see the person's drug use as problematic but they themselves do not. People at the pre-contemplation stage are not motivated to stop using drugs.

The contemplation stage: People at this stage are experiencing increased harm and/or a reduced level of benefit from their drug use. The harm will be recognised and may be considered to outweigh some of the benefits. The individual has begun to feel motivated to change but not made a commitment to do so. If the person is dependent on drug(s), they may be unable to stop or change, at least immediately.

The preparation stage: People at this stage have begun to make small changes and are motivated to make big changes very soon.

The action stage: People at this stage are making behavioural changes that require a considerable amount of effort. They are motivated to change their drug use and lifestyles, so as to reduce or eliminate the harm experienced. They are prepared to experience immediate discomfort in the anticipation of long term gain. People at this stage need to replace the benefits gained from drugs with benefits from other sources.

The maintenance stage: People at this stage are maintaining the changes made in their drug use, usually by gaining continued benefit from their drug-free or altered drug use pattern. The maintenance stage may involve considerable effort in order to avoid relapse. In order to sustain this stage the harm, although no longer experienced, must still be considered to outweigh the benefits of reverting back to using drugs, i.e. the person must consolidate their gains from their changed behaviour.

Relapse: This stage was not included in the model proposed by Prochaska et al (1992), although its significance was implied. Relapse occurs when the person is unable to maintain the changes they have made and revert to gaining benefits from drug use.

The length of time at each stage in the model will vary with the individual and their previous experience of attempting to change. People can move from any one stage to another, change does not necessarily always occur in the order used above. Prochaska et al (*ibid*) showed that in a cohort group the number of successes (i.e. sustained change) increased with time and the more action stages experienced by the individual the better the prognosis. At all stages when the person is participating in drug taking there may be a risk of harm to themselves and their communities. However, only people at the action stage are likely to benefit from interventions that are abstinence orientated. Therefore since the risk of harm occurs at many stages when motivation and ability to stop using drugs is low, a pragmatic solution is to reduce the risk and level of harm experienced by the individual and others as far as possible.

1.2 Harm reduction

1.2.1 Philosophy and practice

Harm reduction (HR) is an umbrella term used to describe a range of actions that reduce the risks from harmful activity, whilst participation continues, often because the individual is dependent on the activity. The aim of HR is to achieve harm minimisation, that is, the lowest level of risk of harm from the given activity (Strang, 1993). More specifically, HR has come to be associated with the philosophy and practices of certain services for PD users. Such services make interventions and deliver care appropriate to the stage in the process of change that the individual is at, rather than enforcing change that the individual has no motivation to maintain. Prochaska et al (1992) reported that the vast majority of dependent people are at the pre-contemplation stage of change and argued that treatment services should reflect this need, instead of only being focused on the action stage. HR interventions aim to work with the individual to achieve small realistic goals to reduce the risks faced by both themselves and their communities from their drug use. Such goals are arranged hierarchically. The individual is supported to achieve the level realistic for them at the present time. If further goals become realistically possible i.e. through motivational change, they are supported to achieve them. If and when they move through the process of change, the interventions are adapted to meet the needs of the individual.

HR interventions are aimed at those who are already using drugs. It is important that they are targeted at these individuals, with their intention made explicit, both to the user, their families and society in general. This is paramount to avoid the interventions being seen as condoning drug use.

HR can involve a range of professionals from different disciplines, e.g. doctors, drugs workers, nurses, pharmacists, psychologists and social workers. This diversity of professions contributes to the difficulties evident from the literature in defining the term harm reduction (Erickson, 1995, Single, 1995, Wodak and Saunders, 1995). To date, no one definition appears to be acceptable to all. HR will mean different things to different people because their professional background will influence their interpretation. Also, the emphasis they place on their own contribution will differ from that placed by others. For example, in a paper in the *Journal of the American Medical Association*, Cotton (1994) describes medicine as '*the cornerstone of...harm reduction*'. The author goes on to argue a tangible case for HR policy based on the belief that drug (ab)use is a 'biological phenomenon' and likens it to disease states such as diabetes. In her analysis of a case

study of a young female drug user, the psychologist, Gillian Tober (1989) presents a different view. Tober describes the prescribing of substitute drugs as an important intervention, but defines drug taking as a learned behaviour, with positive and negative reinforcements being the factors influencing motivation to change. Both authors support using harm reduction interventions to achieve the same result [in this case giving methadone to reduce the need for heroin injection]. However, they have fundamental differences in opinion as to what has caused the person to take drugs. The desired outcome from harm reduction interventions is a reduced level of harm experienced by the individual and in many cases, their community and society at large.

1.2.2 Development of harm reduction within the UK public health care system.

1.2.2.1 The first harm reduction policy

The philosophy of harm reduction is intrinsically linked with human behaviour as the reduction of harm is an act of self-preservation. However, its incorporation into public health care policy and practice is a relatively recent development. Although Berridge (1993) reports anecdotal evidence of opium maintenance doses being used to stabilise dependent people in the 19th century, the first recommendation that any harm reduction intervention should be policy, was made in 1926 by the Rolleston Committee (Tyler, 1995). The Dangerous Drugs Act (1920) had given control of the distribution of many psychoactive drugs to doctors and pharmacists, making people who were dependent on such drugs criminalized by obtaining them (Stimson and Oppenheimer, 1982). The medical-based Committee were asked to review the need for substitute prescribing to these dependent individuals. The committee concluded that prescribing the smallest amount of drug needed to prevent withdrawal effects may be justified when everything possible had been tried to make the person drug-free and failed (Berridge, 1993, Stimson and Oppenheimer, 1982). The Rolleston Committee recommendations were made regarding persons who had largely become dependent on drugs prior to the implementation of legislative controls. However, legislative controls failed to prevent some people from beginning to use PDs, so a small number of people continued to require treatment. Thus, physicians in private practice undertook harm reduction in the form of substitute prescribing for approximately the next forty years (Berridge, 1993, Stimson and Oppenheimer, 1982, Tyler, 1995).

1.2.2.2 The NHS and legislative consolidation

In 1948 the National Health Service (NHS) was established to provide health care for all. However, the NHS did not provide substitute prescribing or other harm reduction interventions. The needs of the small numbers of PD users appeared to be catered for by private practitioners (Derricott et al, 1999). However, the 1950s and '60s saw an increase in the number of people using illegal PDs whilst the use of the injectable route increased, with many of these new users from the working classes (Derricott et al, *ibid*, Stimson and Choopanya, 1998, Stimson and Oppenheimer, 1982). When a hepatitis B outbreak occurred amongst injectors, the NHS found itself having to provide care (Derricott et al, *ibid*). Rolleston had been concerned with, in the main, a small number of middle class medical professionals who had become dependent on opiates. Growing numbers of drug users meant the Rolleston method of private practitioner managed maintenance therapy was not thought to be meeting all needs or achieving politically desirable outcomes (Stimson and Oppenheimer, 1982). It was considered that the NHS needed to provide treatment, so specialist clinics were set up attached to hospital psychiatric departments (Stimson and Oppenheimer, *ibid*). Their remit was to provide programmes that focused only on abstinence rather than the reduction of harm in achievable stages. However, there are anecdotal reports of unofficial harm reduction interventions being made by some clinic workers, at least in London (Strang, 1993). Erickson (1995) notes that recommendation of the harm reduction approach was made in the literature in the 1970s and early 1980s. Morally, there was objection to harm reduction, so the focus of treatment remained abstinence and legislative control was tightened. The various pieces of legislation that had been introduced since the Dangerous Drugs Act (1920) were consolidated in the Misuse of Drugs Act (1971). This act forms the current legislation in place today. The act also established the Advisory Council on the Misuse of Drugs (ACMD), with a remit to inform the government on drugs liable to misuse and advise on policy (Tyler, 1995).

1.2.2.3 The move towards community based care

In 1982, the ACMD recommended an end to the psychiatric approach to managing drug users and advocated the provision of care in the community setting by a multidisciplinary team (Advisory Council on the Misuse of Drugs, 1982). Regions began a revision of their drugs services. Although there was increasing discontent amongst some in public health towards the abstinence focused approach, resistance to policy change was great. This was despite the literature support for alternatives (Erickson, 1995). Harm reduction was

seen as contradictory to the strong moral stance that was being taken in the fight against drug use (Erickson, *ibid*, Tyler, 1995). The abstinence only approach remained the focus of community care services. Those who were at stages other than action in their drug use were not provided with interventions to protect their health (Tyler, 1995). For example, between 1982 and 1986 the council of the Royal Pharmaceutical Society instructed members not to sell sterile injecting equipment to injecting drug users (IDUs) (Anon, 1986).

1.2.2.4 The impact of HIV

The identification of the human immunodeficiency virus (HIV) in 1983 and recognition of unprotected sexual intercourse and the sharing of injecting equipment as vectors for transmission was the catalyst that promoted a rapid change in drug policy (Carbello and Rezza, 1990, Stimson, 1995). It was realised that IDUs who may be at risk of HIV through sharing injecting equipment could be having unprotected sex with non-injectors (Stimson, *ibid*). Consequently, IDUs began to be seen as part of society and not as an isolated population from which non-drug users could be separated, as the threat of an acquired immunodeficiency syndrome (AIDS) epidemic brought the realisation that efforts aimed only at achieving abstinence would not adequately respond to the very real and immediate dangers faced by almost every country in the world (Berridge, 1993). HIV projection figures suggested that if the high incidence of sharing seen in Edinburgh¹ was replicated elsewhere, within ten years 50% of IDUs would be infected with HIV (Stimson, 1995). The concept of harm reduction began to gain popularity on a wider scale (Berridge, 1993). In 1986, some areas of the UK introduced needle exchange (NX) schemes into their newly established community-based services. Some voluntary sector drugs agencies had also begun an exchange service (Stimson, 1995). The aim was to reduce HIV transmission by removing the need for sharing. In 1987 the Department of Health and Social Security commissioned a pilot study and then a national evaluation into the effectiveness of the schemes. The report showed the schemes were utilised by large numbers of injectors, some of which had no contact with other health care services (Stimson et al, 1988).

In 1988, the ACMD issued part one of its report '*AIDS and Drug Misuse*'. The overview on page 1 stated that '*HIV is a greater threat to public and individual health than drug misuse*' (Advisory Council on the Misuse of Drugs, 1988). It supported the principle of minimising the risks from drug use, acknowledging that drug use may continue in some people, even those who come in contact with services. It outlined the hierarchy of goals

that agencies should work towards, acknowledging the need to tailor services to the individual. It also recommended an increase in availability of clean injecting equipment from exchanges and community pharmacy sales. Part two of the report endorsed support for community care and made recommendations for drugs services (Advisory Council on the Misuse of Drugs, 1989). These included adaptability to meet differing needs, the provision of medical and welfare rights support and the explicit provision of safer injecting advice. It also recommended that services should attempt to attract more clients and endorsed the use of outreach. The reports also endorsed the need for effective prevention strategies. The ACMD reports echoed the findings of the Scottish Committee on HIV Infection and Intravenous Drug Misuse, reported in *'HIV Infection in Scotland'* (Scottish Home and Health Department, 1986).

1.2.2.5 The expansion of harm reduction within health and social care.

In the 1990s, harm reduction strategies continued to develop, both in the statutory and voluntary sectors. The publication by HMSO in 1991 of the 2nd edition of *'Drug Misuse and Dependence: Guidelines on Clinical Management'*, endorsed a hierarchical approach to setting goals in substitute prescribing. NX schemes and access to substitute therapies grew within the community setting, including greater involvement of community pharmacists (Roberts and Bryson, 1999). It became apparent from HIV prevalence monitoring in the 1990s that the level predicted in the mid 1980s was not reached. This was attributed to the rapid response to HIV within the UK (Stimson, 1995).

Endorsement of the harm reduction approach was given by independent reviews into drug services in Scotland (Scottish Drugs Task Force, 1995) and England (Polkinghorne, 1996). Performance indicators in Scotland have been set on the basis of these reports (The Scottish Office, 1997) and are shortly to be introduced in England, following the publication of the governments 10 year strategy, *'Tackling Drugs to Build a Better Britain'* (UK Government, 1999). The Scottish strategy *'Tackling Drugs in Scotland: Action in Partnership'* outlines the current Scottish strategy, with an emphasis on joint commissioning and working (The Scottish Office, 1999). These strategies acknowledge the impact harm reduction has made over the past 15 years in preventing HIV and other drug-related infections. In Jersey, the philosophy of harm reduction underpins the current drugs strategy (President's Policy Group, 1999).

Modern drugs services may provide a range of interventions (Derricott et al, 1999). For example, in addition to NX, advice may be given on drugs and their effects, safer sex,

¹ At this time, between 60 and 80% of IDUs in Edinburgh were thought to share injecting equipment (Robertson, 1990).

safer injecting, viral protection, treatment options and welfare rights. One-to-one and group support for drug users and their families may be provided and training for other professionals undertaken. A variety of methods of delivery may be used to encourage contact with services and help them meet needs. For example, outreach and detached work, protected time for women only, joint working with other services and peer education. The recent formation of user activist groups indicates a willingness of some drug users to be identified and have their views represented.

Changes in drug policy and practice have been discussed with respect to harm reduction. There are other components to drug policies and practice that are also important, but not part of this work. These include prevention strategies that are aimed at people who do not use drugs, in order to prevent them from becoming drug users and detoxification programmes to assist people in becoming drug-free. Also, law enforcement strategies which are aimed at both drug users and non users and welfare strategies which are aimed at factors associated with drug use such as poverty, social exclusion, inequalities in health, education, unemployment and social care. A combination of all these are important in providing a comprehensive drugs strategy. The focus of this work is harm reduction strategies with the aim of protecting and promoting the health of people who use drugs.

1.2.3 The future for harm reduction

1.2.3.1 Evidence based practice

To improve the quality of care and management of resources, the current UK health care system is moving towards one of evidence-based practice (Sackett et al, 1996). Interventions and treatments require evaluation to establish if there is justification for their provision, in terms of clinical benefit and cost. The recently published 3rd edition of *'Drug Misuse and Dependence: Guidelines on Clinical Management'* (Department of Health, 1999) endorses the need for evidence based treatments for drug users. This view is also held by the WHO (1999). Evaluation of some HR interventions has already been carried out. For example, the reduction of HIV transmission by the provision of NX has been shown both at national level (Stimson, 1995) and global level (Stimson, Des Jarlais and Ball, 1998). There is also substantial evidence to support the provision of substitute therapies. Ward et al (1994) reviewed the impact of methadone on health, illicit drug use and drug related crime. The authors found maintenance dosing of at least 50 mg per day provided sustained benefits in the areas investigated. Evidence continues to be gathered.

The National Treatment Outcome Research Study, commissioned by the English Task Force that reviewed drugs services (Polkinghorne, 1996), is evaluating the outcomes from four treatment modes². Although not complete, the study has shown that both residential programmes and all methadone treatments substantially improve physical and mental health, reduce injecting and reduce involvement in drug related crime, with these benefits being sustained two years after study intake. Problem drinking however, did not improve (Gossop et al, 1999). There is also some evidence to suggest that the prescription of heroin may benefit mental health and social well-being and reduce involvement in drug related crime amongst individuals who are resistant to conventional treatments (Perneger et al, 1998).

As new harm reduction techniques and services develop, the demand for evidence means they will have to be based on research rather than just a belief that they will benefit the recipient. The process of undertaking such research will have several compartments, from initial investigation, through to implementation and development then evaluation in practice.

1.2.3.2 Harm reduction research: the role of the pharmacist

Through their training, pharmacists gain a unique combination of knowledge and skills. They have an understanding of science-based subjects such as pharmacology, chemistry, therapeutics and formulation and social science subjects such as health psychology and communication. They also have the ability to combine their knowledge and translate it into everyday language, to convey information and deliver health care to the public. They can conduct laboratory-based investigations using analytical research techniques and practice-based research using social science techniques. This wide range of knowledge and skills means pharmacists can gather evidence to support the provision of health care in a variety of settings, using a variety of means, which arguably, other professionals can not do so readily. One example where pharmacists have done such work is the development of high-tech healthcare at home services for cancer patients (Sewell and Hong, 1997). Laboratory-based research has been done to develop stable, accurate drug delivery systems, whereas practice based research has ensured that such systems are manageable by patients and their carers and established their education needs. The area of harm reduction lends itself to similar laboratory and practice-based research that could potentially be undertaken pharmacists.

² These modes being: (i) inpatient units, (ii) residential programmes, (iii) outpatient/community based methadone reduction and (iv) outpatient methadone maintenance.

1.3 The research plan and thesis structure

1.3.1 The original plan of work

At the start of this PhD project, the original plan of work differed from what was actually undertaken. The original plan was to collect information from IDUs on their injection preparation techniques and translate this into a laboratory simulation that could be used to investigate the effectiveness of filters used to remove insoluble material from injections made with street drugs. If appropriate, the findings would then be used to support the provision of filters through all needle exchanges in Grampian³. It was proposed to assess the clinical impact of this filter supply through two means. Firstly, it was planned to establish a nurse-led injection site injury clinic at the specialist drugs agency, Drugs Action. Through this clinic, 'before and after' data on the incidence of injection site injuries linked with the administration of insoluble materials could be gained from clients. Secondly, at the start of this work an audit of drug users use of the Accident and Emergency (A&E) services at Aberdeen Royal Infirmary was being undertaken. Part of this audit recorded the clinical conditions that presented, so therefore those linked to the injection of insoluble materials could be identified. It was proposed that the audit would be repeated in two years, which would mean a reassessment of the incidence of clinical problems linked to the injection of insoluble materials could be made, with the supply of filters having commenced before the re-audit. Discussion with the A&E researchers established that a sub-section could also be inserted into the audit questionnaire to gather further information on the use of filters amongst the patient group.

However, as the work began it became clear that such plans were over-ambitious for a project of this size with limited funds and not possible due to several factors that will now be described. Arrangement of the provision of street drugs from the police for the laboratory work took longer than expected, so that experimental work with heroin could only begin 15 months after the project started. Also the quantity of heroin available was limited. Similarly, it took 11 months to gain approval from the Crown Office and Procurator Fiscal to allow the distribution of filters to injecting drug users. Before this work started neither the researcher or the supervisory team knew that distribution would require legal dispensation to be granted. Access to laboratory equipment was limited by other researchers and undergraduate needs and no automated equipment was available. This was further compounded by the Coulter Counter being broken when it was moved by staff during building work. There was a delay of six months in raising the funds to repair it and getting this done as it had to be returned to the manufacturer. An application for funds for

³ At the start of this work there were eight pharmacy based exchanges and one specialist service (Drugs Action).

the injection site injuries clinic was rejected, enforcing reconsideration of this proposed part of the work. Additionally the audit of A&E services was also delayed. At the time of writing the re-audit has not been undertaken (Summer 2000).

1.3.2 The revised plan of work

As a consequence of the factors described in 1.3.1 the proposed schedule of research was revised to allow a workable study to be carried out. The revisions and their justification will now be summarised.

Despite the equipment difficulties the laboratory work was undertaken although of the work was restricted by time and the drugs available. As the researcher began to consider the implications of distributing filters to IDUs she became aware that a pilot study to establish user acceptability and a further small tightly controlled study to check their safety as predicted from the laboratory work would be required before large scale distribution could be undertaken. Hence a series of laboratory based experiments testing filters and aspects of the injection preparation process were carried out using a simulation technique based on data collected from IDUs. This was followed by a user acceptability pilot study of the most appropriate filter.

Whilst the researcher was collecting data from IDUs at Drugs Action on their injection preparation techniques, staff and clients often asked her for advice on pharmaceutical matters. It was during this period of data collection that the funding for the injection site injuries clinic was refused. The Drugs Action needle exchange worker, who was also an advisor to this project, and the researcher, both considered that there might be a place for a pharmacist-led information and advice clinic at Drugs Action. Such a service could be run on limited funds compared to the injection site injuries clinic. When a funding bid was successful for a six-month pharmacist-led information service at Drugs Action, it allowed this idea to be explored as a research project.

1.3.3 The structure of this thesis

The originally proposed laboratory-based and practice-based research (3.3.1) would have been connected through investigation into the effectiveness and clinical benefits of filters. However, the actual work that could be undertaken (3.3.2) was less closely linked. Consequently, this thesis is presented in two parts with hypotheses for each study that

was undertaken. Each part of the thesis begins with background information and a review of the literature. From this, the hypotheses and research questions posed for each study are derived.

The first study is presented in part one. It began by gathering information on injection preparation processes from IDUs and transferring this into the laboratory setting. There, laboratory-based research techniques were used to investigate aspects of the preparation process. The findings were then transferred back to the IDU environment for the pilot evaluation. Since each stage of the study informed the next, each is presented as a discreet chapter incorporating both the methods and results. The findings from all stages are discussed in the last chapter of part one, which ends with the study conclusions and describes the direction of future work.

The second study, presented in part two, investigated the delivery of a pharmacist-led information and advice service within the specialist drugs service environment. It is presented in the more traditional format of one chapter for methods, one for results and one for discussion. The conclusions from the study are given at the end of the discussion chapter, which also describes the areas for future work.

Finally, the last brief chapter of the thesis reflects on the work that has been undertaken and makes closing comments.

1.4 Search strategies used

The databases initially searched for this thesis were Science Citation Index, Social Sciences Citation index, Medline and Pharmline, all on CD-ROM. The searches were repeated periodically and expanded later in the study when on-line searching became available, using EMBASE (Excerpta medica, EMBASE drugs and pharmacology and EMBASE psychiatry), Web of Science (Science Citation Index and Social Sciences Citation Index), Medline and Science Direct (Elsevier Science publications). The plurals and variations of the search terms used were checked and mapped headings included where applicable.

A variety of search terms were used for this study. An initial search was carried out using the terms '*pharmacist*', '*drug misuse*', '*substance misuse*⁴' and '*harm reduction*' to establish an insight into the nature of the literature. More specific searches were undertaken for the individual studies. For the work presented in part one, searches were

⁴ The term 'substance misuse' is sometimes used in the American literature instead of the term 'drug misuse'.

carried out using the terms *'filter'*, *'cotton'*⁵, *'particle'*, *'illicit'*, *'drug abuse'*, *'drug misuse'*, *'heroin'*, *'base'*, *'tablet'*, *'inject'*, *'intravenous'*, *'injury'*, *'granuloma'*, *'harm reduction'* and *'complication'*. The terms were combined or linked as considered appropriate. For the work presented in part two, searches were carried out using the terms *'pharmacist'*, *'role of the pharmacist'*, *'service'*, *'pharmacy practice'*, *'community'*, *'community pharmacist'*, *'hospital pharmacist'*, *'information'*, *'advice'*, *'education'*, *'training'*, *'undergraduate'*, *'postgraduate'*, *'drug misuse'*, *'substance misuse'*, *'illicit'*, *'drugs agency'*, *'voluntary sector'*, *'treatment'* and *'methadone'*. In addition, searches were undertaken when required to assist with enquiry answering.

In addition, searches were carried on behalf of the researcher by the Institute for the Study of Drug Dependence (ISDD) library using the terms *'filter'*, *'injecting injury'* and *'pharmacist'*. The email alerting service of the British Medical Journal, Lancet and Australian Medical Journal were used. Many web sites were searched during the course of this study including those of the Department of Health, the Scottish Office, the Information and Statistics Division (Scotland), the Lindsmith Center On-line Library (USA) and the National Institute on Drug Abuse (USA).

⁵ The term 'cotton' is used in the USA referring to filters used by IDUs.

PART ONE

Investigation into aspects of the injection preparation process

Chapter Two

Background, literature review and aims of this study.

2.1 Introduction

The intravenous route may be used by drug users for many reasons, a detailed description of which is outwith the scope of this work. Investigation into the circumstances that surround initiation into injecting show this to be a multifaceted issue (Crofts et al, 1996). Injection may be out of necessity, e.g. people who regularly use opiates will develop tolerance to the effects of the drugs and if dependence occurs they will have to use increasing quantities to achieve similar effects (Derricott et al, 1999). The intravenous route becomes the most economical route in such cases as it avoids first pass metabolism and the effects of absorption across membranes e.g. inhalation. Injection may be used to achieve rapid and powerful onset of effects i.e. euphoria. However there are social factors that dictate acceptability, injection is not perceived as acceptable by or used by all drug users, even those who are dependent, hence only a proportion of drug users will use injectable routes such as the intravenous route (Crofts et al, 1996).

The use of the intravenous route to administer drugs carries many potential risks. These may come from the drug product itself, the preparation or administration process or the bypassing of many of the body's defence systems (Benet et al, 1996). The manufacture of pharmaceutical injections is subject to strict quality control to minimise the risks to the patient from the drug product (MCA, 1997, Hugo and Russell, 1987, Chapman, 1998). The preparation and administration of medical injections is also carefully controlled to minimise patient risk (Benet et al, 1996). Illicit drug use, commonly referred to as street drug use, is not subject to such controls, so potentially the health of the IDU is at great risk.

One area that is carefully controlled during the manufacture and preparation of pharmaceutical injections is that of particulate content, as the injection of insoluble materials can have adverse effects on health (Chapman, 1998, Barber, 1993). Several health problems seen in IDUs are caused by the injection of insoluble particles (Ben-Haim et al, 1988, Stein, 1990, Shesser et al, 1991, Haiart et al, 1992, Ruben and Morrison,

1992, Wills, 1997). There is a potential role for harm reduction in reducing the risks from the injection of particulate matter.

2.2 Sources of particulate matter in IDUs injections

Sources of particulate contamination in pharmaceutically prepared injections include the ingredients, the manufacturing process, packaging, the environment and personnel (Barber, 1993). The pharmaceutical industry applies strict controls to minimise particulate contamination (Barber 1993, Chapman, 1998). Limits are placed on the permitted particulate content in large volume parenterals (> 100 ml) (British Pharmacopoeia Commission, 1998). Illicit injecting is not subject to such controls. Although no study could be found examining sources of particulate matter in IDUs injections, when the concerns of industry are considered in the context of the IDU, several likely sources can be identified. These will now be discussed.

2.2.1 The drug substance

Powders that may be used to prepare illicit injections, such as street heroin and amphetamine, are produced in clandestine laboratories (Wills, 1997). It is assumed that the conditions under which illicit drugs are manufactured do not match the standards of the pharmaceutical industry, since no legal control governs quality assurance. The injection of solid oral dosage forms, such as tablets, also occurs (Stein, 1990, Haiart et al, 1992, Ruben and Morrison, 1992). Both illicit powders and tablets are potential sources of particulate matter. Poorly soluble and insoluble materials, such as talc¹, are often used as excipients in tablets (Parfitt, 1999). Street drugs may contain insoluble materials due to lack of refinement in the manufacturing processes. The drug itself may not be in a soluble form. For example, heroin base, which has a low solubility, is prepared for vaporisation², but is known to be used for injection in the UK (Derricott et al, 1999). Attempts are made by IDUs to convert the base to a soluble salt by heating the drug in the presence of acids such as citric or ascorbic acids, in powdered form or lemon juice, or acetic acid in the form of vinegar (Gossop, 1996, Tyler, 1995). Particles of undissolved base could be present if conversion is incomplete. The 'cutting' of illicit powders with insoluble or poorly soluble bulking agents such as talc, chalk, and at cold-water temperatures, starch, may cause particles in prepared injections (Ben-Haim et al, 1988, Shesser et al, 1991, Wills, 1997). However, the use of soluble cutting agents such as sugars appears from analysis

¹ Talc is predominantly composed of hydrated magnesium silicate. It may also contain small amounts of aluminium silicate and iron. It is practically insoluble in water i.e. it has a solubility less than 1 in 10 000 (Parfitt, 1999).

studies to be more common, so this cannot be assumed for all illicit powders (Love and Pannell, 1980, Kaa and Bent, 1986, Chiarotti et al, 1991, Kaa, 1994).

2.2.2 Packaging

Particles may be introduced into pharmaceutical injections from the packaging material or during the packaging process (Barber, 1993). The materials known to be used for the packaging of street drugs include plastic bags, cardboard and paper (Wills, 1997). These are possible sources of particulate contamination. Also, if assumed packaging of street drugs does not take place in a controlled environment, both the packer and the environment may contribute to the particle load. It is also known that street drugs may be repackaged several times before they reach the user (Tyler, 1995), which could increase the number of particles present.

2.2.3 Preparation methods, the IDU and the environment

The packaging used for pharmaceutical injections is such that particulate contamination from the handler or the environment during injection preparation is minimised (Chapman, 1998). The preparation stages used by IDUs described in the literature (Koester et al, 1990, Derricott et al, 1999) indicate that several opportunities for particulate contamination exist. There may be several persons present, in an environment where air quality will be uncontrolled. This creates large numbers of environmental particles (Barber, 1993). The drug is exposed to the environment as the injection is prepared. The water used may be of uncontrolled quality since water for injection cannot be obtained without a prescription in the UK (RPSGB, 1999). Unprotected hands will again be a source of particles. Syringe barrels themselves have been shown to shed plastic particles (Barber, 1993).

2.3 Health problems seen in IDUs attributed to the injection of particles

When insoluble particles are injected intravenously, they may lodge in the lungs or continue around the circulation to other sites (Wills, 1997). Several of the health problems seen in IDUs that have been associated with the injection of particles will now be discussed.

² The process of inhaling heroin in the vaporised form is known as 'chasing'.

2.3.1 Granulomas

The formation of foreign body granulomas around injected particles is reported frequently in the literature (Stein, 1990, Shesser et al, 1991, Posner and Guill, 1985). Keul et al (1993) report the presence of granulomas in 30% of drug users at autopsy, however, do not explicitly state that these people were known injectors. Granulomas have been identified both locally and systematically (Posner and Guill, 1985, Stein, 1990, Shesser et al, 1991). The lungs are often the sites of granulomas, although other systemic sites are reported including the liver, kidney, retina and lymph nodes (Shesser et al, 1991, Wills, 1997). Multiple lung granulomas have been identified in IDUs (Tao et al, 1984, Ben-Haim et al, 1988). Pulmonary fibrosis, which may result from multiple granulomas leads to the formation of venous shunts, causing some blood to by-pass the lungs (Posner and Guill, 1985). Clinical presentation includes dyspnoea, hypoxia, pulmonary hypertension leading to right sided heart failure, and emphysema (Sternbach et al, 1980, Posner and Guill, *ibid*, Wills, 1997). Granulomas have mimicked the symptoms of tumours, both in the lungs and at other sites (Feldman et al, 1999, Rohde et al, 1999). Talc has been particularly cited as a cause of permanent granulomas (Hopkins and Taylor, 1970, Stein, 1990) whereas starch, has been associated with transient pulmonary granulomas (Stein, *ibid*). The authors note it may take several decades for talc granulomas to form and cause clinical symptoms. It has been suggested that this is because the silicate has to be in the colloidal form before a granuloma occurs, a process that takes several years (Posner and Guill, 1985). Sterile abscesses have been attributed to the injection of particles and may eventually form granulomas (Stein, 1990). The subcutaneous route is commonly associated with these abscesses (Derricott et al, 1999).

2.3.2 Inflammation

Phlebitis is commonly seen in IDUs, and although also linked to frequent venous access (Derricott et al, *ibid*), injected particles are known to irritate the vein walls and contribute to the inflammatory response (Stein, 1990, Wills, 1997). Complications of phlebitis are discussed in section 2.3.3. In cases of cellulites, where infecting organisms were not found, tissue irritation due to the extravasation of injected particles as been suggested as the cause (Orangio et al, 1984, Stein, 1990).

2.3.3 Emboli and associated problems

Emboli may be caused directly by particles, or indirectly by thrombi that form as a result of phlebitis (Stein, 1990, Wills, 1997). As a consequence of deep venous thrombosis, varicose ulcers and in extreme cases, gangrene has been seen (Haiart, 1992, Imbert, 1997). Occlusion of pulmonary vessels has resulted in acute and chronic pulmonary hypertension (Shesser et al, 1991), which may lead to cardiac failure. Embolisms have also been held responsible for myocardial infarction in IDUs (Sternbach et al, 1980). Damage to the right side heart valve leaflets or endothelium has been linked with particle injection, giving rise to right sided endocarditis (Haverkos and Lange, 1990). Thrombophlebitis may lead to vein collapse and the consequent formation of venous shunt (Derricott et al, 1999). This in turn will impair vascular functioning, resulting in oedema of the extremities.

2.4 Factors relating to the injection of particles

2.4.1 What can realistically be achieved?

Particulate matter from the drug substance (2.2.1) and packaging (2.2.2) cannot be controlled in the context of illicit injecting. The extent to which factors relating to the IDU and their environment (2.2.3) can be realistically controlled is also limited. However, it may be possible to influence the preparation methods used (2.2.3). Given these factors, the most assured way to reduce the particulate content in illicit injections may be through an end-stage process factor, that is particle removal at the final stage of injection preparation. Before methods that could be used to do this are discussed, it is important to gain some idea of what can realistically be achieved.

In the pharmaceutical industry, the aim is to reduce particulate contamination to below the acceptable levels. In the case of large volume parenterals, this means to within compendia requirements (British Pharmacopoeia Commission, 1998). Although no limits are set for small volume parenterals due to quantification difficulties, manufacturing is designed to reduce contamination to a minimum. When considering particulate removal from illicit injections, the standards of the industry cannot be achieved due to the variables described in 2.2. Particle removal in any environment cannot be absolute and will be subject to variation. The extent of the variation is likely to be much greater with illicit injections due to lack of control over the factors in 2.2. Therefore in contrast to the industry where the aim is to reduce particulate contamination to within acceptable standards, the aim with illicit injections can be no more than to remove as many of the

particles as possible and evaluate whether the levels that are achieved produce any significant benefits to health, both in the incidence of acute problems such as embolisms and inflammation and in conditions which appear over time such as granulomas.

2.4.2 Critical particle sizes

The limits placed on large volume parenterals in the British Pharmacopoeia state the number of particles over 5 μm and 10 μm that are acceptable (British Pharmacopoeia Commission, 1998). In the vascular system, capillaries are the smallest vessels, having a diameter between 5 and 9 microns, with the smallest capillaries situated in the lung (Guyton, 1984). It can be suggested that particles larger than 5 μm in diameter will obstruct pulmonary capillaries. Particles may pass through the lungs, due to their small size (< 5 μm) or the presence of shunts. It is known that talc particles can pass from the blood through the glomerular filter, as they have been detected in the urine of IDUs (Posner and Guill, 1985). This may be true of other particles, however it cannot be assumed on size alone since glomerular filtration also depends on ionic charge (Guyton, 1984). Particles of any size may potentially damage circulatory valves or damage tissue if they leak through ruptured vessel walls.

2.5 Reducing the particulate content in illicit injections

2.5.1 The use of makeshift filters and safer injecting advice

In an attempt to remove insoluble particles, it is known that some IDUs draw their drug solution through a makeshift filter prior to loading it into the syringe. The filters reported to be used are prepared from readily available household items, such as cigarette filters, cotton wool from buds or balls, lint and clothing. (Harrison and Walls, 1990, Koester et al, 1990, Power et al, 1994).

The use of makeshift filters is reported in training information for drugs workers (Health Education Authority, 1993, Derricott et al, 1999) and safer injecting advice given to IDUs describe their use (Exeter Drugs Project, 1992, HIT, 1997, Preston and Derricott, 1997, Viral Protection Campaign, 1998, Lifeline, 1999) (see appendix 2). In these leaflets IDUs are advised always to use a clean filter, never to share or reuse filters and to avoid using loose fibrous filters such as cotton wool. Suggestions are made such as '*an alternative to using a filter is to tip the spoon carefully and keep the 'crap' at the opposite end to where*

you draw up' (HIT, 1997). The specific recommendation to use cigarette filters is made in others (Exeter Drugs Project, 1992, Viral Protection Campaign, 1998, Lifeline, 1999).

Although the use of filters by IDUs has been identified in the literature, there appears to have been no investigation of the effectiveness of this practice in reducing particulate contamination. The only published investigations found that studied the effectiveness of filters at removing particulate matter were concerned with the therapeutic use of pharmaceutical products. No study involving laboratory analysis of illicit drug injections was found. Since this work was undertaken, two pieces of work examining illicit injections and filters have been published, however, neither relate to the effectiveness of filters on particulate matter. One was a Swiss study that examined the effects of syringe filters on bacterial contamination in 20 heroin injections (Caflisch et al, 1999). The other was performed in the USA. The authors developed an HPLC-EA forensic method for analysing the drug content in filters (Huettl et al, 1999). The effectiveness of filters for use by IDUs is an area that warrants investigation.

2.5.2 The reuse of filters by IDUs

Anecdotal reports from drugs workers and trainers suggested that some IDUs believe filters retain some of the drug substance as well as insoluble materials (Bruce, 1996, McDonald, 1996, Speed, 1996, Derricott, 1997). Although no study investigating this could be found in the literature, there is evidence to support this belief. Koester et al (1990) and Harrison and Walls (1990) note that some heroin injectors save used filters and mixed them with water at a later date to release trapped drug. The extent to which makeshift filters retain drug when used in the injection preparation process is therefore a further area for investigation.

2.5.3 Health issues

The use of makeshift filters and their reuse raises several health issues. The literature contains reports of health problems that have been linked to the use of makeshift filters. In a review of injecting complications, Stein (1990) notes that fibres shed from makeshift filters may be responsible for granulomas and embolisms. A febrile syndrome not fully understood has also been associated with the use of makeshift filters. This syndrome, referred to as 'cotton fever' can be mistaken for a more serious conditions such as infective endocarditis or pneumonia, due to similarities in presentation i.e. fever, chills,

lethargy and pain. Harrison and Walls (1990) suggest the pyrogenic properties of cotton shed from filters may be responsible. The authors report no associated infection and resolution of the condition within a matter of hours. The authors note from the literature an association between presentation and the administration of injections prepared from previously used filters. This condition was also reported in a case study by Ferguson and Feeney (1993), but this time associated with systemic infection with *Enterobacter agglomerans*, known to heavily colonise cotton plants. This syndrome was also observed by Sternbach et al (1980), in association with the use of brown heroin, but the authors have not made any link with the use of filters. Derricott et al (1999) suggest 'cotton fever' or 'dirty hits' as they are termed in the UK, may be a response to the drug, an adulterant or a contaminant from the paraphernalia. This may be the case since many cigarette filters in the UK are made from cellulose acetate not cotton (Dobbin, 1998). It has also been suggested by the developers of 'Steribox', an injection paraphernalia kit available in France, that the condition is a response to a protein in the coat of the fungi *Candida albicans*, which may be present in brown heroin, lemon juice and vinegar (Imbert et al, 1999). The sharing of filters, as well as other injecting paraphernalia, has been associated with the transmission of blood-borne viruses. Koester et al (1990) and Power et al (1994) make this suggestion in relation to HIV transmission. The sharing of paraphernalia, including filters has also been implicated in the transmission of hepatitis C virus (HCV) (Crofts and Aitken, 1997, Crofts et al, 1999). The authors made this suggestion after identifying IDUs infected with HCV who reported never having shared needles and syringes, but who reported having shared injecting paraphernalia including filters. Further work is needed in this area to establish the role of each piece of paraphernalia in HIV and HCV transmission.

These reports raise some issues. The first is that IDUs must be encouraged not to share any injecting paraphernalia. This has been the focus of recent safer injecting campaigns (Preston and Derricott, 1997, Viral Protection Campaign, 1998). The second is that even if makeshift filters can be found which reduce the particle content of injections, they themselves may contribute to harm, especially if they are reused. Makeshift filters were not designed for the purpose for which IDUs use them. Hand rolling and cigarette filters for example are designed to remove smoke particles. This points to the suggestion that commercially produced filters made for injection filtration may be more appropriate for use by IDUs as they are designed to fit onto syringes and remove particles bigger than the stated pore size.

2.5.4 The supply of commercially produced filters to IDUs

2.5.4.1 Disc-type syringe filters

Information was sought to establish whether commercially produced filters were being supplied to IDUs. It was established that commercially produced filters were being supplied abroad to IDUs and had been distributed in the UK in the past. Commercially produced disc syringe filters (SF) were promoted in information bulletins produced for IDUs by workers from NXs in New South Wales, Australia (Bergin, 1996, Anon, 1996). However, no details of filter type or pore sizes were given, although illustrations confirmed the disc type. The workers acknowledged in the text a lack of evidence of effectiveness of SFs. Further information established after this study began found SFs also recommended and illustrated in another Australian safer injecting leaflet (NDARC, 1998), but again with no details of make or pore size. Communication with an ex-worker from New South Wales Users Association established that syringe filters had been distributed from this association, but this had stopped due to the expense (Burrows, 1999). Again, no pore size, brand details or information on user acceptability were known.

Anecdotal reports from users of a drugs agency drop-in service in Aberdeen³ established that some had obtained filters some years ago from NXs in Edinburgh. They reported receiving filters which fitted the description of SFs. Contact was made with the director of the Centre for HIV and Drug Services in Edinburgh, who confirmed that no filters were currently being distributed but provided contact details of NXs who had distributed filters in the past (Lewis, 1996). Discussion with these workers established that syringe filters had been given out, but this practice had stopped some years previously (Kerr, 1996, Stritch, 1996). The reason given for stopping by the workers was the opposition of the local public health department, who considered the lack of evidence of effectiveness did not allow responsible provision. Stritch provided contact details of the NX from which the filters had been bought. This agency was visited. Discussion with the co-ordinator (Simmonds, 1996) established that the filters they had distributed to IDUs and other agencies some years previously had come from Switzerland. However, the source was unknown by the current staff working at the exchange. Their description fitted that of SFs, but make and pore size could not be established.

Many disc-type SFs are available commercially for removing particulate matter from prepared injections in the medical or laboratory setting, e.g. those in the catalogues of

³ This drop-in service was provided by Drugs Action, 48a Union Street, Aberdeen. It was staffed by two drugs workers, to provide information and advice to any drug user who chose to attend. No appointment system was in operation.

Gelman Sciences (1991) and Millipore (1996). These filters may be appropriate for use by IDUs, as they have been designed to remove particles with minimal shedding. Also, anecdotal information established that SFs have been distributed to IDUs in the past. However, before they could be considered acceptable for use by IDUs it would have to be demonstrated that they do reduce the particulate contamination in illicit injections. Issues around the potential for reuse would also have to be considered, as would the acceptability of the SFs to IDUs. For example, if the filter withheld drug, IDUs may either wish to release the trapped drug or be unwilling to use the filters in the first place. It appears from the literature that these issues have not been investigated.

2.5.4.2 Cellulose acetate filters

During this study, injection preparation kits were identified which are sold or distributed to IDUs in some European countries. Two kits were obtained from Switzerland and one from France. The *'Flash'* and *'Safety Kit'* kits were produced by Compet Medical AG, Bottighofen, Switzerland. The *'Steribox'* kit was produced by Association Apothicom in association with Co-Pharm-EC, from Ivry-sur-Seine, France. The Safety Kit and Steribox both contain filters. The Safety Kit filter is a small fibre filter packed into a plastic casing that fits onto the end of the syringe, through which the liquid is drawn. The Steribox contains a small fibre filter resembling a hand rolling cigarette filter, which is placed in the preparation spoon, which is also provided. The producers of the kits were contacted to establish whether they had any information on the effectiveness of the filters. Contact with Compet Medical AG established that no work had been done investigating the effectiveness of the filters (Schilling, 1998). Although the filters in the Steribox kit have not been tested in the laboratory in any way, work has been done to investigate user acceptability of the filters. This study is contained in an unpublished report produced by the Association (Imbert, 1997). As a result of this work, the filter in the *'Steribox 2'* kit was changed. It is a small cellulose acetate filter, a third of the size of the original hand rolling filters. Current collaborative work is on going with Association Apothicom to develop an appropriate fibre-free filter for inclusion in Steribox 2.

2.6 Restrictions that apply to the provision of injecting paraphernalia to IDUs in the UK

2.6.1 Current legislation

Although safer injecting advice can be given to IDUs in the UK, the provision of injecting paraphernalia (IP) such as filters, acidifiers, spoons, water for injection⁴ and swabs is prevented by law. Section 9A of the Misuse of Drugs Act (1971) makes it an offence to supply any article if it is believed that it will be used for the unlawful preparation or administration of a controlled drug⁵. Subsection 1 states if the administration is unlawful i.e. not in accordance with the Medicines Act (1969) or Misuse of Drugs Act, the supplier of administration equipment is guilty of an offence. Subsection 2 excludes needles and syringes from this ruling, thus allowing NX to be conducted⁶. Subsection 3 makes it an offence to supply materials that are to be used to prepare controlled drugs, if the preparation is unlawful. There has been no test case of this law, so it is not known what the ruling of the courts would be on such an incidence (Lutener, 1997). Derricot et al (1999) consider it unlikely that prosecution would ever occur, as it would not be in the public interest.

Many paraphernalia items such as makeshift filters (2.5.1) and acidifiers (2.2.1) are obtained from household items. Therefore, unlike needles and syringes, they can be obtained from a range of retail outlets. Enforcement of the law would be difficult, as it would have to be shown that the supplier was aware that the item was going to be used to prepare controlled drugs. However, this may be easier to prove in the case of supply from harm reduction service providers. It is unclear to what extent service providers are aware of the laws that prevent paraphernalia distribution, as this has not been studied. The researcher is aware of the supply of paraphernalia items, in some cases without legal approval. However, as the present law stands, legal supply, with the exception of clean needles and syringes, cannot be made.

2.6.2 The possibility of legal reform

Support for a change in the law to allow IP to be supplied to IDUs has been identified. Commenting on the Association of Chief Police Officers 1997 conference, Wray (1997)

⁴ Water for injection is also controlled by the Medicines Act (1969), restricting supply to prescription only.

⁵ Section 9A was inserted into the Misuse of Drugs Act by section 34 of the Drug Trafficking Offences Act (1986).

⁶ In Scotland the common law crime of reckless conduct means that in theory the supply of needles and syringes could amount to a criminal offence. The Lord Advocate's revised guidance states that the prosecution of doctors, pharmacists or people working under their instruction to provide needle exchange would not be authorised. However, this statement is not extended to all drugs workers (The Scottish Office, 1998).

notes support was given for legal reform. More recently, a press article reported a government official has stated that the law would be changed (Anon, 1999a), a statement that was repeated shortly after at a national conference (Goodman, 1999). The police and Crown Prosecution Service have been reported as unlikely to prosecute for the supply of IP (Derricott et al, 1999, Preston, 1999). The report of the Working Party on Pharmaceutical Services for Drug Misusers (1998) called for a change in the law to allow pharmacists to supply additional paraphernalia, including swabs, water for injection and citric acid. The Royal Pharmaceutical Society of Great Britain (RPSGB) have confirmed that they would not take disciplinary action on a member unless they were prosecuted (Preston, *ibid*) and more recently have reported they will be encouraging the relevant politicians to support a change in the law (Anon, 1999b). An independent enquiry established by the Police Foundation and The Prince's Trust has also called for the supply of paraphernalia, advocating that section 9A be abolished entirely (Runciman, 2000). This information only demonstrates that the law is not being enforced and suggests support for change. Private communication established that a review of the Misuse of Drugs Act is currently being undertaken by the Home Office. However, it may be some time before the bill is put to Parliament, because amendment of the Prescription Only Medicines Order will also be necessary, to allow the prescription only status of Water for Injections to be changed (Mitchell, 1999).

2.6.3 The context in which the current laws place this research

Under current legislation, only information on the use of makeshift filters can be supplied to IDUs. Therefore, the findings of the work from this study on makeshift filters could be used to advise IDUs on the use of filters. There will be a time delay between present moves to change the paraphernalia laws and the application of this reform at service level. It is anticipated that in the event of legal reform, questions may arise such as what types of paraphernalia should be supplied. Conducting the work in this study relating to makeshift filters and acidifiers (discussed in 2.7) before legal reform means that information on their use would be available if and when the supply of IP becomes legal.

2.7 The use of acidifiers in the preparation of heroin injections

2.7.1 Analytical studies of brown heroin

Analytical studies of seized heroin samples in Europe have found the drug to be present in either the base or hydrochloride form, or mixtures of both (Huizer, 1989, Kaa, 1991,

Kaa, 1994, Chadron-Thozet et al, 1992). Kaa (1991) and Chadron-Thozet et al (*ibid*) both categorised the heroin according to colour and identified the forms present. Both studies reported white heroin to be in the hydrochloride form. Kaa found all but one beige sample to also be the hydrochloride. She described 'brownish' colours as dominating the basic forms. Chadron-Thozet reported 'off-white' samples to be hydrochloride and light beige, beige and dark beige samples as being basic. Both authors employed methods to reduce subjectivity in colour classification. Kaa used one operator to categorise the samples, whereas Chadron-Thozet et al developed a coding system. Although this minimised subjectivity within the studies, there can be doubt as to whether Kaa and Chadron-Thozet et al's perceptions of colour were equivalent i.e. is the colour 'beige' the same to both authors? However, the studies do suggest that darker coloured samples are likely to be in the basic form and white in the hydrochloride form.

2.7.2 The chemistry behind the use of acidifiers

In 1997 it was reported that over ninety percent of the heroin seized in the UK originates in South West Asia, being predominantly in the base form (King, 1997). Brown heroin is used in the UK for injection, although it is illegally manufactured for smoking, which is why it is in the volatile basic form. (King, *ibid*, Tyler, 1995, Derricott et al, 1999). Base heroin has a solubility of 1 in 1700 parts of water, whereas salts of the drug have much greater solubility (Moffat, 1986). As said (2.2.1) acidifiers may be used during the preparation of heroin injections and probably convert the drug to a soluble salt. They are combined with the heroin and water then this mixture is heated to promote solubility (Wills, 1997). Acidifiers known to be used include citric acid powder and citric acid from lemon juice, which in theory could produce diamorphine citrate, ascorbic acid (vitamin C) powder, which in theory could produce diamorphine ascorbate and acetic acid, in the form of vinegar, which in theory could produce diamorphine acetate.

In the absence of acid to convert the diamorphine, the heroin powder containing the insoluble base would likely flocculate when mixed with water and the diamorphine not go into solution.

2.7.3 Safer injecting advice relating to acidifier use

Despite the chemistry that explains why acidifiers are required in the injection preparation process, the researcher became aware of anecdotal reports of safer injecting advice

being given to IDUs that said that acidifiers were unnecessary (Speed, 1996, Derricott, 1997). These reports said that IDUs were being told to either heat the drug for longer or use more water to promote drug solubility.

2.7.4 The need for information on the use of acidifiers

Despite information based on chemical theory (Mahan and Myers, 1987), no laboratory work could be found showing that acidifiers were needed to promote the solubility of diamorphine base in illicit heroin. Since this work aimed to investigate the use of filters in the preparation of illicit heroin injections, it was considered appropriate to conduct such an investigation at the same time. Such information would be useful for three reasons:

- (1) to demonstrate to drugs workers and safer injecting trainers the effects of acidifiers versus the effects of adding more water or heating for longer without acid.
- (2) to provide information to illustrate the need for acidifiers in the event of the paraphernalia laws being changed. Such information could also be used by drugs services seeking exemption from prosecution to allow them to distribute acidifiers.
- (3) to provide information for injecting drug users on the effects of acidifiers.

2.8 Issues that require consideration before the use of filters and acidifiers can be studied

2.8.1 Simulation of the injection preparation process.

Before investigation could be carried out into the use of filters and acidifiers in the laboratory, the researcher had to ensure that the preparation methods used to make the injections were as close as possible to those used by IDUs. Therefore, the first stage of this study was to develop a simulation process for the preparation of illicit drug injections. Only then could work be done to address the research questions that have been identified.

2.8.2 UK legislation

It was important to ensure that the work for this project was carried out in strict adherence to the law so legal matters relating to the work had to be considered. No legal restriction

prevents laboratory-based research into the effectiveness of IP. However, work involving the use of controlled drugs, is subject to controlled drug legislation relating to possession and destruction (Misuse of Drugs Act, 1971). The researcher would have to legally be allowed to possess the controlled drugs in questions and store and dispose of them as required by the Home Office. Also, the distribution of IP to IDUs, e.g. for investigation into user acceptability, would require exemption from prosecution to be granted by the regional procurator fiscal (PF).

2.8.2 Ethical approval

Research that involved data collection from IDUs would require approval from the ethics committee of the institution from which the work was conducted. The researcher would have to ensure that any studies that distributed filters to IDUs did not expose them to any increased risk.

2.9 The hypothesis and research questions for this study

This chapter has shown the need for laboratory-based research investigating the effectiveness of injecting paraphernalia as a first step towards developing an evidence-base for the provision of information and, subject to legal reform, equipment, to IDUs. On this basis the hypothesis for this study was set as:

Through development of a simulated injection preparation process and analysis using laboratory-based experiments, it is possible to gather information on the effectiveness of injecting paraphernalia to inform harm reduction practice.

Based on this hypothesis, the following research questions were generated:

1. Can a simulation of the injection preparation process used by IDUs be developed, which can be used to conduct representative investigations in the laboratory setting?

If so,

2. Can a measure be made in the laboratory of the effectiveness of makeshift filters at removing insoluble particles?

3. Are commercially available syringe filters more effective at removing insoluble particles from injections than makeshift filters?
4. Can the extent to which makeshift filters retain drug be established?
5. How does the amount of drug retained by syringe filters compare to the amounts retained by makeshift filters?
6. Is the most effective filter, according to the laboratory work, acceptable to IDUs and does it produce health benefits?
7. Does laboratory investigation support the need for acidifiers in the preparation of brown heroin for injection?

Chapter Three

Design of the injection preparation technique simulated in the laboratory.

3.1 Methodological considerations

Several methodological factors had to be considered when choosing the methods used to simulate the injection preparation techniques used by IDUs. It was important for the simulation to represent what is done by IDUs as closely as possible, however, in order to conduct meaningful laboratory work, the simulation process also had to be reproducible. Hence the process had to be controlled, allowing all factors to be kept constant except the variable under investigation. It was anticipated that this work would focus on heroin, but the popularity of this drug had to be confirmed. Several processes had to be gone through to arrange the supply of heroin, so the conduction of preliminary work using pharmaceutical drugs was conducted in the interim.

3.1.1 IDU preparation vs. researcher simulation

The highest degree of representation of true to life results would have come from the analysis of injections and filters prepared by IDUs in their own environments. However, this was considered not viable for the following reasons: Providing IDUs with controlled drugs (CDs) to prepare in their own environments and return for analysis would be illegal, because this would not be a lawful possession of a CD. Asking IDUs to supply their own injections and used filters would be unacceptable as again it would be an unlawful supply of a CD when the injections and filters were given to the researcher. Analytically this would also be unacceptable as it was important for analysis to be performed as soon as possible after preparation, to allow results to reflect those of an injection just about to be used. It would also be unlikely that IDUs would agree to surrender their drugs for research. The use of ex-IDUs as observing advisors in the laboratory was considered, but after discussion with ex-IDUs this was rejected, as they did not feel comfortable with this exposure. Therefore, simulation of the injection preparation technique by the researcher was selected. This allowed the work to be carried out in strict adherence with legal requirements and avoided ethical problems, as the researcher, who is a pharmacist, was

able to ensure lawful supply and possession of CDs, as discussed in chapter 4. The decision to use the simulation technique presented further methodological issues.

3.1.2 How can the simulation technique be made as close as possible to 'real life'?

To allow the laboratory investigation to give the most realistic results, it was important to copy the injection preparation techniques used by IDUs as closely as possible, using drugs commonly used by injection. To inform this process, information had to be collected from IDUs and other appropriate sources, which were considered to be published statistics, safer injecting information and drugs agencies. This information had to then be converted to a simulated process. Several methodological options had to be considered to allow the most appropriate methods for achieving the aim to be selected.

3.1.3 Establishing the drugs injected by IDUs.

To confirm the anticipated popularity of heroin amongst IDUs and to establish pharmaceutical drugs used by injection published national drug misuse statistics were consulted (ISD, 1996). However, since these statistics report data from new contacts with drugs services only, it was considered prudent to confirm whether the most popular drugs reported in this data were also commonly used by other IDUs. Sources of such information include drugs agencies and IDUs. Contact with drugs agencies established that the formal statistics recorded were those submitted to ISD, so no further information was available. Therefore, informal discussion with drugs workers was considered the most appropriate method of contact to establish whether they considered the statistics reflected drug use amongst their clients overall. Information about known preparation techniques was collected at the same time, as this was needed to inform the laboratory simulation. The methodological issues around consultation with IDUs are discussed below.

3.1.4 Consultation with IDUs.

3.1.4.1 Issues around the method of data collection

Consideration had to be given to the various methods that could be used to collect information from IDUs. The first option was to use non-participant observation of the

injection preparation process. This would produce the highest degree of accuracy, by allowing the researcher to observe and make field notes on the drugs, preparation and administration techniques used (Amsel et al, 1976). This was rejected for several reasons: The length of time which was necessary to establish networks and gain trust for such work made it impractical for the purpose of this study. The illegal nature of injecting drug use and being present while it occurs carried ethical implications for the researcher, as a pharmacist.

The second option was to interview people with first hand experience of injecting drugs. This would provide data recalled on questioning, so included the chance of error in information recall and reporting, especially if they had not been asked to recall the information before or the activity had not occurred in their recent past (Moser and Kalton, 1971). There was also the question of whether the information reported would be valid. It was considered possible that fear of disclosing illegal behaviour or feelings of shame may inhibit honesty. This matter has been investigated by previous researchers, as reviewed by Stephens (1972). The author describes the work of Cottrell and O'Donnell who compared data collected from 339 subjects by hospital admissions clerks with information obtained from the same subjects, at a later date, by a social scientist, in the interview setting. He also cites the work of Ball, who compared data collected from 59 narcotic users with medical, police and urinalysis records and the work of Robins and Murphy. They compared interview response with hospital and police records to investigate validity of self-reported heroin use in 235 male subjects. All studies concluded that a high degree of validity between the self reported data and that obtained from other sources had been found, demonstrating that respondents had been honest and truthful. Maddux and Desmond (1975) cite an investigation conducted by Maddux et al previously which studied interviews conducted by probation officers. They found a higher correlation between the data that was perceived as pleasing to the interviewer than unpleasing data. This suggests if the interviewee perceives pleasing responses may benefit them, then there may be a tendency towards inaccurate reporting of unpleasing information. This was not considered to be significant in this study as the researcher would have no influence over any treatment or legal issues relating to the IDU, unlike the probation study, so the interview method was considered the most appropriate. A semi-structured format was chosen as this allows the discussion to be guided, whilst allowing a range of responses to be given and further investigated (Moser and Kalton, 1971, Coolican, 1994).

3.1.4.2 Issues around the recruitment of IDUs

Randomised sampling

A random sample of interviewees taken from the IDU population would give the most representative sample, but is not possible because this population is unknown. Two lists of known IDUs were identified from which a random sample could potentially be obtained. These were the Addicts Index, held by the Home Office and the client list of the local Substance Misuse Service (SMS)¹. Both would provide a list of people who were or had been in contact with prescribing services. The Addicts Index was held in London and not considered practical to use for an investigation this size as it would be too time consuming achieving access and locating subjects with experience of injecting drug use who would be willing and suitable for interview². Also it would involve locating subjects at their home address, which would raise suspicion and encourage association with the authorities, which may not be conducive to encouraging honest answers (Maddux and Desmond, 1975). The SMS client list was also considered unsuitable because interviewees would have to be made aware that they were accessed through the SMS. If any were currently injecting and receiving substitute therapy, they may fear that any injecting drug use revealed would become known to SMS staff, leading to inaccurate responses as described in section 3.1.4.1.

Non-randomised sampling

Three sources from which a non-random sample of IDUs could be obtained were identified. These were (1) known IDUs held within the local prison (2) the local drug counselling and needle exchange agency and (3) community pharmacies. Consideration was given to each option. The prison was rejected because it was felt there would be reluctance to reveal honest information, due to fear of disclosure. Also, injecting practices used whilst incarcerated may not be representative, due to the restricted access to equipment (Murray, 1996).

Aberdeen has one drug counselling and needle exchange agency, Drugs Action (DA). This is a non-statutory service, which was established in 1986 (Drugs Action, 1994). Previous research has shown that drug users trust the service and feel a good rapport with the staff (McKeganey et al, 1997). There is no prescribing arm to the service, so no conflict for clients in revealing current drug use exists. The agency confidentiality policy

¹ At the time of this work the Substance Misuse Service (SMS) was known as the Drug Problem Service (DPS).

² At the time of this work, the Addicts Index was still actively in use and kept at the Home Office, London.

offers guaranteed confidentiality unless there is a serious risk to health or life from withholding information (Bruce, 1996). By approaching DA clients either in the needle exchange or drop-in, their drug use is being acknowledged from the outset. Therefore, it was decided that DA clients would have little reason to be dishonest, if they were located through this service. Apart from the client database, all other records are kept using the client's initial and date of birth only. In theory the database could have provided names and addresses from which a random sample of clients could have been selected, but given the client led nature of the service and confidentiality policy, neither the researcher or staff considered this acceptable. Therefore, a quota sampling method was used instead to recruit DA clients for interview.

At the time of this work, none of the needle exchange pharmacies in Grampian had facilities suitable for private interview and the RGU School of Pharmacy safety officer was unwilling to approve the use of a remote location, such as a cafe for meeting IDUs. A community pharmacy with a private area and a large number of clients receiving substitute therapy was identified as a potential source of interviewees. It was assumed that many of these clients would have a history of injecting drug use. The pharmacist was known to be trusted and respected by these clients, which may have helped to instil trust in the researcher (Moser and Kalton, 1971). This may have been suitable for accessing IDUs who had never used drugs agency needle exchanges and allowed comparison of data between these people and specialist needle exchange agency clients. Contact was made with the pharmacist who was willing to assist in recruitment. However, the sudden death of the pharmacist involved, led to this not being pursued. Discussion was held with the subsequent relief manager, but she felt uncomfortable in assisting with recruitment. Also, many clients were known to be upset by the pharmacist's death, so the researcher felt it inappropriate to pursue the matter.

Ethical Approval

Because the proposed research involved contact with IDUs through a care provider, approval from the Joint Ethical Committee of Grampian Health Board and the University of Aberdeen was considered good practice. The purpose of the Committee is to ensure that research complies with ethical standards, including the provision of choice in participation, the collection of informed consent and the option to withdraw at any time. It also ensures that participation does not prejudice the care received from the care provider. Although RGU is not officially accountable to the committee, it was considered good practice to obtain their approval. The ethical standards that were applied to this work are described in the relevant section of the methods (3.2). The application form and

ethical approval is shown in appendix 3. Relevant attachments that were included with the application are in later appendices and referred to in 3.2 where their use is explained.

3.1.5 Laboratory issues

Although the technique used in the laboratory to prepare injections had to simulate the way IDUs prepare injections, it also had to be such that all variables could be controlled, to allow results to be as reproducible and comparable as possible. In this sense, the laboratory technique had to be subject to controls that may not be present in real life. The variables had to be defined, such as quantities of drug, acid and water used and the heating time. A flow chart of the established preparation processes was considered the most appropriate way to represent this as it could be easily followed in the laboratory.

3.2 Methods

3.2.1 Review of published statistics

The most recent Scottish Drug Misuse Statistics were identified, which summarised information submitted by service providers on new client contacts over the time period 1 April 1994 to 31 March 1995 (ISD, 1996)³. From these statistics, table 4, which details the main drugs used, and table 5a, which details all drugs used, have been copied with the permission of the publishers and are shown in appendix 4⁴. From these statistics, the number of people who reported using a given drug by injection was calculated as a percentage of the total number of injectors. This was done for both Grampian and Scotland as a whole, to produce tables, ranking the drugs in percentage order. From this the perceived popularity of heroin and pharmaceutical drugs amongst new contacts to services could then be seen.

³ These were the most recent statistics at the time of this work. Details are submitted to ISD on form SMR22 (medical services) and SMR23 (non-medical services).

⁴ Data recorded relates to drug use in the month preceding contact only.

3.2.2 Review of safer injecting leaflets and training materials

The safer injecting leaflets referred to in chapter 2 were gathered from drugs agencies. Health Education Authority (1993) training materials were obtained, no materials were available from the Health Education Board for Scotland at this time. In-house training materials produced by the Drugs Action (DA) needle exchange worker were also consulted (Drugs Action, 1996). A safer injecting training day for drugs workers was attended and notes made on the injection preparation process⁵. The information was subject to content analysis, to identify stages in the injection preparation process. This information was then used to produce a flow chart to illustrate the sequence of the stages. Variations identified in the content analysis were noted at each stage. The information on injection preparation established in the literature review was also noted (Koester et al, 1990).

3.2.3 Consultation with needle exchange workers.

Drugs agencies in four UK cities were visited and discussions held with the needle exchange workers. These agencies are detailed in appendix 5. Workers were asked to describe the drugs and preparation methods they thought their clients used and safer injecting advice they gave. Qualitative data was collected in note form made at the time of meeting and follow up telephone calls were made if necessary to establish further information. Information was incorporated into the flow chart described in 3.2.2.

3.2.4 Consultation with injecting drug users.

Consultation with IDUs was undertaken to confirm that the stages in the injection preparation process identified were actually used and to establish quantitative information on the stages. The methods used to consult with IDUs will now be described.

3.2.4.1 Recruitment

A definite target number of interviewees was not set prior to commencement. It was important to identify if there were themes in the preparation techniques and it was unknown whether there would be large differences or similarities in the information gathered. Therefore, the quota was set as the interviews progressed. If consistent themes

⁵ HIT, Safer Injecting Training Day, held at Drugs Action, 48a Union Street, Aberdeen. May 1996. Trainer: Shaun Speed.

emerged the quota sample could be smaller than if large differences were found. The most recent Drugs Action annual report gave the ratio of male to female clients as 62:38 (Drugs Action, 1996). It was decided to try to represent these proportions in the sample interviewed.

3.2.4.2 Questionnaire design and piloting

Guidance on questionnaire design was obtained from Moser and Kalton (1971) and Bailey et al (1995). The original questionnaire asked for some demographic details about the IDU and drug use history, then used a series of questions with probes based on the information in the established flow chart (3.2.2 and 3.2.3). However, after piloting the questionnaire on four people a general open question was asked before the questions and probes were used. This was '*Tell me how you prepare your injections*'. Then questions on each preparation stage were asked if it had not been mentioned. The reason for this change was that in the pilot studies often information was given describing the whole preparation process in response to one of the questions, since the researcher had told the IDUs at the start that she wanted to know how they injected. Also it was felt that this open general question allowed more freedom.

The first section of the interview schedule gathered information about the interviewee and established their current injecting status, to allow for variations in preparation technique to be compared against factors such as length of time injecting. Next, details of the drugs and equipment were gathered. Next the preparation techniques used investigated. The drug misuse statistics and the flow chart detailed in sections 3.2.2 and 3.2.3 were used to inform the questions. Closed questions were used when a dichotomous response was required, whereas open questions were used when more a variable response and detailed information was required. Both quantitative and qualitative data was collected. Leading questions were avoided, to minimise bias. Information was collected on the injection administration to assist the researcher in understanding the process. However, this data was not directly used for the work presented here. A copy of the schedule is shown in appendix 6.

Internal reliability

Internal reliability checks were in built to allow the reliability of the interviewee's information to be checked. The interviewer repeated two of the questions at the end of

the questionnaire to recheck the information originally given. These were chosen at the time of interview, to avoid asking a question that did not apply to the interviewee.

External validity

In order to validate the questionnaire, external validity was checked. As part of the interview, 'age', 'age when first injected', and 'all drugs ever used by injection' were asked. The responses of a selected number of interviewees to these questions were validated against similar information held at Drugs Action, as follows: At initial contact with DA, clients are asked to provide their date of birth (so age can be calculated), age when first injected and list all the drugs that they have injected in the past month. Although the latter may not be the same as 'drugs ever used by injection', those listed should have been included in the interview response to the 'all drugs ever used by injection' question, if a valid response was given.

The information recorded by DA at initial contact is held on the DA client database. Records can be retrieved from the database by either searching using the client's initials and date of birth or by entering their name. As the interviewees were anonymous to the researcher, she could not directly search the DA database. Instead the DA advisor to this project, who was at the time of study also the NX/drop-in worker, retrieved the information from the database for the researcher. She was the principle worker who introduced clients to the researcher, so she was aware of which clients were interviewed. She was also aware of their initials and date of birth as these are used on the records of all client contacts, including NX. It was agreed that the NX/drop-in worker would obtain the required information from the database on 20% of interviewees. This meant in practice that for every five interviews, the NX/drop-in worker provided information on one of the clients, whom she selected. She obtained the information on the day the interviews were conducted and identified the clients to the researcher by description. This was appropriate as only a small number of interviews were conducted each day, so a description of the client including their position in the daily interview order was satisfactory in allowing the researcher to compare the information from the interviews with the information from the database, hence undertaking validation.

3.2.4.3 The influence of the interviewer

The researcher conducted all interviews. How the interviewee feels about giving information to the interviewer may affect his response (Moser and Kalton, 1971). The

authors advise a rapport should be established but highlight the danger of over-rapport. The interviewer must not be too familiar or this may make the subject feel uneasy. Ball (1970) suggests the interviewer must have past experience of the field, a knowledge of the drugs sub culture and ideally prior contact with the client before the interview. In an attempt to address some of these issues, the interviewer attended the DA drop-in for three months, prior to the interviews being conducted. The drop-in was an informal session with no appointment system. IDUs could use the session to have a drink and meet with workers and other IDUs. The session was used by the workers to make opportunistic interventions with people who may otherwise not attend a more formalised appointment system. Attendance by the researcher allowed observation of the drugs workers skills and familiarity with the 'scene' to be established. During the interview care was taken to use a friendly, respectful approach as used by the drugs workers, without over familiarity. The researcher made sure she was familiar with the interview schedule and the meanings of the terms used.

3.2.4.4 The Interview

Introduction of the interviewer to the NX clients

The researcher attended as many of the NX and DA drop-in sessions as possible, until a satisfactory number of interviews had been conducted. The NX was open for nine 3-hour sessions per week and the drop-in for one 3-hour session. The NX worker introduced clients to the researcher, stating where she was from, that she did not work for DA and that she was doing research into the use of filters. The researcher then explained the study was looking at the effectiveness of filters and that she was looking to interview IDUs to find out how they prepare and administer injections. She explained that the interview was anonymous, all information would be kept confidential and it was expected to last about 20 minutes. The clients were informed that they were free to withdraw at any time and participation or refusal would not affect the service they received from DA. The client was then asked if they would like to go into one of the private rooms to find out more and consider participating.

Interview atmosphere

The interviews were conducted in a private room next to the needle exchange. Attempts were made to create a relaxed atmosphere by offering the interviewee a cup of tea or coffee and allowing them to help themselves to cigarettes.

Information and consent

Information, as detailed at the beginning of the interview schedule, was told to the client, supported by a written information sheet. The client was then given time to read this and ask questions about the study. After this they were asked if they wished to proceed with an interview. If they agreed, the consent form was signed. The information sheet and consent form are shown in appendix 7. These were kept in a locked cabinet. Both the information sheet and consent form were included with the Ethical Committee application (appendix 3). The interviewee was then asked if they were comfortable with the interview being taped, having been assured that only the interviewer would listen to the tapes. They were also told that answers could be transcribed if preferred. Each tape was sequentially numbered, with only one interview recorded on a tape. Interviewees were told they did not have to answer all questions and could leave at any time. They were assured that the interview was not an investigation into safest injecting practice or a test of who followed DA advice and no information on injecting practices would be discussed with the workers. They were asked to be honest and open to help the research be 'real'. This was done to minimise the temptation to be untruthful if the interviewee found any questions uncomfortable.

The interview procedure

The researcher noted the time the interview commenced. After the data on the interviewee and drugs used was collected, the open question '*Please tell me how you prepare your hits*⁶' was asked or '*Please tell me how your hits are prepared*' if the interviewees injections were prepared by someone else. This was done to allow information to be provided which was not influenced by the interview. The specific questions given under the headings on the interview schedule were asked if an interviewee did not mention or fully explain this step. For example, the researcher could make sure filter use was discussed, if the interviewee did not mention it. Probes, as detailed in brackets on the schedule, were used if the answer given was not full enough. The use of probes is discussed below.

Another open question was then asked. 'Please tell me how you inject' or 'Please tell me how you are injected' if the person did not self-administer, based on revision after the pilot study. Specific questions and probes were again used. Although this information did not inform the laboratory simulated technique, it was gathered to give the researcher a complete insight into the injecting process.

Finally the interviewee's opinions on the most effective methods for delivering harm reduction information and why they thought people did not always follow advice were sought using open questions. This was collected with the view that safer injecting information may be produced from this study. The interviewer closed the recording by stating the time of the interview to the nearest 5 minutes.

The use of probes

The interviewer was careful not to use the probes too soon, to prevent the interviewee interpreting the probe as the expected answer (Moser and Kalton, 1971). The researcher learnt how to identify inadequate response and use the probes only in order to gain an adequate response. Kahn and Cannell (1957) identified five types of inadequate response, as listed:

- I. *partial response*, where the answer is relevant but not complete
- II. *irrelevant response*, where the subject doesn't answer the question asked
- III. *inaccurate response*, where the answer is biased or distorted
- IV. *the verbalised response*, where the subject explains why he cannot answer the question, maybe because he doesn't understand it or is not in a position to answer it because he does not know the answer
- V. *non-response*, where there is no response or the subject refuses to answer.

Because the interview topic was considered to be of a sensitive nature, it was decided that any responses of the types (I) to (IV) warranted the use of probes. Type (V) responses would be acknowledged as an acceptable response and not probed further. This would respect the drug users privacy and avoid pressure to respond, which may lead to an inaccurate answer.

⁶ The term 'hits' is slang, used by drug users to refer to injections or the action of injecting.

Close of interview

After the interview was over, the clients were thanked for their time and participation and again assured of confidentiality. A selection of pens, note pads and sweets were offered as a token of appreciation for their time. Tapes were stored in a locked cabinet with access restricted to the researcher only.

3.2.4.5 Data Analysis

The complete recordings were transcribed. Interviewee information and drugs used by injection were collated in an Excel spreadsheet. Themes from the preparation and administration procedures were identified, based on the guidance of Bailey et al (1995).

These were compared with the flow chart of injection preparation processes developed from the safer injecting advice and drugs workers (3.2.2 and 3.2.3). A revised flow chart of each stage was designed. The details for each procedure at each stage were highlighted on the transcription. The most commonly used procedures were selected for use in the laboratory. For example, the most commonly used quantity of heroin.

The answers to the final two questions were subject to content analysis and kept aside for later use.

3.3 Results

3.3.1 Drugs use by injection

3.3.1.1 Scottish Drug Misuse Statistics

The data tables derived from these statistics are given in appendix 8. Key results, rounded to the nearest whole number are quoted below. Heroin was by far the most commonly reported main drug used in the past month by injectors who were new contacts with services, both in Grampian (88%) and Scotland overall (81%). Buprenorphine, was the second most popular drug amongst injectors nationally (9%), but less popular in Grampian (<1%). The second most common main drug in Grampian was amphetamine (7%), with use greater than the national average (2%). Temazepam was also less common in Grampian (<1%) than nationally (2%). Morphine and methadone injecting showed similar figures at each level, with main use being less for Grampian (1%) than Scotland as a whole (2%). Dipipanone, which is combined with cyclizine in the

pharmaceutical formulation Diconal[®], showed equal incidence at both levels (1%). Other benzodiazepines and opiates were the main drugs of use in a small number of both Grampian and national injectors.

The results of all drugs used by injection in the past month showed that nationally 75% of new contact injectors had used Diconal[®], with a figure of 61% for Grampian. In Grampian, 75% of injectors had used morphine, whereas nationally this figure was 63%. Heroin had been used by 72% of injectors nationally and 66% in Grampian. Buprenorphine had been used by more injectors in Grampian (67%) than the national figure (63%). Nationally, amphetamine had been injected by 26% of injectors at some stage in the month prior to their contact with the service. In Grampian this figure was 38%. Temazepam and other benzodiazepines had been used by 25% of injectors nationally, and 11% of Grampian injectors. Methadone had been injected by 7% nationally and 5% in Grampian.

3.3.1.2 Information from needle exchange workers

The workers from all four needle exchanges reported the majority of their injecting clients used heroin. They reported amphetamine injectors also to be seen, but considered this to be less habitually than heroin. They reported knowledge of some clients injecting tablets, which varied with area, but all considered tablet injection to be less common than that of heroin or amphetamine. In Aberdeen and Dundee, Diconal[®] and buprenorphine were thought to be popular, with the Aberdeen worker also reporting known injection of MST^{®7}. The Edinburgh worker reported previous popularity of temazepam but considered use had recently declined. Injection of methadone tablets was considered to occur, with buprenorphine injection also known. The London worker reported clients receiving methadone and diamorphine ampoules on private prescription. This was considered a rare occurrence by the Scottish workers. The London worker reported frequently seeing cocaine injectors, which was considered rare by the Scottish workers. However, the injection of Diconal[®], buprenorphine and temazepam was considered rare by the London worker. He also knew of the injection of methadone and morphine tablets, but considered this to happen only when ampoules were not available.

3.3.1.3 Information from interviewees

The drugs used by injection reported by the interviewees are detailed with the other interview results in section 3.3.4.6.

3.3.2 Injection preparation methods reported in safer injecting leaflets and training information for drugs workers.

Two main injection preparation processes were identified, those used for heroin and those used for other drugs such as amphetamine and tablets. The difference between the processes was due to heroin requiring conversion to a soluble salt, not required by the others. Six stages in the preparation process of heroin were identified. The flow chart developed from this information is shown in figure 3.1 and discussed below.

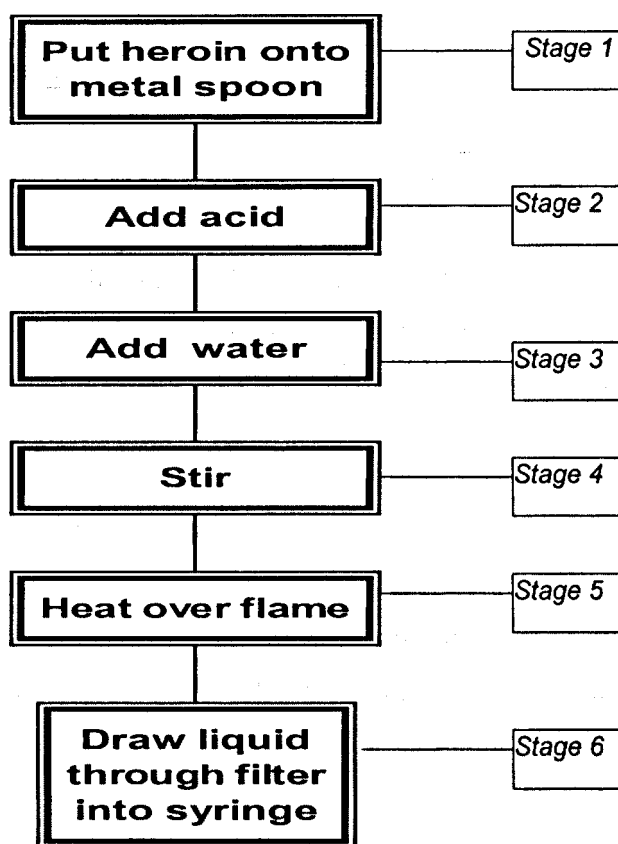


Figure 3.1 Six stages in the heroin preparation process identified from safer injecting information.

Heroin is mixed with acid on a metal spoon. Citric and ascorbic acids are recommended over lemon juice and vinegar. Water is added. Sterile water is a prescription only medicine in the UK, so cannot be purchased or distributed without medical authority. Boiled and cooled water is therefore recommended (Health Education Authority, 1993, HIT, 1995, Exeter drugs Project, 1992, Lifeline, 1992). This mixture is then heated. The filter is then placed on the spoon and the liquid drawn through it into the syringe, ready for

⁷ MST[®] is a sustained release formulation of morphine sulphate, available in a series of strengths.

injection. Unsmoked cigarette filters are recommended in safer injecting booklets (Exeter Drugs Project, 1992, Lifeline 1992). Cotton wool and tissue paper are advised against as they are reported to shed coarse fibres and damage veins (Exeter Drugs Project, 1992, Health Education Authority, 1993, HIT, 1995 Lifeline, 1992).

It is advised that tablets and amphetamine are crushed as finely as possible (Exeter Drugs Project, 1992, HIT, 1995 Lifeline, 1992) and mixed with a small volume of water (HIT, 1995). No addition of acid or heating was mentioned. The use of filters is encouraged.

3.3.3 Injection preparation methods reported by needle exchange workers

The preparation stages for heroin cited by the drugs workers were the same as those in the published information discussed above. For the injection of tablets, many drugs workers reported that clients were thought not to crush the tablets. Instead, they were shaken in warm water in the syringe barrel to dissolve them. It was generally perceived that their clients do not use filters for tablets as they think this will cause them to 'lose the hit', which means reduce the amount of drug in the injection and hence reduce the effects. One of the agencies visited distributed hand-rolling cigarette filters to IDUs through their needle exchange. They reported them being used by placing the whole filter in the spoon and drawing the liquid through. Another agency distributed Water for Injections. This was a statutory agency, which worked closely with one of the trust public health doctors. When the researcher asked how legal supply was arranged, she was told that the doctor had issued a 'blanket' prescription to cover all agency clients. The Water for Injections was distributed by the nurses who staffed the agency. As the prescriptions were not issued to named patients or the packages labelled with their names, the supply was not in fact legal.

3.3.4 Results from the injecting drug user interviews

3.3.4.1 Piloting

The pilot group were perceived to have the same understanding of the questions as the rest of the interviewees, only a lot of repetition existed due to them providing information earlier than it was formally asked. Since it was only the extent of repetition that was

considered to differ the pilot group from the rest of the interviewees, their responses were included in the analysis.

3.3.4.2 Quota Sample

The pilot group gave very similar responses to each other and this trend continued to be seen. After ten interviews, all reporting similar stages, which were also identified from the safer injecting information and drugs workers, it was decided to set the quota at twenty. Twenty clients were interviewed over a period of six weeks. Four were recruited from the drop-in and 16 from the needle exchange. Eighteen were previous clients of the agency and two were new contacts. The desired quota of 8 women and 12 men, set to represent the DA client base, could not be reached in the time available. As a result 4 women and 16 men were interviewed.

3.3.4.3 Data Recording

All twenty interviewees agreed to being taped. The average length of time of interview was 20 minutes, with the shortest being 15 minutes and the longest one-hour. Often the interviewee engaged in conversation after taping had stopped, which was not counted in the interview duration, although relevant information provided was noted. Details shared in this further conversation included information on interviewees drug using careers, personal lives and experiences.

3.3.4.4 Internal Reliability and External Validity Checks

Reliability

No interviewee gave a response to the reliability questions which contradicted the initial response, although the repetition of the question often led to expansion of the information provided initially, which was included in the analysis.

Validity

The response given for age matched exactly for all interviewees. The age when first injected exactly matched for two interviewees and varied by two years for the other two.

For drugs ever used by injection, all interviewees mentioned drugs that were recorded on the DA database at initial contact. Three interviewees reported all drugs that they had reported at initial contact, while one interviewee did not mention one drug reported at initial contact.

3.3.4.5 Interviewee statistics

The mean age of the interviewees was 25 years, with a range of 17 to 47 years. The mean age when first injected was 20 years with a range of 9 to 31 years. Nineteen of the twenty interviewees were currently injecting while one had not injected for one month. The reason given for stopping injecting was an inability to access veins, due to peripheral damage, prompting him to stop. The frequency of use of the 19 injectors varied from occasionally to six times a day. This is further discussed in section 3.3.4.6. Eighteen of the 20 interviewees prepared their own injections. Of these, 17 had learned to prepare by watching or being shown by someone who was already injecting. One reported learning from a feature film that gave detailed illustration of the process, although he later stated that his flatmate had been injecting longer than him and he had watched him prepare. Eleven had shown someone else how to prepare injections, six had not consciously shown someone else how to prepare and one did not answer this question. Two interviewees, who were both female, had their injections prepared by their partners.

3.3.4.6 The manner in which drugs are currently used

Drugs ever used by injection

In considering both current and past use, nineteen of the interviewees had injected heroin and one had never injected heroin. Four of the 19 had injected heroin only, whereas the other 15 had injected other drugs. Nine had injected amphetamines, eight of which were also heroin injectors. Fifteen had injected pharmaceutical tablets. Five had injected Ecstasy tablets. Four reported having mixed more than one drug in an injection. The combinations reported were heroin and cocaine ($n = 1$), cyclizine and morphine ($n = 1$) and multiple combinations of pharmaceuticals and street drugs ($n = 2$). Table 3.1 summarises the drugs the interviewees had ever used by injection.

Drugs currently used by injection

The frequency of injection ranged between once or twice a week, to six times a day. The most common frequency was twice a day (n = 4) or three times a day (n =4). All those who injected tablets, reported using various drugs and formulations, depending on availability. The frequency of injecting was alluded to being less than for heroin. There was some suggestion that tablet injecting was done as a 'treat' for example at the weekends or on special occasions.

Those who had first injected many years ago had a tendency to have injected a greater number of drugs than those who reported recent initiation into injecting. However, the numbers are too small to make any association from this.

Drug ever injected	No. of clients (n=20)
heroin	19
methadone ^a	9
dipipanone	9
amphetamine	9
buprenorphine	6
morphine ^b	5
ecstasy	5
temazepam ^c	3
other sedatives	3
diazepam	2
cocaine	2
other opiates	1
hallucinogens	1
other drugs	1

Table 3.1: Drug and number of clients who indicated they had used it by injection.

^a All 9 methadone injectors reported using Physeptone[®] tablets, while one had also used ampoules.

^b All 5 morphine injectors reported using MST[®] tablets, while one had also used ampoules and another had used morphine sulphate tablets.

^c All 3 temazepam injectors reported using capsules, while one had also used tablets.

3.3.4.7 Quantities used by injection

The quantities used varied, with interviewees stating that availability of drug, money, level of dependency and desired effect were factors that influenced the amount used. However, most heroin users described preparing 'a quarter G bag'⁸ if the drug and money was available. Larger amounts were suggested by some if they wished to be under a greater influence of drug. In some cases the prepared injections were shared with another person. A 'wrap' was the quantity of amphetamine and cocaine reported by all who injected these drugs, which describes a quantity packaged for sale in a single dose amount (Wills, 1997). The amount of tablets prepared for injection also varied with the user, the drug and availability. Several interviewees stated the quantity used would depend on the level of dependency at the time. When indicating approximate amounts used, five was the most common number of buprenorphine tablets injected. Those who injected Diconal^{®9} stated usually one or two tablets were injected. Among those who injected methadone, all had injected tablets and two had also used ampoules. Nine was the most common quantity of tablets injected. One or two Ecstasy tablets were reported to be injected. For morphine, the quantity and formulation varied greatly, so no common amount and type can be concluded. For benzodiazepines the quantities used appeared to depend on other drugs with which they were mixed or the reason for using.

3.3.4.8 Preparation methods.

The main factor that governed the overall preparation method used was the drug concerned. No fundamental differences were found between those who prepared for themselves and those who watched, or length of time since first injection.

Heroin

The six stages identified from the safer injecting literature and drugs workers, shown in figure 3.1, were reported by all interviewees who injected heroin (n=19). No additional stages were reported by anyone, although variations within some stages were identified. Two stages showed no variation. These were, Stage One 'Put into metal spoon' and Stage Four 'Stir'. All interviewees identified a metal teaspoon as being used at stage one and at stage four the spoon contents was stirred using the sheath of the needle until homogenous. All heroin injectors reported using 1 ml insulin syringes, although 1 ml detachable syringes and orange or white sheathed needles were additionally used by one

⁸ G is pronounced 'gee'.

⁹ Diconal[®] is the only available formulation of dipipanone.

heroin user. Another had once used 0.5 ml insulin syringes. Four stages (Stage Two, Stage Three, Stage Five and Stage Six) showed variations. These will be discussed further.

- I. **Stage Two: Addition of Acids:** All nineteen heroin users added acid to their heroin to facilitate solubility. Sixteen people reported citric acid to be used. One these reported a preference for vitamin C, but because the injection was prepared by and shared with their partner, citric acid was used because it was the partner's preference. One person used citric acid or vitamin C. One person used vitamin C. One person said they used either citric acid or vitamin C, and had used lemon juice and vinegar. The quantity of acid added was described in various ways. Two interviewees quantified the amount by describing it as 'about ten grains' and 'four or five grains'. Most of the interviewees (n = 15) described the quantity as a 'small pinch' or other similar terms. Two people indicated the quantity may vary with the quantity of heroin injected. A few interviewees demonstrated the quantity in a 'small pinch' using soil from a plant in the room.

- II. **Stage Three: Source of water:** Ten heroin users used water that was boiled from the kettle. Nine said they used water straight from the tap. The quantity of water used varied, described in units of an insulin syringe. The amount used for a '*quarter G*' bag of heroin varied between 0.5 ml to 2.0 ml. Bigger quantities of water were indicated in some cases to be for shared injections. The amount most commonly reported was 0.8 ml.

- III. **Stage Five: Heating:** All nineteen heroin users heated the drug during preparation. Nine said they stopped heating when the solution bubbled and eleven said they stopped heating when they could see the powder breakdown and the solution go clear. It was noted that some users perceived boiling to mean that they were evaporating some of the drug.

- IV. **Stage Six: Filtering:** All nineteen heroin users filtered their solutions prior to injection. Filtering was perceived to remove solid particles from the liquid on the spoon. All injectors filtered using a piece of a cigarette end. This was described quantitatively by some as a '*quarter*' of the filter or qualitatively as '*a piece*' or similar terms. Nine reported having used a cotton bud or cotton wool, described in the case of the former as being the whole bud removed from the stalk and in the latter, a small piece rolled into a ball. Two people reported having used hand-rolling cigarette filters, placing the filter in the spoon and drawing the liquid through into the syringe. Two also reported having used tissue paper, again placing it in the spoon and drawing the liquid through.

One person had also used a torn piece of clothing. Two people reported having used commercial syringe filters, which one described as '*a couple of centimetres across*' and the other as '*the size of a 2p*'. In both cases the filter was attached to a detachable syringe barrel and the liquid drawn through from the spoon. One person obtained them from a needle exchange in Edinburgh some time ago. The other person obtained them from his mother, who worked in a hospital.

Amphetamine:

Nine of the interviewees had injected amphetamine. Only one of these had not injected heroin. Only one person added acid to their amphetamine, and stated they prepared all drugs the same way for injection, including adding acid and heating. No one else heated the amphetamine. All mixed the amphetamine with water. Four people filtered prior to injection. Five people did not filter, they put the amphetamine powder straight into the syringe barrel and shook it with water. 1 ml insulin syringes were reported for amphetamine use.

Tablets

Of the sixteen tablet injectors, 15 of whom had injected heroin and one who had injected amphetamine, four people stated they used 2 ml syringes and two people stated they used 5 ml syringes with detachable needles for tablets. This information was volunteered, not specifically asked, so it cannot be assumed that the others used 1 ml insulin syringes. For tablets, the preparation method appeared to vary depending on the drug and formulation, but not between users. Three variables were identified, when preparing tablets for injection:

- I. **Crushing:** Coated formulations such as MST[®], were crushed by all users before use. Ecstasy was also crushed. Various other tablets were reported by some not to be crushed and by others to be crushed. Specific details were not asked for. Methods of crushing reported chopping with a razor blade, pressing in the fold of a piece of paper and crushing between two spoons.
- II. **Addition of acids and heating:** Only one person added acid and heated tablets. The other fifteen who had injected tablets did not add acids or heat the solutions using a

heat source. The addition of warm water to promote dissolution was reported as being adequate.

III. Filtering: One person (who also added acid and heated), filtered tablets. One other person reported filtering everything except Diconal[®], because it was perceived that the effects were reduced. One person reported filtering MST[®], but nothing else. The others who injected tablets did not filter as this was perceived to remove some of the drug.

Ampoules.

Ampoules were reported to be mixed with water and then injected, with no further preparation stages.

Reuse of filters

All 19 heroin injectors used filters with heroin and the non-heroin injector, who used amphetamine and Ecstasy, also filtered. Of the heroin injectors, 10 saved their filters for reuse, five did not reuse and four did not give a clear answer. The non-heroin injector did not reuse filters.

3.3.4.9 Injection techniques

Ten of the interviewees stated that they rotated their injecting sites, seven firmly stated that they did not while three did if they could, but stated it depended on available veins. Several reported difficulties accessing veins. Thirteen used a tourniquet, two did not and five did sometimes. All interviewees said drawing blood back into the syringe was done to check if the vein was accessed, which the definition of 'flushing' given at the time by the interviewer. The use of swabs varied, with 12 stating they swabbed prior to injection.

3.3.4.10 Safer injecting advice

Fifteen of the interviewees had received safer injecting advice, 14 of which said they'd received it from DA and one who received it from the Substance Misuse Service. Five people had not received safer injecting advice. The researcher told them such advice was available in booklets from DA workers.

3.3.4.11 Injecting injuries

All twenty interviewees had experienced some adverse effects on health due to injecting. These included bruising, collapsed veins, abscesses, painless lumps taken to be granulomas, pain and swelling after injection and 'track marks' (thrombophlebitis). A few had sought assistance from Accident and Emergency (A&E) for severe symptoms, such as swelling and loss of feeling in a limb and in overdose situations. Two people specifically mentioned they had obtained illicit antibiotics to treat abscesses. Many had not sought medical advice but several reported they had asked a drugs worker for advice. In terms of how people could get treatment, several people said help is only sought if symptoms are severe. Suggestions included A&E, a homeless shelter with a nurse-run health clinic and having medical help at Drugs Action.

3.3.4.12 Delivering harm reduction information

Suggested methods

Several suggestions were made as to how HR information could be delivered. The most common suggestion was for drugs workers to talk to clients and listen. The distribution of leaflets was also specifically mentioned by seven interviewees, with one stating a cartoon style was preferred. Five interviewees specifically mentioned allowing users to work at NXs. The use of videos was mentioned by one. Several interviewees mentioned that users share information. This is illustrated by this quote from one, who was a new contact to the service:

'People pass on what they hear, so even if they don't use the service here [at DA], you might hear the advice through friends'.

Perceived barriers

When asked why people didn't always follow safer injecting advice, eight people specifically mentioned being '*strung out*', which means being in withdrawal. This was also linked to lack of access to clean injecting equipment. Some people stated specific cases such as weekends, night times and when remote from a NX. Three interviewees specifically mentioned information could not be followed while incarcerated, due to lack of access to clean equipment. Factors relating to the individual were also mentioned

including laziness, feelings of no self worth, lack of intelligence, not caring and lack of trust for professionals. Two interviewees also highlighted a culture amongst drug users of not following advice.

3.4 Use of results to develop the laboratory simulation technique

3.4.1 Selection of drugs for the laboratory investigation

Heroin

The decision was made to focus the study on heroin injections as it can be seen from the Scottish Drug Misuse Statistics it was by far the most common main drug used by IDUs (appendix 8, table 1, 2a and 2b). Nationally, 81 % of injectors reported it to be the main drug they used, with a figure of 88 % for Grampian. When all drugs used by injection are considered, 72 % of national injectors had used heroin in the past month, with this figure being 66 % for Grampian. This was also supported by heroin having been injected by 95 % of the IDUs interviewed and perceived by the drugs workers to be the most commonly injected drug amongst their clients. The interviewees who injected the most frequently i.e. between one and six times daily, all injected heroin, illustrating frequent exposure to risk. It was anticipated that arrangement of a legal supply from seized samples would take some time, as discussed in chapter 4. While arrangements were being made, investigation was conducted into injections prepared with tablets, as these could be obtained from pharmaceutical wholesalers. Amphetamine showed greater popularity at local level than nationally in the SDMS. However, it was not studied as it would also require to be obtained from seized samples and it was felt unreasonable to try to obtain more than one drug in this way. The study described in part 2 was also conducted in parallel to the tablet work being done.

Tablets

The tablets were selected on the basis of their overall popularity and with respect to specific identified issues. The decision was made to investigate three types initially, until it was known whether heroin samples could be arranged. From appendix 8 it can be seen that a range of tablets were reported in the SDMS as having been used intravenously, either as the main drug of misuse or at least once in the month preceding contact. Buprenorphine was popular nationally, this is also noted in the literature (Lavelle et al,

1991, Makower et al, 1992, Simpson et al, 1993, Robinson et al, 1993), so it was selected. Temazepam and morphine were also popular, but since several formulations exist and the ones used are not reported in the SDMS, they couldn't be selected¹⁰. Methadone and dipipanone (Diconal[®]) were also popular. Diconal[®] was specifically mentioned by the Aberdeen and Dundee drugs workers as being injected by some clients. Concerns were also being expressed locally about the injection of prescribed methadone tablets at this time. Therefore, Diconal[®] and methadone tablets were selected on the basis of local interest and their indicated use in the SDMS. Although formulation of methadone used cannot be obtained from the Scottish Drug Misuse Statistics, all interviewees who reported having injected methadone had used the tablets. Only one of these had also injected methadone ampoules and no interviewee reported injecting methadone liquid.

3.4.2 Quantities of drugs used in the laboratory investigation.

3.4.2.1 Quantity of heroin used

Ideally, a range of quantities of heroin would have been investigated based on the different quantities stated by the interviewees. However, the amount of heroin available for this study was limited, so the investigation was restricted to the most popular amount. The quantity of heroin indicated as most commonly used in the interviews was 'a quarter G'. This was sometimes injected by one person and sometimes prepared then split between two. The researcher needed to establish whether 'a quarter G' did equal 250 mg. Discussion with drugs workers indicated the units to be grams. Discussion with Grampian Police Forensic department established the weight of heroin in recently seized wraps had varied between 30 mg and 330 mg, with quantities at the higher end of the scale being more common (Wilkie, 1997). This suggests that the quantity in a wrap may vary greatly. As discussed in section 3.1, the use of IDUs or ex-IDUs to measure out approximate quantities of heroin would be illegal and unethical. It appeared from the police data that the quantity in a wrap varied greatly. A study of dealer's adulteration practices carried out by Coomber (1997), showed that dealers do split bulk drugs into multiples or divisions of grams. However, no validation of actual weights was conducted. Also, the survey was conducted using the world wide web, so inclusion depended on dealers having internet access, finding the site and volunteering to participate. Since no direct confirmation of the quantity could be made, it was decided to use the exact representation of a 'quarter G' i.e.

¹⁰ Work investigating the filtration of a range of brands, formulations and strengths of morphine was undertaken as an honours project at RGU. The report by Lois Pollock, 'A Study of Drug Addicts Filtration Techniques Using Morphine Sulphate Preparations', details this work and is available from the School of Pharmacy (012224 262500).

250 mg, for the experiments. This was within the range of seized wraps stated by the police.

3.4.2.2 Quantities of tablets used

Only one quantity for each drug was initially set for investigation, as this preliminary work was done until the heroin could be supplied. The most frequently reported number of Temgesic[®] tablets used to prepare an injection stated by the interviewees was five. Temgesic[®] is available in two strengths. The strength used was not asked and is not determinable from the SDMS. The colour of the packaging was cited by one interviewee, indicating the 200 microgram strength. Therefore, investigation was performed using 5 x 200 microgram Temgesic[®] tablets per injection. Those who injected Diconal[®] stated either one or two tablets were injected. It is only available in one formulation containing 10 mg dipipanone and 30 mg cyclizine. Investigation was performed using 2 x Diconal[®] tablets per injection, as it was thought likely that two tablets would present a particulate scenario worse than one. Among those who injected Physeptone[®], the most frequent quantity used was nine. Only one strength is made (5 mg). Investigation was performed using 9 x 5 mg Physeptone[®] tablets.

3.4.3 Injection preparation: simulated process for heroin.

The six stage flow chart established from the safer injecting advice and discussion with drugs workers, was endorsed by the interviewee information. No further stages were identified. Therefore, these six stages were simulated in the laboratory with the interview information informing the setting of the factors controlled for each stage in the laboratory (e.g. length of time heating). The preparation process used is shown in figure 3.2 and the rationale discussed below.

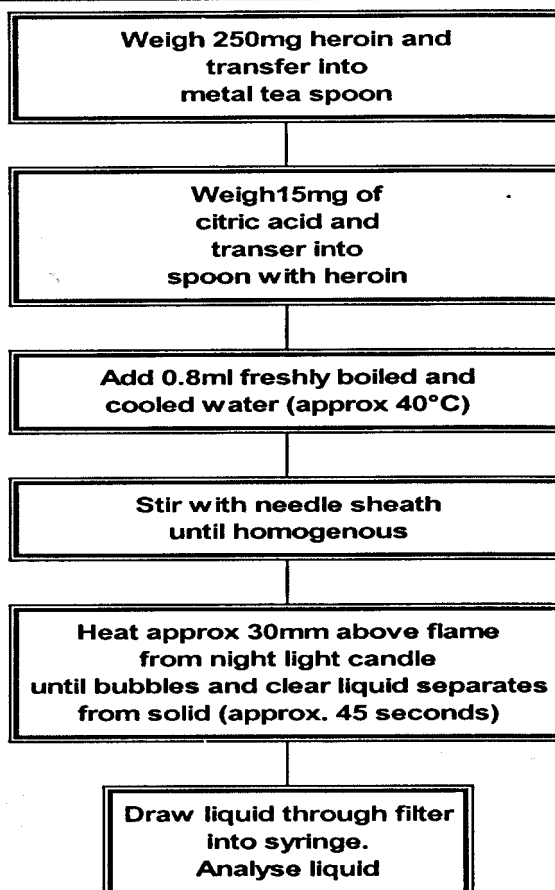


Figure 3.2. Preparation process used for heroin injections made in the laboratory.

3.4.3.1 The choice and quantity of acidifier

Citric acid and ascorbic acid were advocated in the safer injecting information, with vinegar and lemon juice being discouraged. All interviewees used citric acid with ascorbic acid being mentioned by four. Citric acid was chosen for the filter experiments because all the heroin injectors used it interviewed. The most common way of describing the amount used was 'a *small pinch*' or terms considered to mean the same. The quantity of citric acid used was established by weighing ten '*small pinches*' of acid and taking the average weight. This was 14.83 mg, which was rounded up to 15.0 mg

3.4.3.2 The source and quantity of water

The volume of water reported by the interviewees again varied, but the most commonly described quantity was 0.8 ml, so this was used for the study.

Although the interviewees reported water from the tap (45 %) almost as commonly as water from the kettle (55 %), the safer injecting information suggests the use of the latter. This was assumed to be because freshly boiled water is known to contain a reduced

pyrogen load (Collett, 1990). It was freshly boiled and cooled to a temperature of approximately 40°C, which was the temperature of the water used for the first experiment, so set as the standard for all experiments.

The purpose of making the starting temperature constant was to make the effect of the length of time of heating reproducible. The water was decanted from the kettle into a mug, as observed in the literature (Koester, 1991) and described in the safer injecting information. A thermometer was used to monitor temperature. If the water cooled the temperature was raised to 40°C by the addition of hotter water from the kettle.

3.4.3.3 The stirring

The mixture was stirred with the needle sheath until it appeared homogenous, ensuring any lumps were broken down, as described by all the interviewees. 1 ml insulin syringes were used as they were reported by the interviewees and drugs workers to be commonly used for heroin injection.

3.4.3.4 Heating

The spoon was heated by holding the base over a candle flame. Lighters, the gas cooker, burning swabs and matches were used by the interviewees but it was not considered that the source of heat was significant, so for convenience and laboratory safety, a night light candle was used.

The height between the base of the spoon and top of the flame was measured as 30 mm on the first experiment and used for all further work. The time until the end point was described by the interviewees as either when the solution bubbles or when the powder breaks down and the solution goes clear. In practice, it was established that both these end points occur simultaneously, they had just been expressed differently. On the first experiment the time for this to happen was recorded as 45 seconds. This time of heating was used for all further work.

3.4.3.5 The selection of the makeshift filters to be tested

A range of makeshift filters were identified from the literature and safer injecting information (2.5.1) and several were mentioned by the interviewees. The cigarette was

used by all interviewees and observed in the literature (Koester et al, 1990). The drugs workers also considered that they were used frequently. They were therefore selected for investigation. The cotton bud was mentioned by some interviewees (n = 9). The safer injecting information expresses concern around the shedding of large numbers of fibres from cotton wool. The cotton bud was therefore selected for investigation to see if it does result in a higher particle load in the filtrate than the others. The hand-rolling filter was selected because two interviewees had used them and also because they were distributed by one of the agencies visited, who were keen that they were tested. It was also considered that if the paraphernalia laws were changed to allow filter distribution, hand-rolling filters may be considered by some agencies, since the distribution of filters attached to cigarettes would be unlikely. Tissue paper, lint and clothing were rejected as they were not popular amongst the interviewees or mentioned by any of the drugs workers. Tissue paper was mentioned by two interviewees and clothing by one interviewee, but indicated only to be used if a cigarette filter was not available.

3.4.3.6 Selection of the commercially produced filter

As said in 2.5.4, the distribution of syringe filters to IDUs has been identified abroad and anecdotal evidence suggests they have been distributed in the UK in the past. Particles over 5 μm have been discussed as being of particular concern in injections (2.4.1). Therefore, a 5 μm syringe filter was selected for investigation in this study. Preliminary tests using injections prepared with Temgesic[®] tablets did investigate the feasibility of filtering through a 0.2 μm syringe filter (25 mm diameter), which would render the injection sterile, but the filter blocked and complete filtration could not be achieved. The illustrations in Australian IDU safer injecting information (Bergin, 1996, Anon, 1996) and descriptions from those who were aware of previous distribution indicated the 25 mm diameter syringe filter to have been used by IDUs. Also, this had a large surface area considered to aid quick filtration, so this was the diameter chosen. The Gelman Acrodisk[®] brand was chosen in the absence of information on brand type used by IDUs elsewhere, as this was the cheapest brand available.

3.4.3.7 Makeshift filter brand details and methods used to prepare for use

The methods described in the interviews were copied to prepare the filters for use in the lab, as detailed below:

The cigarette filter (Lambert and Butler[®], King Size)

The Lambert and Butler brand was selected because this brand was observed to be commonly smoked by the interviewees and other needle exchange clients. It was also known to be lower priced. The manufacturers were contacted and confirmed the filters are made by Filtrona (see below) and covered with coloured paper. The filter was broken off an unsmoked cigarette and loose tobacco removed. The paper from around the filter was also removed. The filter was torn in two lengthways. One portion was again halved, this time cut across it's length, as described by the interviewees. This gave a quarter of the filter, which was used in the experiments. It was placed in the edge of the liquid and the liquid drawn through it until air bubbled into the syringe.

The hand-rolling cigarette filter (Rizla+ Extras[®], 7 mm acetate Streamline filter tips and Wilson & Co. of Sharrow, 7 mm Streamline filter tips)

The Rizla+ Extras brand was selected because they were distributed by one of the agencies visited. During the course of this project, the brand was discontinued. The supplier informed the researcher that the same filters were now being sold under the name Wilson & Co. of Sharrow¹¹. To confirm this, a letter was written to Rizla and a response given by telephone from Imperial Tobacco, who own Rizla. Imperial Tobacco informed the researcher that the filters were made of cellulose acetate coated in triacetine and purchased in long lengths, 7 mm in diameter, from the manufacturers, Filtrona. They were cut and packaged for sale as the Rizla+ Extra 7 mm brand. Filtrona were contacted by telephone and confirmed that the same manufactured material was supplied to Imperial Tobacco and Wilson & Co (Dobbin, 1998). Wilson & Co. were contacted by telephone. They confirmed their Streamline filters come from Filtrona and are exactly the same as the Rizla Streamline tips. The length and width of both brands of filter were measured and found to be equivalent. Therefore, the Rizla brand was used for the particle work and the Wilson & Co. brand used to continue the analysis work. The whole filter was placed in the edge of the liquid in the spoon and the liquid drawn through until air bubbled in the syringe barrel, as described by the two interviewees who had used them and the drugs workers at the agency where they were distributed.

¹¹ The supplier was Betty Whites Tobacconists, 5 Crighton Street, Dundee. Tel: 01382 266719.

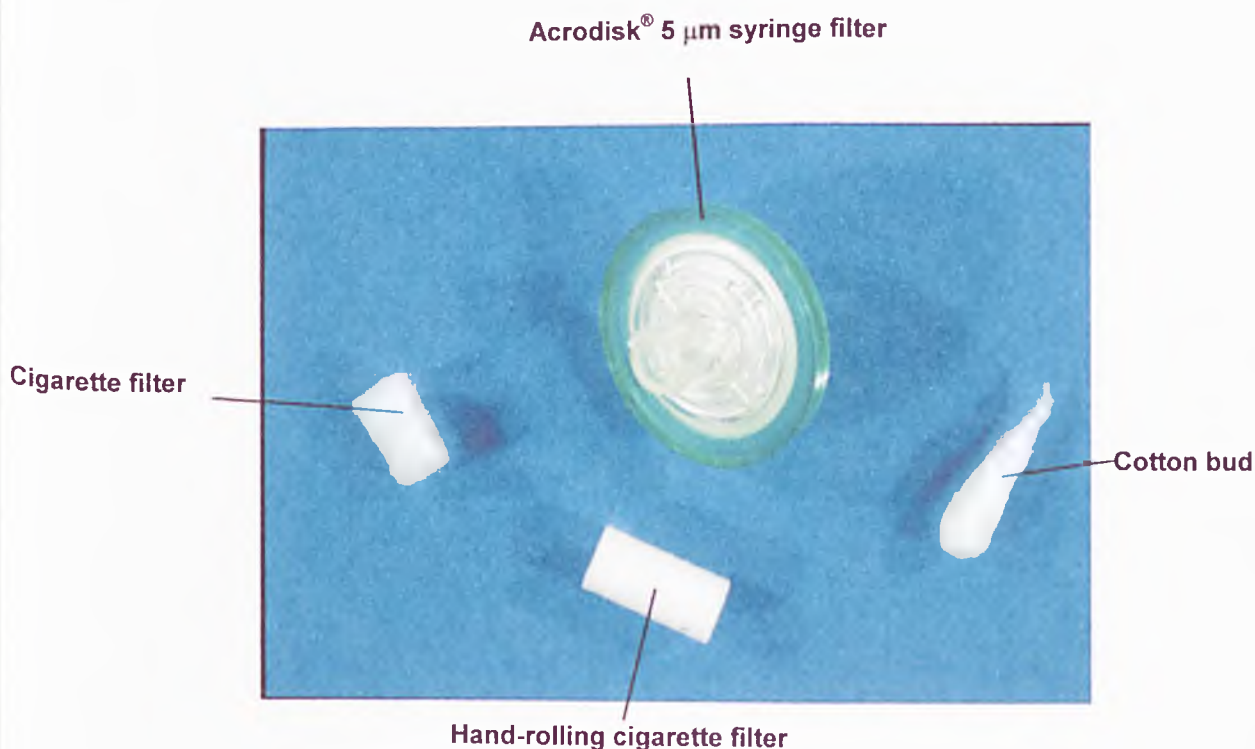
The cotton bud (Unichem Cotton Buds)

The cotton bud tip was removed from the stalk by holding it at the base of the bud and twisting, as described by the interviewees. The loose fibres at the end were then rolled between the fingers to smooth them into a tight strand. IDUs had not been asked about brand of cotton bud, although this was considered likely to vary. The Unichem brand was an arbitrary choice. The packaging stated the buds to be 100% cotton. The cotton wool was placed in the edge of the liquid and the liquid drawn through it until air bubbled into the syringe.

The syringe filter (Sterile Acrodisk[®], 5 microns, Gelman Sciences, product no. 4199)

The 5 micron Acrodisk[®] filter membrane is made of Versapor[®]. This is a hydrophilic acrylic co-polymer on a non-woven nylon support. It has a tensile strength of 3,000 psi, so was considered able to withstand the pressure of filtering a high particle load liquid, such as may be found in the case of IDUs injections. The female luer lock on the filter was attached to a 1 ml detachable syringe. The liquid was drawn through the nozzle, across the membrane and into the syringe, as suggested in the Australian IDU safer injecting information (Bergin, 1996, Anon, 1996) and by the interviewees who had experience of using syringe filters. The filtration was stopped when no more liquid was drawn into the syringe and the filter could be heard to be sucking in air.

A photograph of the filters prepared for use is shown below.



3.4.4 Injection preparation: simulated process for tablets

The information established from the safer injecting information was expanded, based on the drugs workers and interview data. The experimental conditions used to investigate the effects of the filters on injections made from the tablets are shown in figure 3.3 and discussed below.

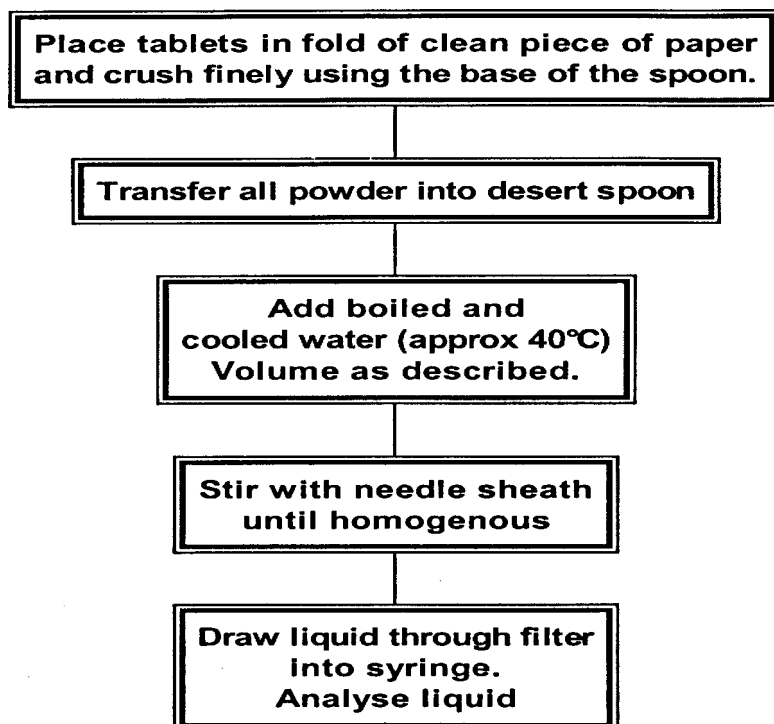


Figure 3.3 Preparation process used for tablets in the laboratory.

3.4.4.1 Crushing

No consistency on crushing or correlation with tablet types under investigation could be made. The safer injecting leaflets state if tablets must be injected they should be crushed as finely as possible prior to dissolving in water. This was reported by some interviewees. However, others also split tablets and shook them with water in the syringe. It was considered possible that the particle load may vary depending on which method was used. Both methods were therefore investigated in the laboratory. Crushing was done by placing the tablets in the fold of a piece of paper and pressing on them with the spoon.

3.4.4.2 Transferring onto the spoon.

The spoon was needed as a vessel from which filtration could take place. Crushed tablets had to be transferred onto a spoon prior to mixing with water. Tablets that were split and shaken were transferred after they had been mixed in the syringe. No acid was added as the interviews and published information indicated that this is not normally done. Also, the drugs in the formulations are in the hydrochloride form, which are soluble (Parfitt, 1999) so this stage was considered unnecessary.

3.4.4.3 Addition of water

Boiled and cooled water from the kettle was used. The volumes used were derived as the most popular stated in the interviews and were as follows. Physeptone[®] = 5 ml, Diconal[®] = 2 ml, Temgesic[®] 2 ml. Five ml and 2 ml syringes were used respectively.

3.4.4.4 Stirring

The crushed powder was stirred using the sheath of an orange needle attached to the syringe, until it all appeared to be wetted and evenly distributed within the liquid on the spoon. The mixture of split tablets that was shaken in the syringe was poured onto the spoon without further agitation.

3.4.4.5 Filtration

The filters used were the same as those described for the heroin work, used in the same way (3.4.3.6).

3.4.5 Investigation into the use of acidifiers

The simulation process used to investigate the use of acidifiers was that used for heroin (fig. 3.3), with the amount and type of acid being the variable under investigation. The filter type used had to therefore be kept constant. Since the cigarette filter was the most popular filter amongst the interviewees, it was used for this work.

3.5 Chapter summary

The methods used to establish the types of drugs commonly injected by IDUs and their injection preparation techniques have been described in this chapter, followed by the results from these investigations. From these results, simulations of the injection preparation processes have been developed to allow controlled investigation in the laboratory. The next chapter will describe the methods used to conduct the laboratory investigation and the consequent results from this work.

Chapter Four

The laboratory investigation

4.1 Methodological issues

4.1.1 Procurement of drugs

4.1.1.1 Tablets

The researcher had to ensure that the drugs used for this study were obtained, stored and destroyed according to the legal requirements of the Misuse of Drugs Regulations (1985). Methadone and dipipanone containing products are controlled by schedule 2 of the regulations whereas buprenorphine is controlled by schedule 3. Pharmacists can lawfully obtain these drugs from licensed wholesalers and possess them for the purpose of professional duties. Discussion with the Home Office inspector for the area, confirmed that they were in agreement with these tablets being obtained from a pharmaceutical wholesaler for this work (Morgan, 1997).

4.1.1.2 Heroin

The Home Office inspector also confirmed they had no objection to the work and that no license would be required for the possession of heroin, as long as it was obtained from a lawful supply. A lawful supply was termed as obtaining police samples that have been released by the courts for destruction (Evans, 1997, Napier, 1997a). Contact was made with all Scottish police forces and it was established that the procedure for destruction varied between regions. In Grampian, the drugs are returned to the police forensic laboratory for destruction (Wilkie, 1997). The police agreed to make the supply, if the Procurator Fiscal (PF) was in agreement. Contact was made with the PF who referred the matter to the Crown Office, as they considered their approval more appropriate in Scotland than that of the Home Office. The Crown Office informed the PF they had no objection to this research, which in turn gave approval to the researcher (Napier, 1997b). A copy of this approval is given in appendix 9. The whole approval process took nine

months from initial contact with the Home Office to supply from the police. The storage and destruction method used are explained in section 4.2. Reference compounds could be obtained from licensed wholesalers so no further legal approval was required for these.

4.1.2 Selection of appropriate particle size analysis equipment

No previous particle analysis work on IDUs injections could be found in the literature, so a method had to be developed. The two principles on which particle size analysis may be based are light extinction and the Coulter principle.

4.1.2.1 Light extinction

The light extinction method is now the B.P stated method for particle size analysis (British Pharmacopoeia Commission, 1998). It uses laser light, which is diffracted when the beam is broken by a particle. The extent of the diffraction is measured to give particle count and sizing. The equipment can be fully automated, quick and easy to use with built in software that allows storage of data. Water is a suitable dispersant for samples. Although the minimum volume for analysis (8 ml) exceeds the volume of the prepared injections, sample dilution to 8 ml with filtered water would have been appropriate. However, at the time of study this equipment was not available within the School of Pharmacy. Although the equipment was available at other RGU sites, use of this equipment was not considered appropriate due to storage and transport issues regarding the controlled drugs.

4.1.2.2 Electrical zone sensing

The electrical zone sensing technique [Coulter principle] quantifies the effects of particles on the flow of electrical current. The Coulter Multisizer operates on this principle: The number and size of particles suspended in a sample of conductive liquid are determined as follows: A sample of the material under investigation is added to the conductive fluid and the particles are kept in suspension by a glass paddle. Two electrodes are immersed in the conductive liquid, the cathode inside a glass tube that has a small orifice in it and the anode outside. Particles are drawn through the orifice, the flow being controlled by a mercury manometer. As each particle passes through the orifice it causes a change in the

resistance between the two electrodes. Voltage pulses are generated with amplitudes proportional to the particle volume, thus allowing the number and size of particles passing through the orifice to be determined. Because the sample is diluted in the conductive liquid, liquids with a heavy particle load can be analysed by adding only a small number of drops. A diagram of the equipment is given in appendix 10 (part A).

4.1.2.3 Advantages and disadvantages of the Coulter Multisizer

Setting up and calibration of the Multisizer can be lengthy, and operation may be disrupted e.g. by a blocked orifice. If this happens, the sample must be discarded and the measurement repeated. However, once optimised, the Multisizer performs rapid measurement (Barber, 1993). Particle colour, composition or refractive index does not affect response, unlike light extinction methods. However, the Multisizer is less sensitive to particle shape than laser diffraction machines. This may mean that long thin particles are not sized accurately. Different types of particle cannot be discriminated, so if more than one kind are present they cannot be separated. This meant particle type and possible source could not be studied, however, this would also be the case for light extinction. The Multisizer counts for a given time or to a given number, it cannot count all particles present in the conducting fluid. Addition of the same sample volume and analysis over the same time period allowed suitable comparison of the results. For the purpose of this work, this was satisfactory, as the aim was to establish measurements that allowed comparison between unfiltered injections and injections prepared using the different methods of filtration. As long as each measurement was made in the same way they could be compared. Background vibration such as a nearby centrifuge can cause reading errors, so it was important to ensure such equipment did not operate at the same time as analysis was performed. Temperature of the conducting fluid must be approximately constant, to prevent variation in response recorded, so this was again controlled as described in section 4.2. It was considered that for the purpose of this study the Multisizer could give satisfactory results, providing the factors described above were controlled. A Coulter Multisizer (Mark IIe) (Coulter Electronics) was kept within the School of Pharmacy and was available for sole use by the researcher in a non-teaching lab, which meant the settings would not be adjusted by others in use and attention would not be drawn to the work with controlled drugs. This was considered an important security measure. The Multisizer was therefore selected for this work.

4.1.2.4 Selection of the Coulter Multisizer orifice size

The Multisizer can measure particles within the size range 0.4 to 1200 μm . However, to cover this range a series of orifice sizes needs to be used. The experiments performed for this study would have been repeated using several orifice sizes to determine if a large spectrum of particles sizes existed in the injections. However, changing the orifice and conducting fluid several times was not satisfactory, as this would take too much time for one operator to prepare the machine, so the sample would not be fresh when analysed. Not enough street heroin was available to allow the preparation of fresh samples for a range of orifice sizes. Therefore, one size range had to be selected. The Multisizer determines particles within the size range of 2 to 60 % of the diameter of the orifice being used. The 100 micron diameter orifice was chosen because it determines particles between 2 and 60 μm , a range which includes the sizes of critical interest in relation to capillary blockage, discussed in chapter 2, section 2.4.1. Using this orifice, particles less than 2 μm and over 60 μm will be sized, but the accuracy in these ranges will be reduced. Particles over 100 μm would block the orifice. When the orifice blocks, this is indicated on the in-built monitor screen.

4.1.3 Selection of appropriate drug analysis equipment.

It was anticipated that diamorphine would be the principle psychoactive drug in the street heroin and it was diamorphine content that would therefore be used to compare the filters. A method had to be found which would allow this to be confirmed and could be used to measure the amount of diamorphine in the injections and filters. Diamorphine rapidly degrades to 6-monoacetylmorphine (6-MAM) and morphine in aqueous solution and both compounds are psychoactive (Parfitt, 1999). Although they would contribute to some extent to the effects experienced by the IDU, they are likely to be present in smaller amounts compared to the diamorphine. However, if a significantly different amount of diamorphine was measured in an analysed injection, an awareness of the amount of 6-MAM and morphine also present would be useful, since this would indicate whether the reduction was due to retention of diamorphine in the filter or decomposition of the diamorphine. In the latter case, the amount of diamorphine would be reduced and the amounts of 6-MAM and morphine increased. In the former case, only the amount of diamorphine would be reduced. An appropriate method had to be found to measure diamorphine, 6-MAM and morphine.

4.1.3.1 High Performance Liquid Chromatography

Love and Pannell (1980) developed a reverse phase high performance liquid chromatography (HPLC) system for the analysis of illicit heroin. Kaa and co-workers used this method as the basis for analysis techniques used to study heroin samples seized in Denmark over a 12 year period (Kaa and Bent 1986, Kaa 1991 and Kaa 1994). The Love and Pannall method has been criticised by Lurie et al (1982), who found diamorphine was not separated from quinine, an adulterant the authors report to be commonly found in their samples. However, Lurie et al analysed heroin seized in Virginia, USA. Analysis of heroin seized in Europe, namely, France (Chaudron-Thozet et al, 1992), Rome (Chiarotti et al, 1991) and Denmark (Kaa, 1991) has failed to detect quinine. Quinine has a similar bitter taste to street heroin and may be added as a bulking agent, (Stein, 1990). This is thought to be done once the heroin is in the USA, because the average purity of heroin is much lower than that found in Europe (Kaa, 1991, Gossop 1993). Given the acceptability of the Love and Pannall method to other European investigators, it was chosen for investigation for suitability for this work. Also, HPLC is known to be robust and give good reproducibility, when optimised. Equipment is readily available in the School of Pharmacy. Also, the Love and Pannall method would be relatively cheap.

Love and Pannall used a 30 cm microbondpak column, which was not available to the researcher. Instead, the ratio of water to acetonitrile in the solvent was increased in an attempt to prolong retention time to compensate for the shorter column. Preliminary work found diamorphine, 6-MAM, and morphine could be isolated using different ratios of solvent, but no one ratio separated them all within a satisfactory time, giving sharp peaks. It was therefore decided that a gradient elution system would be necessary. However, the necessary equipment was not available, so an alternative available analysis method was sought.

4.1.3.2 Capillary Zone Electrophoresis

At this time, Dr Ann Low, also from the Robert Gordon University, School of Pharmacy was completing her Ph.D. project (Low, 1998). In her work, Low developed, optimised and compared methods of analysis for a range of opiates, including diamorphine, 6-MAM and morphine, extracted from urine. The analysis methods Low investigated were: thin layer chromatography (TLC), gas chromatography (GC), both reverse and normal phase HPLC, capillary zone electrophoresis (CZE) and liquid chromatography coupled with mass spectrometry (LC-MS). Low and co-workers concluded that the CZE method was

preferred over the others due to its greater resolution, increased speed and minimal use of solvents (Taylor et al, 1996, Low, 1998). This suggested that this method may be appropriate for this work. In collaboration with Low, her CZE method was used to conduct a preliminary investigation using a sample of the street-heroin. This showed that diamorphine, 6-MAM, morphine and papaverine¹ present in the sample could be separated satisfactorily using a UV light detection method with a wavelength of 220 nm. Caffeine, which is a common adulterant in street heroin (Kaa, 1991, Kaa, 1994) does not absorb at this wavelength, so would not interfere with the analysis. Low's CZE method was used for this work, with the permission of Low. The general principles, benefits and problems of CZE will now be described.

The Capillary Electrophoresis Principle

CZE uses the principle of capillary electrophoresis. A diagrammatical representation of the equipment is given in appendix 11 (part A). The solutes of interest are injected onto a capillary made of fused silica. Applying a high voltage to the capillary filled with buffer creates an electrical field. The solutes separate on the basis of their mobility in the electric field. Mobility is influenced by electro-osmotic flow (see below), balanced against the frictional drag that it experiences. Factors that will influence movement include ionic charge of the solute, molecular size and the viscosity of the liquid with which the capillary is filled. In a given medium, smaller, more highly charged molecules will reach the detector first (Heiger, 1997).

Electro-osmotic Flow (EOF)

The application of a voltage across a capillary filled with buffer (electrolyte) causes a flow of solution along the capillary. This flow pumps solute ions along the capillary towards the detector. This flow occurs because of ionisation of acidic silanol groups on the inside of the capillary, when in contact with the buffer solution. At a high pH, these groups are dissociated resulting in a negatively charged surface. To maintain electro-neutrality cations build up near the surface. When a voltage is applied, these cations migrate to the cathode. Water molecules solvating the cations also move causing a net solution flow along the capillary. The extent of flow is related to the charge on the capillary, the buffer viscosity and the dielectric constant of the buffer. Generally, positively charged ions (cations) will reach the cathode first, followed by neutrals then negatively charged ions

¹ Papaverine is a non-psychoactive opiate, which comes from raw opium (Parfitt, 1999). It is present in street heroin due to lack of refinement in the preparation process.

(anions) (Heiger, *ibid*). This is represented in figure 4.1. The grey circles represent cationic molecules and the black represent anionic molecules. N represents neutral molecules. The arrows represent electro-osmotic flow. The detector will be at the cathode end of the capillary.

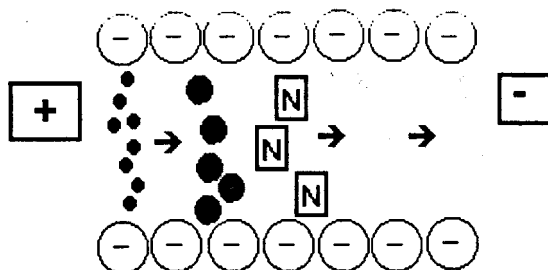


Figure 4.1. Diagrammatical representation of solute migration influenced by electro-osmotic flow in CZE.

Capillary injection techniques

In generally, three injection techniques can be used. These are pressure, gravity and electrokinetic injection. The first two result in homogenous sample volumes being loaded onto the capillary, whereas the last can result in a degree of bias. Electrokinetic (EK) injection was used in this work. In EK injection, the sampling end of the capillary plus a high voltage electrode are inserted into the sample vial, a voltage is applied causing solute ions to enter the capillary by electrophoretic migration and electro-osmotic flow. The more mobile ions enter first, so bias is encountered. However, this increases sensitivity. The bias means non-reproducible peak heights are encountered. To compensate for this, yet to maintain the advantage of the increased sensitivity, an internal standard (IS) is used. The use of the IS is detailed in section 4.4.3.

Advantages and Disadvantages of CZE

CZE requires only small sample sizes, which is an advantage if the amount of material under investigation is limited. However, this was not the case in this work. The equipment is easy to operate and quick, especially automated machines. CZE uses small amounts of relatively simple buffer. Not only does this keep costs low, it also means buffer pH and concentration can be easily varied for optimisation. The capillary itself is also relatively cheap. It is long, so efficiency is high, which gives good separation (i.e. high selectivity). As said, the bias of EK injection means sensitivity is high, which is also an advantage.

This disadvantages of CZE are that the peaks are not reproducible so an IS has to be used. Also, the high voltage used is potentially dangerous, so stringent safety systems have to be applied. The disadvantage of non-automated equipment means if there is an error encountered with the chart recorded, the analysis data is lost.

Automated equipment was the first choice for this work, as it would have allowed analysed data to be stored and recalled if required. It would also conduct automatic data manipulation, which would be quicker than manual measurement and calculation. It would also have avoided loss of data, for example through failure of the chart recorder. This was considered especially important since the amount of heroin available for this work was limited by the quantity that the police were able to supply. However, at the time of this work, only manual equipment was available at the RGU School of Pharmacy for use by the researcher, so this had to be used.

4.2 Procurement, storage and disposal of the drugs used in the laboratory investigation

4.2.1 Procurement

4.2.1.1 Heroin

Grampian Police toxicology laboratory supplied 19.61g of brown heroin to the researcher, which came in four bags from three separate cases. Due to the potential for variation between the samples, they were mixed together to give one batch for the experimental work, allowing the results to be compared. The mixing was done in a mortar and pestle then the powder was transferred into a jar. No information on the sample content was available from the police, as only diamorphine content of individual samples is measured and results from closed cases are not kept in the department.

4.2.1.2 Tablets

The tablets were obtained from a local wholesaler, AAH, East Tullos, Aberdeen. The managing director was contacted prior to ordering as it was thought that the company might query a sudden increase in the amount of CDs being ordered by the School of Pharmacy. As agreed, an outline of the research project was sent to the manager, who then confirmed to the researcher that his company were willing to make the supply to the School of Pharmacy (Cooper, 1996).

4.2.2 Storage, destruction and disposal

The Home Office Inspector for the area, Mr Y Morgan, visited the School of Pharmacy in May 1997 to ensure storage and disposal methods were satisfactory. The following arrangements were agreed:

4.2.2.1 Storage

All drugs were stored according to the controlled drug regulations (RPSGB, 1999). The schedule 2 drugs² were kept in an approved locked cabinet. Buprenorphine, although a schedule 3 drug is also subject to schedule 2 storage requirements, so was also stored in the cabinet. The cabinet was within the School of Pharmacy dispensary. The drugs for this work were separated from other cupboard contents by being stored on a separate shelf in a box marked with the researchers name. Access to the cupboard was restricted to the researcher and designated staff who were all pharmacists. For security, knowledge of the presence of the research materials was restricted to only these people. Both schedule 2 and 3 CDs are subject to CD record requirements (RPSGB, *ibid.*). These were satisfied as follows. Quantities of tablets received were recorded in the dispensary controlled drug register. As they were removed for research, this was entered in the register, with the person authorised to receive them being the researcher. For the street heroin, a controlled drug book was made to record the quantity received and usage. This was done to distinguish it from pharmaceutical diamorphine, as requested by the Home Office inspector. This register was kept in a locked cabinet in the researcher's office. Each quantity of heroin removed was recorded in the register.

The reference compounds that the researcher used were stored in the controlled drug cupboard and again recorded in the reference compound register, which was in use prior to this study.

4.2.2.2 Destruction and disposal

It was agreed with the inspector that tablets remaining at the end of the study could be left in the cupboard for use in student teaching. Any remaining heroin would be required to be destroyed under the Misuse of Drugs Act certificated procedure. This means the area pharmaceutical inspector, police pharmacy liaison officer or Home Office inspector

² i.e. diamorphine including street heroin, methadone and dipipanone.

would have to witness the destruction. All of the street heroin was used in the study so this procedure was not necessary. After analysis, the remaining sample solutions were disposed of immediately, as advised by the inspector, as follows: Both aqueous and methanolic solutions were mixed with quantities of a noxious compound such as acetonitrile and diluted with water. Further quantities of water were added to produce dilute solutions. These were added to either aqueous or organic waste containers and disposed of following standard laboratory procedure.

4.3 Particle size analysis method used for this study

4.3.1 Conductive fluid preparation

The conductive fluid used for this work was normal saline, prepared in-house. Variation between batches may cause variation in electrical conduction, so it was important to be exact in the preparation. Batches of 2 litres were prepared by weighing 18g of sodium chloride (Fison Scientific Equipment, Loughborough), which was transferred into a 2 litre volumetric flask. The sodium chloride was dissolved in sufficient de-ionised water, which was prepared in-house using the Milli-Q ion exchange system (Millipore, Watford). The weighing boat was rinsed with some water into the flask. The solution was made up to the mark with water. The resulting saline was filtered twice through 0.2 μm filter paper (German, Michigan, USA) to minimise particulate contamination. The filter paper was changed after each batch was prepared. The saline was left to equilibrate at room temperature before use.

4.3.2 Equipment handling

Deionised water was rinsed through the Multisizer before and after use to prevent and remove salt deposits. The conductive fluid jar was handled carefully to minimise particulate contamination. Conducting fluid was run through the system before use to remove any water. The sample beaker and stirrer were cleaned with deionised water and rinsed with conducting fluid prior to use. When not in use, the beaker was covered and stored within the sampling stand to minimise atmospheric contamination.

4.3.3 Multisizer settings

The Multisizer was set to count and measure linear diameter of the particles. The output gives a size distribution curve for the measured sample. An example of a Multisizer data output screen reproduced from the Multisizer Operational Manual with permission from Beckman Coulter is given in appendix 10 (part B). On the data output screen, the following information is given. The total number of particles (N) is the raw count of the machine during the analysis period. The coincidence corrected count (\underline{N}) is also given. This is the particle count that the machine considers to represent the actual number of particles, once the correction factor has been applied. This factor takes into account possible errors such as two particles passing through the orifice together, being counted as one. The correction factor that is being applied as analysis is undertaken is shown on the percentage indicator, left of the y-axis. This is shown as the percentage of the total count. For \underline{N} to be accurate, this should be below 20 % (Coulter Electronics, 1988). During operation, results were only recorded if this 20 % or less was achieved, otherwise the experiment was repeated. Cursors on the screen can be moved to either side of the size range of interest, giving the number of particles in this range on the screen (represented by Σ). The cursors can also be moved to allow a count for each channel to be determined. The Multisizer was set to measure the standard 256 channels. The standard time option of 12 seconds was selected. The total number of particles that are drawn from the sample beaker through the orifice in this time is counted. The sample stirrer was set to speed 2 for all analysis to keep the particles suspended. The conducting fluid was used at room temperature. This allowed comparisons in particle load to be made, as all samples were measured under the same conditions.

4.3.4 Background count

Although care was taken in the saline preparation and equipment set-up to avoid contamination with particles, the introduction of particles into the system may not have been avoided altogether. Therefore analysis was performed by recording a background count for the saline and subtracting this from the sample count. Communication with Coulter Electronics confirmed that a background count of approximately 200 or below was considered satisfactory for non-diagnostic analysis (Crouch, 1997). If the background count was above this, the saline in the sample beaker was discarded and the measurement repeated with fresh saline. This was done until a satisfactory background medium was achieved.

4.3.5 Calibration

The Multisizer was calibrated to 256 channels using a standardised suspension of latex beads (Coulter Electronics, Luton) with a label stated diameter of 14.1 μm . The label stated diameter on each standard is determined for each batch of latex by the manufacturer. Calibration gives a measured calibration constant, known as the Kd value. The expected Kd value for the 100 μm orifice stated by the manufacturers is 930.00. A measure calibration constant within 10 % of this value is considered acceptable. On calibration, the width of each channel is equal, but the minimum and maximum values on the range will vary slightly, hence channel borders vary with calibration. The machine was re-calibrated after a period of non-use greater than one week, as recommended (Coulter Electronics, 1988).

4.3.6 Validation

Validation of the Multisizer was necessary to allow confidence to be placed in the results obtained. It was performed using calibration standard latex beads of a range of stated label sizes. The greatest number of particles in the distribution should be equal to or close to the stated label size of the latex beads. For the validation work, the channel that contained the peak number of the particles in the distribution was recorded (i.e. the measured size of the majority of the latex beads in the calibration standard). For comparison purposes an actual particle size was needed, not a size range, so this was taken to be the median of the channel. The particle size range (i.e. the base width of the particle size distribution) was recorded as follows: the smallest particle was taken to be the lower size of the smallest channel and the largest particle was taken to be the bigger size of the biggest channel.

No previously published method could be found describing Coulter Multisizer validation, so validation methods had to be designed. This was done on the basis of standard factors usually assessed in other experimental work as described in 4.3.6.1 to 4.3.6.5.

Relative standard deviation (RSD) was chosen as the value used to measure the validity of the experimental equipment for both the Coulter Multisizer and CZE work, because it allows the variation in the results, termed the standard deviation (SD), to be compared with the mean from the set. As an example, in theory, the results obtained from a repeated set of analyses of the same material should be the same, but in practice they

rarely are. The acceptable RSD is the limits of variation allowed in order for the results to be considered valid.

As said, no previous guidance on conducting validation experiments with the Coulter Multisizer could be found. Therefore no guidance existed on the acceptable RSD value that could be used to determine whether the results of the validation experiments were indeed valid. However, since RSD values are usually below 5%, a value of 4% was considered to be acceptable for this work, following discussion with the Director of Studies, who has experience in the particle size analysis field.

4.3.6.1 Reliability

A reliable machine should give consistent results when a measurement is repeated, assuming the sample is standardised. Separate analyses were done on four sample suspensions each containing three drops of 13.7 μm latex. The peak base width and height were recorded. The readings were compared by calculating their RSDs.

4.3.6.2 Precision

Latex beads do not dissolve or swell in saline, so repeated measurements on one suspended sample should be the same. To check the precision of the Multisizer, three drops of latex (13.7 μm diameter) were added to the sample beaker. Four readings were taken over a period of approximately fifteen minutes from the same sample suspension. The same readings were taken as for 4.3.6.1 and RSDs again calculated.

4.3.6.3 Accuracy

To check accuracy, five latex calibration standards of the label stated sizes 5.96, 9.5, 13.7, 14.1 and 19.2 μm were analysed. The mode size was compared with the stated label size to investigate how close the measurement was to the manufacturer's measurement.

4.3.6.4 Within-day variation

Latex calibration standards of the stated label sizes 5.96, 9.5, 13.7, 14.1 and 19.2 μm were analysed four times within the same day, with measurements taken as in 4.3.6.1 and results compared by calculating the RSDs.

4.3.6.5 Day to day variation

Latex calibration standards of the stated label sizes 5.96, 9.5, 13.7, 14.1 and 19.2 μm were analysed four times over the period of one week, with measurements taken as in 4.3.6.1. The RSDs were again calculated.

4.3.7 Experimental work comparing the effectiveness of the filters

4.3.7.1 Sample readings

For each sample, the value of \underline{N} was recorded. The number of particles within the size ranges of interest was obtained, by moving the cursors to the size range limits. These size ranges were set as follows:

- 2 to < 5 μm
- 5 to <10 μm
- 10 to <20 μm
- 20 to 50 μm

The size range 2 to <5 μm was selected because it would show the presence of particles smaller than lung capillaries. The range 5 to <10 μm would show particles that may potentially block lung capillaries. The other sizes were set because the terminal arterioles of the vascular system are between 20 and 50 μm (Friedman et al, 1996), so particles within these size ranges may block these small vessels. The size range was split in two to give more detail of the size of the particles in this range of interest. Because the channel limits vary with each calibration, actual sizes were rounded up or down, whichever was nearest, to the above size limits.

To make calculation quicker, background and sample readings were input into a Microsoft Excel (ver.5) spreadsheet, where subtraction was performed automatically, to give the

adjusted results. Each experiment was performed three times. The average \bar{N} and average number of particles in each size range were calculated from the three experiments. The average number of particles in each size range was then calculated as a percentage of the average \bar{N} to show the distribution of the particles in the size ranges measured.

4.3.7.2 Sample addition

The volume of analyte added for each measurement was 50 μl , removed using an automatic pipette, which had been previously validated. It was considered possible that a reduction in particle count may occur due to particles dissolving when stirred in the saline. To minimise this effect, analysis was performed immediately after the sample dispersed³. If the orifice blocked, the sample was discarded and the injection prepared again.

4.3.7.3 Controls

To check the contribution to the particle load of the injecting paraphernalia and other factors involved in the preparation process (e.g. operator and environment), controls were performed. Both water from the kettle and Water For Injections (WFI) were used as this also allowed comparison of the resulting particle load between water with an uncontrolled particulate count (kettle water) and water prepared under conditions to minimise particulate contamination (WFI). The controls were performed as follows:

2 ml of water was put onto the spoon. It was stirred with the needle sheath and heated until it bubbled. Unfiltered samples were analysed. Samples that had been filtered with the four filters under investigation were analysed. Also tested was 2 ml water put into the 2 ml syringe barrel and shaken then the sample removed.

4.3.7.4 Experimental data comparison

Direct comparison of samples removed from the same injection before and after filtration was not considered possible. Initially, this was attempted but after some difficulties it was decided to compare filtered injections with separate unfiltered injections, prepared in exactly the same way, save for the filtering. The difficulties experienced when attempting to remove the sample before and after filtration from the same injection were: (1) the first

³ The coloured nature of the injections made it possible for this to be observed.

work done was with the tablets. The unfiltered sample commonly blocked the orifice so the injection had to be discarded and the experiment repeated. This became quite wasteful of drug and was viewed as a potential problem in the heroin experiments due to the limited amount of drug anticipated. (2) removal of liquid from the unfiltered material reduced the volume of the final injection, which at the time was considered unacceptable, as it would prevent the final injection representing exactly what the IDU would obtain. (3) while the analysis of the unfiltered sample was performed and the Multisizer prepared for the filtered sample analysis, the filtered injection would be waiting, so it would not be analysed 'fresh' and hence not represent as close as possible what the IDUs inject. (4) physically, it was difficult for all the work to be performed by one person quickly, especially since the equipment was not automated.

The experiments with unfiltered injections made using tablets were performed using both tablets that had been crushed prior to mixing with water, as described in safer injecting leaflets, and tablets which had been split in two and mixed with water, as described by some of the interviewees. This was to determine which method resulted in the least particulate contamination. For the comparison with filtered injections made from tablets, the results from the injections prepared by crushing the tablets were used as this practice is suggested in safer injecting leaflets.

To summarise the work that was done for each drug. Each type of filter was used to prepare three injections. Immediately after preparation, particle size analysis was performed on a sample removed from the injection. The average results were taken and particle size distributions in the injections produced. The filters were compared by calculating the percentage reduction that they produced in the total N . This was done by taking the average N from three analyses of unfiltered injections to represent 100% and calculating the average N from the filtered injections as a percentage of this. Although in diagnostic and formulation work this type of comparison would be inaccurate, it was considered appropriate for this work given that the particle count and distribution will vary greatly. Exact results would be meaningless in this situation, but the overall trends gave an indication of the effects of the filters.

4.4 Heroin quantification methods

4.4.1 Equipment and Materials

The ISCO Model 3850 Capillary Electropherograph with built in ultraviolet detectors was used. The wavelength of detected used was 220 nm, as Low found this to be the optimum wavelength for opiate detection in her work. A further advantage is that caffeine does not absorb at this wavelength, so interference from caffeine that may be present in the samples (Huizer, 1983, Kaa, 1991, Kaa, 1994) is not an issue. The capillary was unmodified silica, Lincoln ISCO Quality CE, 50 μm in diameter and length of 1 metre. The chart recorder used an ABB Servogor SE120, set at a speed of 1 cm min^{-1} .

Water was prepared to HPLC grade in-house, using a Millipore Milli-Q system (Millipore, Watford). HPLC grade methanol was obtained from Ratheburn (Walkerburn, UK). Disodium hydrogen orthophosphate and orthophosphoric acid were of AnalaR grade supplied from Fisons (Loughborough, UK). Standard compounds were diamorphine and levallorphan from D.M Wood, (Aberdeen UK), morphine from Sigma (Poole, UK) 6-monoacetylmorphine from McFarlane Smith (Edinburgh, Scotland) and papaverine from BDH (Poole, UK).

4.4.2 Electrolyte

The optimum electrolyte that Low established was used. This contained disodium hydrogen orthophosphate 100 mM, buffered to pH 6 with orthophosphoric acid. It was prepared in 1 litre volumes, and degassed by filtration through a 0.45 μm Acrodisk[®] (Gelman, MI, USA) prior to use. The system was run for 10 minutes before use to allow it to equilibrate.

4.4.3 Internal Standard

As explained (4.1.3.5), an internal standard (IS) was required to allow results to be compared. Levallorphan was used, as Low had shown it had similar mobility to the analytes of interest in the buffer used. This would mean there would not be a long delay between IS peak and sample peak detection. A stock solution of levallorphan in methanol was made at concentration of 104 μgml^{-1} . This was used for all the work except the preliminary analysis of heroin where a stock solution of 112 μgml^{-1} was used.

4.4.4 Data collection.

Low had shown that the first three injections from an aliquot of sample gave satisfactory linear response. Further injections lost linearity. Therefore, for each analysis the resulting peak heights from the initial electropherogram and two consecutive runs were taken. The peak height ratio to the internal standard was calculated for each and the average ratio taken. This average ratio was used to calculate the amount of diamorphine, 6-MAM and morphine in the sample solutions and consequently, the prepared injections.

4.4.5 Preliminary analysis of street heroin

Prior to validation, preliminary analysis was performed on a small quantity of street heroin. This was done for three reasons:

1. To confirm whether Low's method could give a satisfactory separation of the peaks seen from the analysis.
2. To investigate for the presence of the opiates that were expected to be contained in the sample (diamorphine, 6-monoacetylmorphine, morphine and papaverine) and investigate whether other peaks were seen at the 220 nm wavelength of determination.
3. To determine the percentage content of the opiates under investigation in the street heroin, allowing appropriate dilution factors to be used in the sample preparation process.

A standard solution containing diamorphine $5.06 \mu\text{gml}^{-1}$, 6-MAM $2.24 \mu\text{gml}^{-1}$, morphine $1.00 \mu\text{gml}^{-1}$ and papaverine $1.02 \mu\text{gml}^{-1}$ was prepared. 10.9 mg^4 of street heroin was dissolved in 50 ml of methanol. Methanol was used to ensure complete dissolution, because opiates are more soluble in methanol than water (Parfitt, 1999). Two 10 ml flasks were taken, into each 0.2 ml of IS ($112 \mu\text{gml}^{-1}$) was added. In one, 0.2 ml of the standard solution was added, while 0.2 ml of the street heroin solution was added to the other. Both were made up to 10 ml using water and analysed. The electropherogram produced from the standard was compared with that of the sample as follows: Migration times were measured and compared. The electropherograms were visually inspected for satisfactory

⁴ From the work of Low (1998), the quantity of street heroin, the dilutions factors used to prepare the sample and the corresponding sensitivity setting of the CZE equipment could be estimated. This was based on the assumption, as identified in the literature that the diamorphine content of street heroin might be between 40 and 60% (King, 1997). It was predicted that a dilution as described of approximately 10 mg of street drug would be satisfactory and allow the settings to be optimised. 10.9 mg was the exact weight achieved

peak separation and the presence of any other peaks. 0.2 ml of the standard solution was added to the sample flask and analysis of the sample repeated. This was done to confirm the identity of the peaks. Since the concentration of opiates in the standard solution was known, the peak height ratios of the opiate peaks to IS could be used to determine the concentration of opiates in the sample flask using simultaneous equations. Consequently the percentage content of the opiates of interest in the street heroin could be calculated.

4.4.6 Linearity

To ensure the results could be used to accurately determine the amount of opiates in the analysed samples, the linearity of the analysis method over the range of concentrations had to be checked. A range of concentrations was made from stock solutions, which encompassed the concentration range of the analysed samples. These were injected with internal standard, at a concentration of 10.0 μgml^{-1} (6-MAM and morphine) and 11.2 μgml^{-1} for the diamorphine. A greater concentration range of diamorphine was investigated due to its greater content in the street heroin, as was determined by the preliminary analysis. The resulting peak height ratio was plotted against concentration, using Excel (2000), and linear regression analysis performed. The correlation co-efficient, slope, standard deviation of the slope and y-intercept were all determined. The concentration ranges investigated are shown in μgml^{-1} in table 4.1.

Diamorphine	6-MAM	Morphine
0.00	0.00	0.00
11.54	1.00	2.50
23.00	5.00	5.00
34.50	10.00	10.00
46.00	-	-
57.50	-	-

Table 4.1 Concentration shown in μgml^{-1} of solutions used to investigate the linearity of responses obtained using the CZE experimental method.

4.4.7 Validation

To ensure confidence could be placed in the results obtained and the experiments conducted over time were meaningful, the CZE method had to be validated. Although Low

had conducted extensive validation in her work, the equipment used for this work was of a different model and the researcher was different, so validation had to be performed. RSD was chosen as the method of assessment for the same reasons as given in 4.3.6.

In her CZE analysis of opiate solutions, Low (1998) considered that RSD values of less than 3.5 % indicate a method has sufficient ruggedness to allow analysis to be undertaken. Although Low was considering peak area ratios as opposed to peak height ratios, as they are computed from the same data output, this was also considered an acceptable limit for this study.

4.4.7.1 Within day variation

A standard solution containing diamorphine $9.28 \mu\text{gml}^{-1}$, 6-MAM $9.23 \mu\text{gml}^{-1}$, morphine $9.31 \mu\text{gml}^{-1}$ and IS $10.4 \mu\text{gml}^{-1}$ was prepared. Analysis was performed five times within one day. The average peak height ratio for each drug was taken and the SD and RSD of the average ratios calculated.

4.4.7.2 Day-to-day precision

A standard solution containing diamorphine $9.28 \mu\text{gml}^{-1}$, 6-MAM $9.23 \mu\text{gml}^{-1}$, morphine $9.31 \mu\text{gml}^{-1}$ and IS $10.4 \mu\text{gml}^{-1}$ was prepared. Analysis was performed daily over a five-day period. The average peak height ratio for each drug was taken and the SD and RSD of the average ratios calculated.

4.4.8 Standard solutions

One set of standard stock solutions was prepared for use in all the injection and filter analysis work. They contained diamorphine $92.8 \mu\text{gml}^{-1}$, 6-MAM $92.3 \mu\text{gml}^{-1}$, morphine $93.0 \mu\text{gml}^{-1}$ and levallorphan $104.0 \mu\text{gml}^{-1}$ respectively. Low had shown deterioration of these compounds when dissolved in HPLC grade water, so the stock solutions were prepared using methanol and stored in the refrigerator. Further analysis showed them to be stable over the period of study. Each day, these standard solutions were allowed to equilibrate to room temperature then used to prepare a solution. This was done by mixing 1 ml of each and diluting to 10 ml with HPLC grade water. The ratio of standard peak height to IS peak height was calculated. When samples were run the ratio of sample

peak to IS peak was also calculated. Using simultaneous equations, the amount of drug in the injections was calculated.

4.4.9 Analysis of blank injections (controls)

To be sure that factors in the injection preparation process other than the drugs were not contributing to the peaks seen, blank injections were analysed. They were equivalent to the analysed injections, prepared in the same way (fig. 3.3), but without the addition of drug. One was prepared using each of the four filters to be tested and analysed. One was also prepared using ascorbic acid (15 mg) instead of citric acid and filtered through the cigarette filter. They were analysed in the same way as described for the injections (4.4.10).

4.4.10 Analysis of the filtered injections.

Injections were prepared from street heroin, as detailed in chapter 3 and figure 3.3. They were diluted for analysis as follows: The resulting injection was transferred into a 100 ml flask. The syringe was rinsed with methanol and the washings transferred to the same flask, which was made up to the mark with methanol. These flasks were stored in a refrigerator in case of a need for reanalysis. 1 ml of this methanolic solution was mixed with 1 ml of the IS stock solution in a 10 ml flask. This was made up to the mark with water to give the sample for analysis. For each filter, the experiment was repeated five times. The amount of diamorphine, 6-MAM and morphine in the analysed sample was calculated by comparing the peak height ratios with those of the standard. After considering the dilution factors applied, the amount of opiates in the 100 ml methanol flask and hence the prepared injection was calculated.

To compare the effects of the different filters on the amount of diamorphine in the prepared injections, the calculated quantities of diamorphine were compared statistically using Tukey's Honestly Significant Difference (HSD) (95% c.i, one-way) (Li Wan Po, 1998), which was performed using Statistical Package for the Social Sciences v.6.0 (SPSS inc, Illinois). This test was chosen after consultation with RGU statistician, Alex Wilson. It considers all results not just the average in a set of data, so gives greater sensitivity over tests that only use averages, such as the student t-test.

4.4.11 Analysis of the drug retained in the filters.

The filters used for the above experiments were analysed. For the makeshift filters, the whole filter was dropped in a 25 ml flask containing approximately 10 ml of methanol and shaken. For the syringe filter, the filter was flushed with methanol twice in both directions into a 25 ml flask. In all cases the resulting solution was made up to the mark with methanol. Samples for analysis were prepared by mixing 1 ml of this methanolic solution with 1 ml of IS and diluting with water to 10 ml. The calculated quantities of diamorphine released from the filters were compared statistically, again using Tukey's HSD test (95% c.i, one-way), as in 4.4.10.

The filters were also weighed before and after use to find out the weight of material that they retained.

4.4.12 The effects of acidifiers, water and the preparation process

As said in chapter 2, the purpose of conducting experiments investigating the effects of acidifiers was to show that acidifiers are required in the preparation of brown heroin and to test the belief that heating the injection for longer and adding more water would not increase the amount of diamorphine in the injections.

The cigarette filter was used to filter all the injections prepared in the acidifier experiments. Injections were diluted and analysed as in 4.4.10.

Altering the quantity of acid

The quantities of acid investigated were based on fractions or multiples of the pinch (15 mg) that was used for the filter work. This was to allow the findings to be explained in IDUs terms. The amount of heroin available was limited. As citric acid was the most popular acid, three quantities were tested. These were 30 mg ('two pinches'), 7 mg ('half a pinch') and 3 mg ('quarter a pinch'). The last quantity was tested instead of no acid, which was initially planned. The first attempt to filter a mixture with no acid established that this couldn't be done as the flocculated suspension of heroin was too thick and very little fluid could be drawn into the syringe.

Two quantities of ascorbic acid were tested. These were 15 mg (to allow comparison with the 15 mg citric acid results) and 60 mg (to illustrate the effects of using a significantly greater quantity).

pH

The pHs of the injections were measured using a pH meter with a probe small enough to fit into a small vial (Corning, model 12). The injections were decanted into the vial, then washed into the 100 ml flask for analysis sample preparation. All experiments were performed three times and the average results taken.

Increasing the quantity of water

Three experiments were performed using 15 mg of citric acid and increasing the quantity of water by 50 % from 0.8 ml to 1.2 ml. The average amount of diamorphine in the injections was calculated.

Detection of drug lost in preparation

Qualitative tests were performed to identify whether diamorphine could be found on the spoon, on the tip of the needle sheath and in the vapour that evaporated from the spoon on heating. The solid material remaining on the spoon after one of each of the experiments conducted with the four filters was washed with approximately 10 ml of methanol into a beaker. From this, 1 ml of the solution was diluted to 25 ml with methanol. 1 ml of this was mixed with 1ml of IS in a 10ml flask and made up to the mark with water. A sample of this was then analysed. Vapour from the bubbling liquid on the spoon was collected in a watch glass above the spoon. This vapour was washed from the watch-glass using methanol, into a beaker. 1 ml of this was mixed with 0.5 ml of IS and made up to 10 ml with water, a sample of which was analysed. A used needle sheath from one of each of the experiments was stirred in about 1ml of methanol and analysed in the same way as the washings from the watch-glass were. These qualitative experiments were only performed once.

4.5 Tablet quantification by other researchers

Time restraints prevented the analysis work for the tablets being performed. Instead, RGU students carried out work investigating Diconal[®] and morphine as undergraduate honours projects. These are not discussed, as this researcher did not perform them. Instead the reader is referred to the reports of Heney (1998) and Pollock (1998), available from the Robert Gordon University, School of Pharmacy, tel. 01224 262500.

4.6 Results: Particle size analysis

4.6.1 Calibration

The Multisizer was calibrated four times during this work, once before validation, once after the tablet work had been performed and twice during the heroin work. All Kd values were within the acceptable range, with the value furthest away from the expected Kd value (930.00), being 909.22.

4.6.2 Validation

4.6.2.1 Reliability

The results from the reliability check are given in table 4.2.

	Mode particle size (μm)	Smallest size in distribution (μm)	Biggest size in distribution (μm)
	14.06	11.05	18.02
	14.54	10.81	17.72
	14.06	11.05	17.54
	14.3	10.81	18.02
Mean	14.24	10.93	17.83
SD	0.23	0.14	0.24
RSD %	1.62	1.28	1.35

Table 4.2 Results of the reliability check performed four times using calibration standard latex beads 13.7 μm diameter.

4.6.2.2 Precision

The results from the precision check are given in table 4.3.

	Mode particle size (μm)	Smallest size in distribution (μm)	Biggest size in distribution (μm)
	14.06	10.81	18.26
	14.3	10.81	17.06
	14.06	11.05	18.02
	13.82	10.57	17.78
Mean	14.06	10.81	17.78
SD	0.20	0.20	0.52
RSD %	1.42	1.85	2.92

Table 4.3 Results of the precision check performed four times over a fifteen-minute period using one sample of calibration standard latex beads 13.7 μm diameter.

4.6.2.3 Accuracy

The results from the accuracy check are given in table 4.4.

Stated Latex Diameter	Mode channel size
5.96	5.769-6.009
9.5	9.134-9.615
13.7	13.7-13.94
14.1	14.18-14.66
19.2	18.99-19.23

Table 4.4 Accuracy of Multisizer measurement. (n = 1).

4.6.2.4 Within-day variation

The results from the within-day variation measurements are given in table 4.5.

	Labelled latex size (μm)				
	5.96	9.5	13.7	14.1	19.2
Mean	5.68	9.25	14.06	14.69	18.96
SD	0.06	0.00	0.20	0.11	0.41
RSD %	1.06	0.00	1.42	0.74	2.16

Table 4.5. Within day variation of Multisizer measurements ($n = 4$)

4.6.2.5 Day-to-day variation

The results from the day-to-day variation measurements are given in table 4.6.

	Labelled latex size (μm)				
	5.96	9.5	13.7	14.1	19.2
Mean	5.95	9.28	13.97	14.33	19.17
SD	0.3	0.21	0.15	0.2	0.12
RSD %	5.04	2.26	1.07	1.40	0.63

Table 4.6. Day-to-day variation of Multisizer measurements ($n = 4$)

4.6.3 Controls

The results from the controls are shown in table 4.7 and 4.8.

4.6.3.1 Kettle water

	Shake in Syringe	Stir on Spoon	Cigarette filter	Hand rolling- filter	Cotton bud filter	Syringe filter
<i>N</i> avg.	41	30	23	65	39	77
Particle size distribution: avg.number of particles (% of total <i>N</i>)						
2 - 5 μm	38 (92.7)	23 (76.7)	18 (78.3)	58 (89.2)	31 (79.5)	77 (100.0)
5 - 10 μm	1 (2.4)	2 (6.6)	3 (13.0)	5 (7.7)	7 (17.9)	0
10 - 20 μm	2 (4.9)	4 (13.3)	1 (4.4)	2 (3.1)	1 (2.6)	0
20 - 50 μm	0	0	1 (4.4)	1 (1.5)	0	0

Table 4.7 Average coincidence corrected particle count and average particle size distribution (shown to the nearest whole particle) in blank injections prepared with kettle water (n = 3).

4.6.3.2 Water for Injections

	Shake in Syringe	Stir on Spoon	Cigarette filter	Hand rolling filter	Cotton bud filter	Syringe filter
<i>N</i> avg.	107	8	16	17	112	9
Particle size distribution: avg.number of particles (% of total <i>N</i>)						
2 - 5 μm	96 (89.7)	8 (100.0)	14 (87.5)	12 (70.6)	104 (92.9)	4 (44.4)
5 - 10 μm	7 (6.5)	0	1 (6.3)	2 (11.8)	7 (6.3)	1 (11.1)
10 - 20 μm	2(1.9)	0	1 (6.3)	2 (11.8)	1 (0.9)	4 (44.4)
20 - 50 μm	3(2.8)	0	0	0	1 (0.9)	0

Table 4.8. Average coincidence corrected particle count and average particle size distribution (shown to the nearest whole particle) in blank injections prepared with Water for Injections (n = 3).

4.6.4 Effects of filters on particle content of heroin injections

Observations on use:

All four filters were quick and simple to use. The needle did not block during the filtrations performed through the needle i.e. the makeshift filter experiments. The syringe filter required slightly longer than the makeshift filters, as time had to be allowed to draw the liquid out of the filter disc and air through, after all the liquid from the spoon had been removed. All four filter times and processes were considered likely to be acceptable to IDUs. All four filters took on a brown appearance on use with undissolved material obviously attached to the makeshift filters and drawn into the tip of the SF.

The results from the filter experiments on heroin injections are given in table 4.9.

	Unfiltered injection	Cigarette filter	Hand rolling filter	Cotton bud filter	Syringe filter
N avg.	2326	487	225	255	63
Particle size distribution: avg.number of particles (% of total N)					
2 - 5 μm	1895 (81.5)	477 (98.0)	210 (93.3)	208 (81.6)	59 (93.7)
5 - 10 μm	347 (14.9)	6 (1.2)	11 (48.8)	32 (12.5)	3 (4.8)
10 - 20 μm	7 (0.3)	4 (0.8)	4 (1.8)	11 (4.3)	2 (3.2)
20 - 50 μm	14 (0.6)	0	0	5 (2.0)	0

Table 4.9 Average coincidence corrected particle count and average particle size distribution (shown to the nearest whole particle) in injections prepared with street heroin (n = 3).

4.6.5 Effects of filters on Physeptone[®] injections

Observations on use:

When the Physeptone[®] was mixed on the spoon with the water, the mixture was thick and had several clumps of undissolved tablet material in it. When attempts were made to filter it, only a small amount of liquid could be drawn through any of the filters immediately. The needle blocked in some cases and liquid had to be discharged to unblock it. With further filtration, larger quantities could be filtered, but this required longer time periods and

several unblocking actions, giving an overall process considered to be unacceptable to IDUs. Therefore, the only preparations that were analysed were the unfiltered injections. These results are given in table 4.10.

	Crush & mix on spoon	Split & shake in syringe
<i>N</i> avg.	40844	26009
Particle size distribution: avg.number of particles (% of total <i>N</i>)		
2 - <5 μm	12613 (30.9)	12937 (49.7)
5 - <10 μm	9239 (22.6)	4744 (18.2)
10 - <20 μm	17571 (43.0)	6729 (25.9)
20 - 50 μm	1356 (3.3)	1620 (6.2)

Table 4.10. Average coincidence corrected particle count and average particle size distribution (shown to the nearest whole particle) in injections prepared with Physeptone[®] tablets (n = 3).

4.6.6 Effects of filters on Diconal[®] injections

Observations on use:

The Diconal[®] injections did filter immediately, with similar ease to the heroin. The filtration time and process was considered likely to be acceptable to IDUs.

The results are given in table 4.11.

4.6.7 Effects of filters on Temgesic[®] injections

Observations on use:

The Temgesic[®] injection filtered quickly with all four filters, again with similar ease to the heroin and Diconal[®] injections, so again were considered potentially acceptable to IDUs.

The results are given in table 4.12.

	Crush & mix on spoon	Split & shake in syringe	Cigarette filter	Hand rolling filter	Cotton bud filter	Syringe filter
<i>N</i> avg.	21132	17520	16033	13662	14440	238
Particle size distribution: avg.number of particles (% of total <i>N</i>)						
2 - <5 μm	6158 (29.1)	6498 (37.1)	8214 (51.2)	6062 (44.4)	6131 (42.5)	233 (97.9)
5 - <10 μm	5623 (26.6)	4471 (25.5)	4302 (26.8)	3819 (28.0)	4224 (29.3)	4 (1.7)
10 - <20 μm	8793 (41.6)	5971 (34.1)	3484 (21.7)	3738 (27.4)	4017 (27.8)	1 (0.4)
20 - 50 μm	778 (3.7)	582 (3.3)	34 (0.2)	44 (0.3)	56 (0.4)	0

Table 4.11 Average coincidence corrected particle count and average particle size distribution (shown to the nearest whole particle) in injections prepared with Diconal[®] tablets (n = 3).

	Crush & mix on spoon	Split & shake in syringe	Cigarette filter	Hand-rolling filter	Cotton bud filter	Syringe filter
<i>N</i> avg.	20121	16491	16460	12587	9893	32
Particle size distribution: avg.number of particles (%)						
2 - <5 μm	1904 (9.5)	1695 (10.3)	2505 (15.2)	2204 (17.5)	2514 (25.4)	25 (78.2)
5 - <10 μm	6209 (30.9)	5581 (33.8)	7010 (42.6)	4650 (36.9)	3490 (35.3)	5 (15.6)
10 - <20 μm	11632 (57.8)	8643 (52.4)	6862 (41.7)	5460 (43.4)	3757 (38.0)	2 (6.3)
20 - 50 μm	378 (1.89)	574 (3.5)	84 (0.5)	273 (2.2)	132 (1.3)	0

Table 4.12. Average coincidence corrected particle count and average particle size distribution (shown to the nearest whole particle) in injections prepared with Temgesic[®] 0.2 mg tablets (n = 3).

It was observed that for all unfiltered injections prepared with tablets, some sediment remained at the bottom of the syringe barrel after the prepared injection had been discharged into glass vial. Although not quantified, the amount remaining from the injection prepared by splitting and shaking the tablets appeared visually to be greater.

4.7 Data summary and filter comparisons

A series of graphs will now be presented which summarise the particle size data and compares the effects of the filters on particulate matter.

Figure 4.2 shows the average total particle counts for the experiments performed with each drug. The results obtained with the controls are included also. Figure 4.3 shows the same results but with the removal of the Physeptone[®] results which were very large, to allow clearer viewing of the other results. Since the injections prepared with tablets contained much greater numbers of particles compared to the injection prepared with heroin, the results of the work with heroin and the controls are shown again in figure 4.4a and with the control values removed in figure 4.4b. These are shown for clarity and because heroin was the main focus of this work.

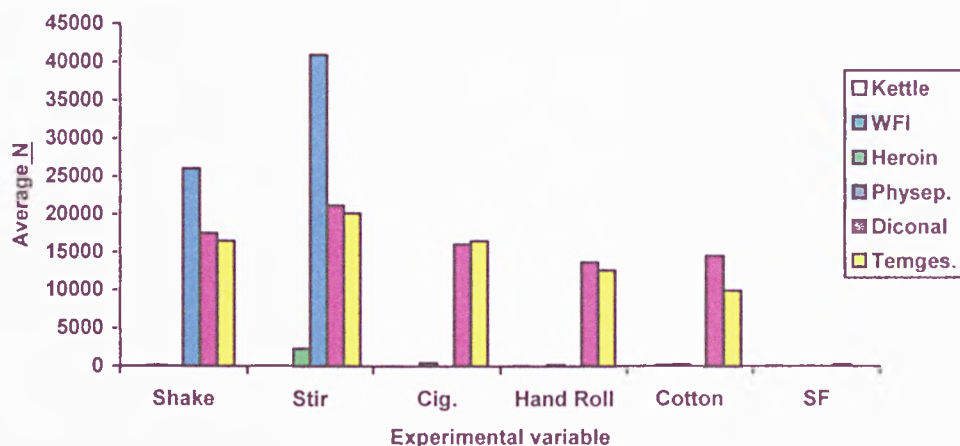


Figure 4.2 Average total number of particles detected during standardised analysis of samples from all drug injections and the controls (n = 3). Shake = shaken in syringe barrel, no filtration. Stir = stirred on spoon then drawn into syringe, no filtration. Cig. = filtered through the cigarette filter then drawn into syringe. Hand Roll. = filtered through the Hand-rolling tobacco filter then drawn into the syringe. Cotton = filtered through the cotton bud then drawn into the syringe. SF = filtered through the syringe filter then drawn into the syringe.

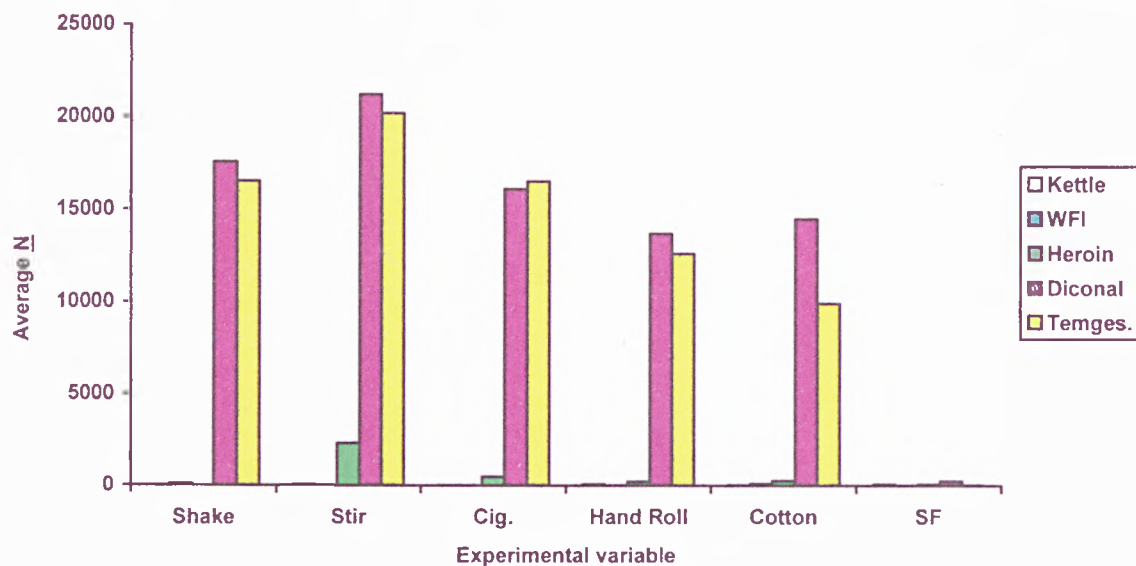


Figure 4.3 Average total number of particles detected during standardised analysis of samples from heroin, Diconal[®] and Temgesic[®] 0.2 mg injections and the controls ($n = 3$). Abbreviations as for fig. 4.2.

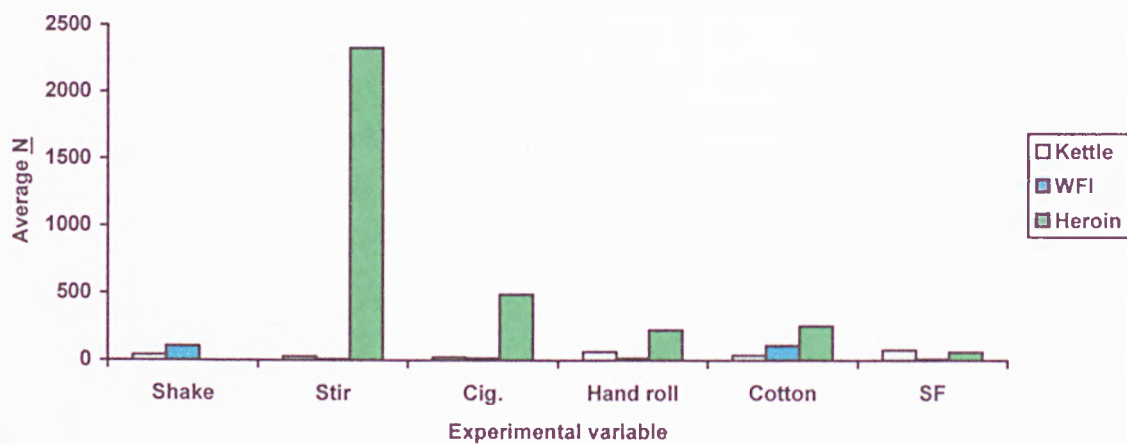


Figure 4.4a Average total number of particles detected during standardised analysis of samples from heroin injections and the controls ($n = 3$). Abbreviations as for fig. 4.2.

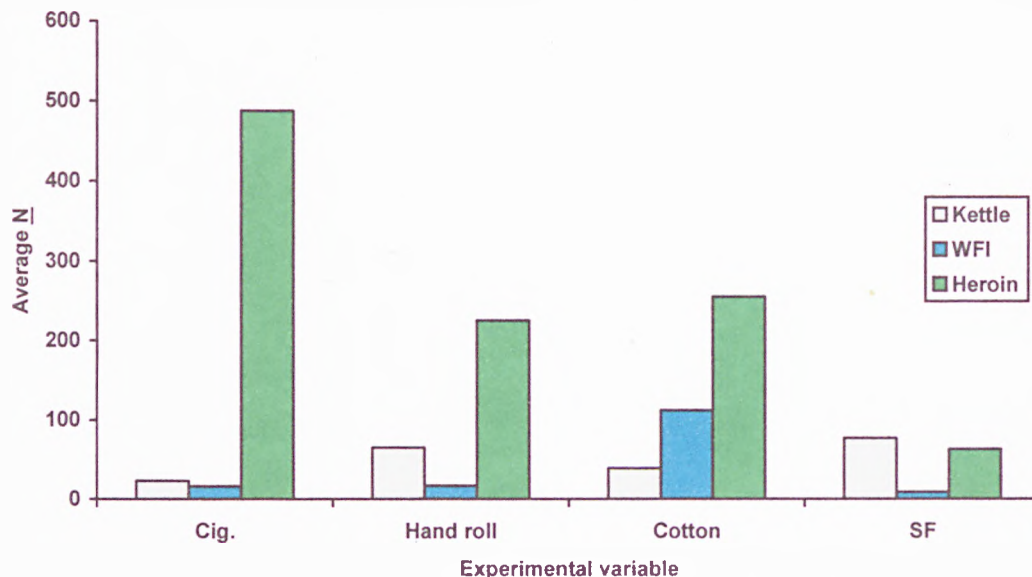


Figure 4.4b Average total number of particles detected during standardised analysis of samples from heroin injections (controls not shown) ($n = 3$). Abbreviations as for fig. 4.2.

Taking the total number of particles detected from the sample of unfiltered injections as 100 %, the percentage reduction produced by each filter with each drug can be calculated. This is shown diagrammatically in figure 4.5. Note, the results from the unfiltered injections prepared by crushing the tablets and mixing the resulting powder on the spoon were taken as 100 % as this practice was used to prepare the filtered injections as it is advocated in safer injecting leaflets (Exeter Drugs Project, 1991, HIT, 1997).

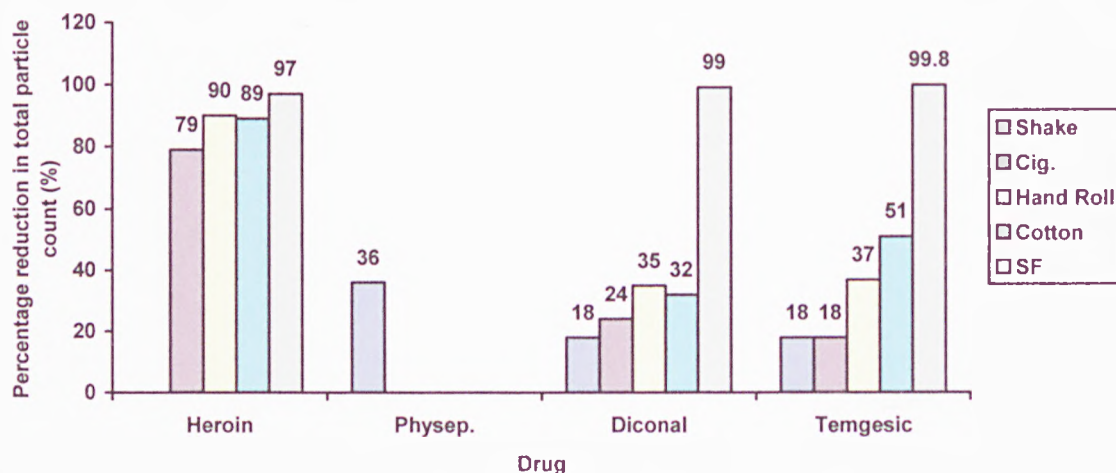


Figure 4.5 Percentage reduction in the total number of particles in filtered injections, taking the average total number of particles in unfiltered injections to be 100%.

To illustrate the effects of filtration on the particles in each size range, figures 4.6, 4.7 and 4.8 show the percentage change in particle count after filtration. A positive value shows the count was higher for the filtered injection and a negative value shows it was lower. Note for the heroin results, only the 2 to <5 μm and 5 to <10 μm data is shown as the number of particles in the larger size ranges were so low that the effects from the operator and environment were not considered distinguishable from the filter effects.

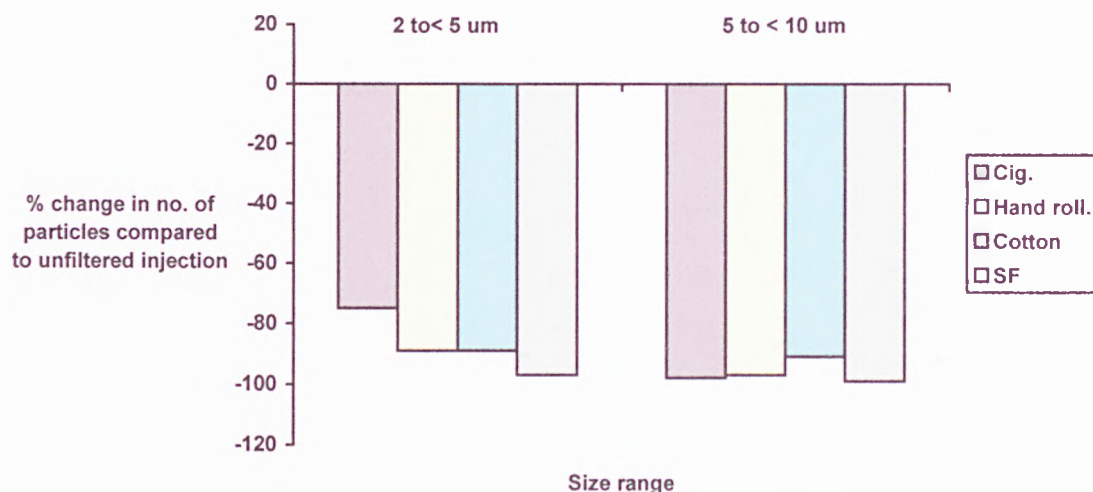


Figure 4.6 Percentage change in the number of particles in each size range of interest after filtration of heroin injections by the filtration methods stated.

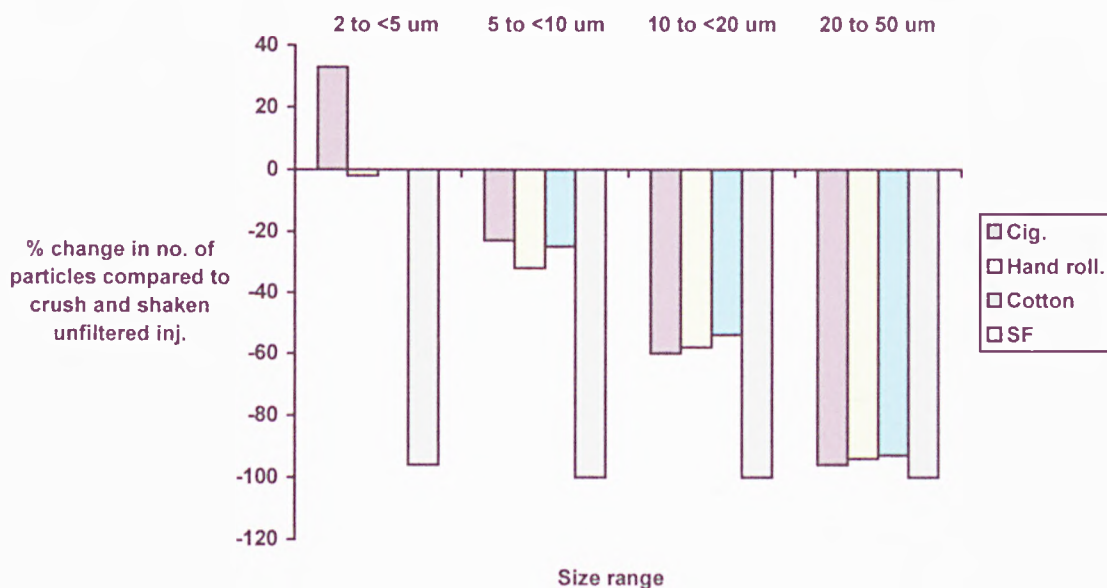


Figure 4.7 Percentage change in the number of particles in each size range of interest after filtration of Diconal[®] injections by the filtration methods stated.

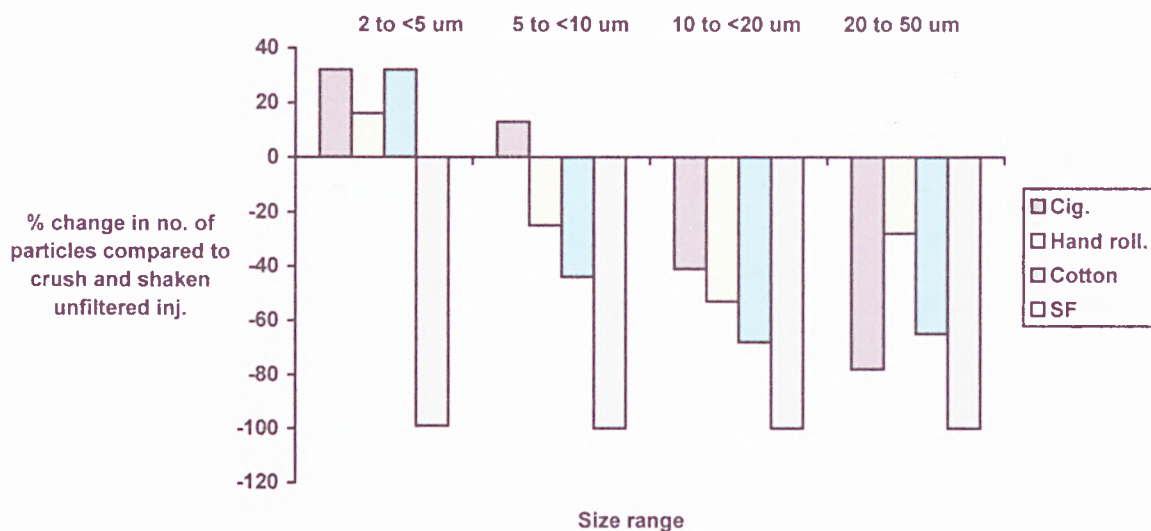


Figure 4.8 Percentage change in the number of particles in each size range of interest after filtration of Temgesic[®] injections by the filtration methods stated.

4.8 Results: CZE analysis

4.8.1 Controls

No peaks were seen with any of the control injections prepared without the addition of heroin. This gave confidence that the peaks seen in the analysed injections were due to the drug and not other aspects of the preparation process.

4.8.2 Preliminary analysis of street heroin

The initial analysis identified the IS peak and five peaks in the heroin sample at 220 nm. Overlaying the sample electropherogram with the standard and standard addition to the sample identified the first peak as morphine, the third peak as 6-MAM, the fourth peak as diamorphine and the final peak as papaverine. As papaverine would not contribute to the psychoactive effects of street heroin or be involved in diamorphine decomposition, it was not considered further (Parfitt, 1999). The second peak may have been acetylcodeine that was also noted to be common in heroin sample analysis reported in the literature (Love and Pannall, 1980, Kaa, 1991, Kaa, 1994), however, a standard could not be obtained to confirm this.

Satisfactory separation of the peaks on the electropherogram was demonstrated by the preliminary analysis, with morphine eluting first at 6.40 minutes, followed by 6-MAM at 6.55 minutes and diamorphine at 6.65 minutes. A heroin electropherogram is shown in appendix 11, part B.

The content of the three opiates of interest in the street heroin sample was as follows:

diamorphine	55.68 % w/w
6-MAM	6.64 % w/w
morphine	3.60 % w/w

4.8.3 Linearity

The results of the linearity checks are given in table 4.13

	Std conc. (μgml^{-1})	Peak Height Ratio	Correlation co-efficient	Slope (+/- SD)	Intercept
Diamorphine					
	0.0	0.00			
	11.54	1.45			
	23.0	3.12	0.997	0.14	-0.12
	34.5	4.39		(3.63×10^{-3})	
	46	6.31			
	57.5	8.02			
6-MAM					
	0.0	0.0			
	1.0	0.18	0.993	0.11	0.04
	5.0	0.59		(4.61×10^{-3})	
	10.0	1.12			
Morphine					
	0.00	0.0			
	2.5	0.31	0.997	0.11	1.80×10^{-2}
	5.0	0.54		(3.26×10^{-3})	
	10.0	1.07			

Table 4.13. Results of the linearity checks performed for the CZE equipment.

The linear response graphs are shown in figures 4.9a and 4.9b. Diamorphine is shown on a separate graph for clarity as the concentration range used was much greater than that

tested for 6MAM and morphine. Note the slope of the diamorphine line differs from those of the 6-MAM and morphine because the concentration of IS that was added differed from that used for 6-MAM and morphine.

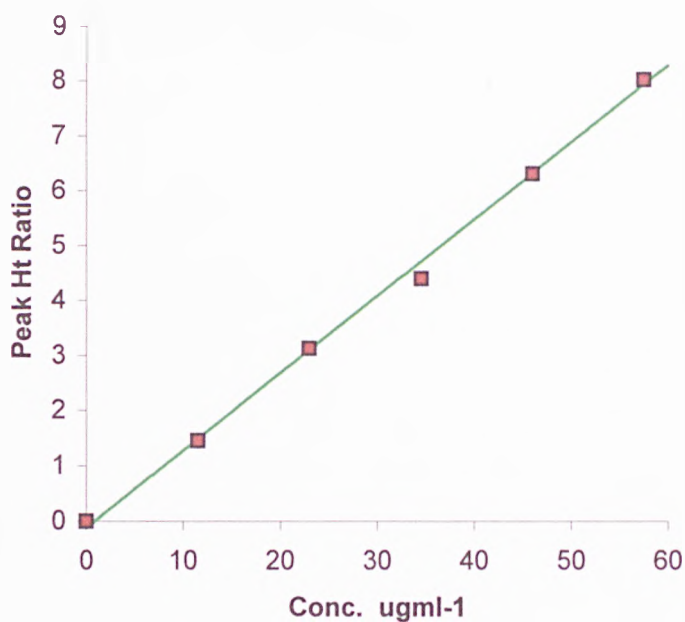


Figure 4.9a Linear regression graph for diamorphine

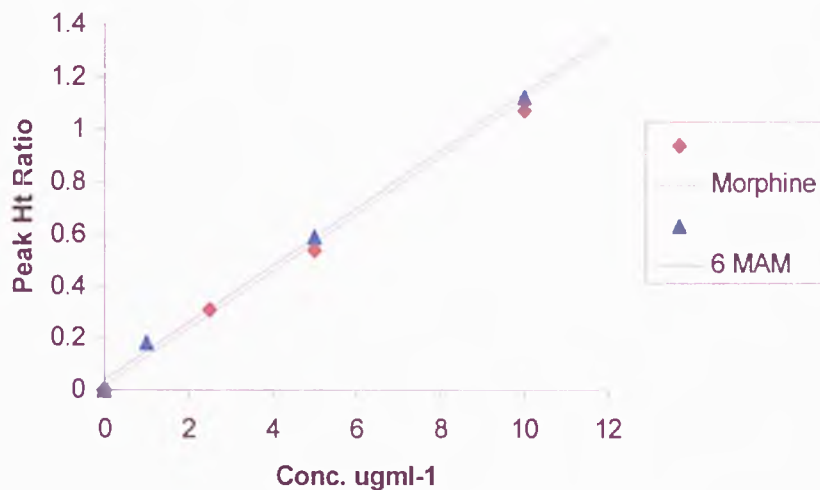


Fig. 4.9b Linear regression graph for 6-MAM and morphine

4.8.4 Validation

4.8.4.1 Within day variation

The within day validation results are given in table 4.14.

	Avg. peak height ratio (n = 3)	RSD %	Avg. migration time (n = 3)	RSD %
Diamorphine	0.72	1.39	6.95	1.25
6 MAM	0.78	1.28	6.78	1.53
Morphine	0.90	1.92	6.62	1.15

Table 4.14. Within day validation results

4.8.4.2 Day-to-day precision

The results for the day-to-day precision check are shown in table 4.15

	Avg. peak height ratio (n = 4)	RSD %	Avg. migration time (n = 4)	RSD %
Diamorphine	0.88	1.14	6.41	1.61
6 MAM	0.92	2.28	6.30	1.83
Morphine	1.02	2.61	6.14	1.22

Table 4.15. Day to day validation results.

4.8.5 Injection analysis

4.8.5.1 Amount of drug detected in injections

The peak height corresponding to morphine was too small to allow accurate calculation at the sensitivity required for the diamorphine and 6-MAM. The time between the detection of the 6-MAM and the morphine peaks was short (approx. 0.15 second), making it impractical to change the sensitivity before the morphine peak (this would have increased peak size). The comparatively small morphine peak suggests that the quantity of

morphine in the resulting injections was small compared to the quantities of diamorphine and 6-MAM, hence its contribution to the psychoactive effects would be small. Calculations were performed for diamorphine, 6-MAM and morphine, but the purpose of calculating for morphine was only to check for any large increases, which would indicate degradation. The calculated quantities in the resulting injections for each experiment are shown in table 4.16.

It was observed that some insoluble material remained on the spoon after filtration with the makeshift filters. This material was solid in nature, with an appearance that could be likened to wet sand. Liquid was observed to be drawn from it during the filtration process. When removed from the spoon, the filters were observed to have some of this solid material attached to them also. Discussion of this matter with two ex-IDUs identified that in their experience, presence of this material may lead to the addition of further acidifier and water during preparation. Alternatively, the remaining material on the spoon and filter may be used to produce a second injection, possibly given to another IDU who does not have their own drugs.

The syringe filter was observed to behave like a vacuum cleaner, in that most of the solid material was drawn from the spoon towards the syringe. This material formed a plug in the nozzle of the filter, which was removed with by flushing methanol from the syringe through the filter, when the filter remains were removed for analysis. It could also be removed by the expulsion of air from the syringe through the filter.

4.8.5.2 Statistical comparison of diamorphine content

Tukey's HSD test (95% c.i, one-way) showed there to be significant differences between the amounts of diamorphine in the injections filtered with the hand-rolling filter and the injections filtered with both the cigarette filter and the cotton bud. From table 4.22 it can be seen that the quantity in the hand-rolling filter injections would be statistically less. There was no significant difference between the syringe filter and any of the makeshift filters.

Quantity of drug in resulting injection (mg)				
	Cigarette filter	Hand-rolling filter	Cotton Bud	Syringe filter
Diamorphine				
<i>Expt. 1</i>	31.16	21.65	27.72	29.94
<i>Expt. 2</i>	30.06	24.75	27.49	18.69
<i>Expt. 3</i>	27.42	16.76	27.84	27.53
<i>Expt. 4</i>	29.09	24.06	27.96	26.38
<i>Expt. 5</i>	25.89	18.80	30.93	25.55
<i>mean</i>	28.72	21.20	28.39	25.62
<i>SD</i>	2.10	3.41	1.43	4.21
6-MAM				
<i>Expt. 1</i>	8.86	7.83	8.72	6.27
<i>Expt. 2</i>	7.75	7.10	9.10	4.62
<i>Expt. 3</i>	7.26	4.97	8.72	7.99
<i>Expt. 4</i>	7.88	7.53	9.36	7.05
<i>Expt. 5</i>	7.61	5.59	8.52	8.71
<i>mean</i>	7.87	6.60	8.88	6.93
<i>SD</i>	0.60	1.26	0.34	1.59
Morphine				
<i>Expt. 1</i>	0.63	0.66	0.61	0.52
<i>Expt. 2</i>	0.53	0.78	0.61	0.31
<i>Expt. 3</i>	0.85	0.52	0.48	0.62
<i>Expt. 4</i>	0.64	0.54	0.73	0.52
<i>Expt. 5</i>	0.54	0.54	0.72	0.72
<i>mean</i>	0.64	0.60	0.63	0.54
<i>SD</i>	0.13	0.11	0.10	0.15

Table 4.16 Quantities of diamorphine, 6-MAM and morphine in resulting injections filtered using the stated methods (Each sample was analysed three times and the average taken).

4.8.6 Filter analysis

4.8.6.1 Amount of drug released from used filters

Table 4.17 shows the amount of diamorphine released from the used filters.

	Quantity of diamorphine released from filters (mg)			
	Cigarette filter	Hand-rolling filter	Cotton Bud	Syringe filter
<i>Expt. 1</i>	7.31	8.37	8.27	16.05
<i>Expt. 2</i>	8.38	8.56	7.63	23.02
<i>Expt. 3</i>	13.37	13.78	8.96	17.75
<i>Expt. 4</i>	7.62	9.13	6.84	18.09
<i>Expt. 5</i>	6.30	13.71	9.15	16.37
<i>mean</i>	8.60	10.71	8.17	18.26
<i>SD</i>	2.77	2.78	0.96	2.80

Table 4.17. Amount of drugs released from the used filters (Each sample was analysed three times and the average taken).

4.8.6.2 Statistical analysis

Tukey's HSD test (95% c.i, one-way) showed there to be a significant difference between the amounts of diamorphine released from the syringe filter and the amount released from all three of the makeshift filters. From table 4.17 it can be seen that the quantity released from the syringe filter was significantly greater than the makeshift filters. No significant differences were found between the makeshift filters.

4.8.6.3 Weight differences before and after filter use

The mean difference in weights of the filters before and immediately after use is given in table 4.18.

	Cigarette filter	Hand-rolling filter	Cotton bud	Syringe filter
mean weight diff. (mg)	66.66	225.40	80.58	262.53
SD	8.54	86.26	19.09	62.10

Table 4.18. Difference in weight of filters before and after use, for each experiment ($n = 5$).

4.8.7 Results of the experiments to study the effects of acidifiers

4.8.7.1 Varying quantities of citric acid

Table 4.19 shows the mean amount of drug in the resulting injections prepared using the stated quantities of citric acid. The results are illustrated graphically in figure 4.10

Citric acid quantity		Quantity of diamorphine in resulting injection (mg)
3 mg	<i>mean</i>	6.47
	<i>SD</i>	0.62
7 mg	<i>mean</i>	13.90
	<i>SD</i>	1.42
15 mg ⁵	<i>mean</i>	28.72
	<i>SD</i>	2.10
30 mg	<i>mean</i>	53.62
	<i>SD</i>	1.29

Table 4.19 Mean quantity of drug in injections prepared using the stated quantities of citric acid and their corresponding standard deviations ($n = 3$).

⁵ The results quoted for 15 mg citric acid are from the filter comparison experiments, cigarette filter results. The mean quoted is the mean of the five experiments that were performed.

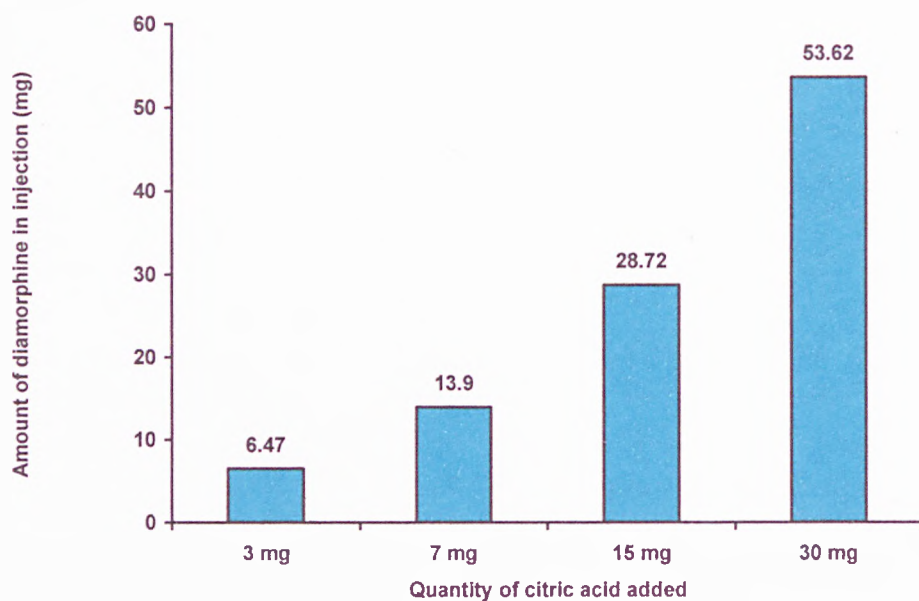


Figure 4.10 Effect of quantity of citric acid on diamorphine concentration in injections ($n = 3$).

4.8.7.2 Varying quantities of ascorbic acid

Table 4.20 shows the mean amount of drug in the resulting injections prepared using the stated quantities of ascorbic acid. The results are illustrated graphically in figure 4.11.

Ascorbic acid quantity		Quantity of diamorphine in resulting injection (mg)
15 mg	mean	9.80
	SD	0.59
60 mg	mean	46.93
	SD	2.56

Table 4.20 The mean quantity of diamorphine in injections prepared using the stated quantities of ascorbic acid and their corresponding standard deviations ($n = 3$).

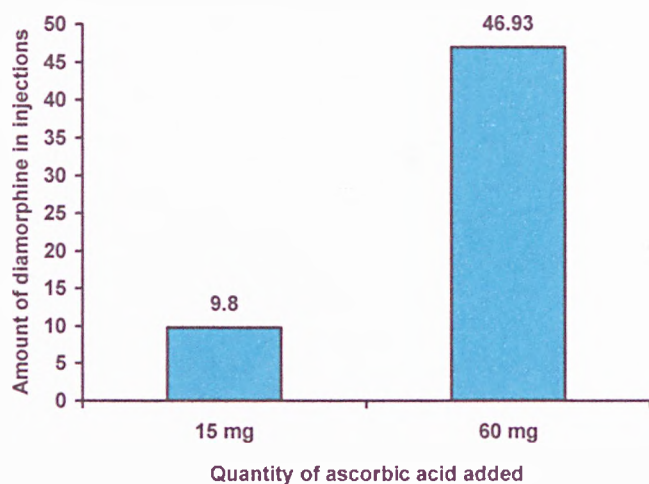


Figure 4.11 Effect of quantity of ascorbic acid on drug concentration in injections ($n = 3$).

4.8.7.3 pH

The pH meter was checked for accuracy using acidic and alkali standards of known pH prior to measurement of the pH of the 15 mg citric acid injections. Accuracy was later checked after the 3 mg and 7 mg measurements, however, the meter was found to be giving inaccurate results. It was re-calibrated and checked prior to the measurement of the 30 mg citric acid and ascorbic acid injections. Due to the likelihood of inaccuracies in the 3 mg and 7 mg results, they have been excluded from this work. The results are shown in table 4.21.

Acidifier	pH
<i>no acid</i>	7.5
<i>15 mg citric</i>	6.3
<i>30 mg citric</i>	5.8
<i>15 mg ascorbic</i>	6.7
<i>60 mg ascorbic</i>	6.2

Table 4.21. pH measurements from selected acidifier investigations ($n = 3$).

4.8.7.4 Amount of water varied and identification of opiates lost in preparation process.

When the volume of water was increased to 1.2 ml, the effect on the amount of diamorphine in the resulting injection is shown in table 4.22. Including the results using 0.8 ml of water, this can be represented graphically, as shown in figure 4.12.

<i>Amount of water added</i>	<i>Quantity of diamorphine in resulting injection (mg)</i>	
<i>1.2 ml</i>	<i>mean</i>	28.99
	<i>SD</i>	2.78

Table 4.22 Average amount of diamorphine detected in injections prepared with 1.2 ml water ($n = 3$).

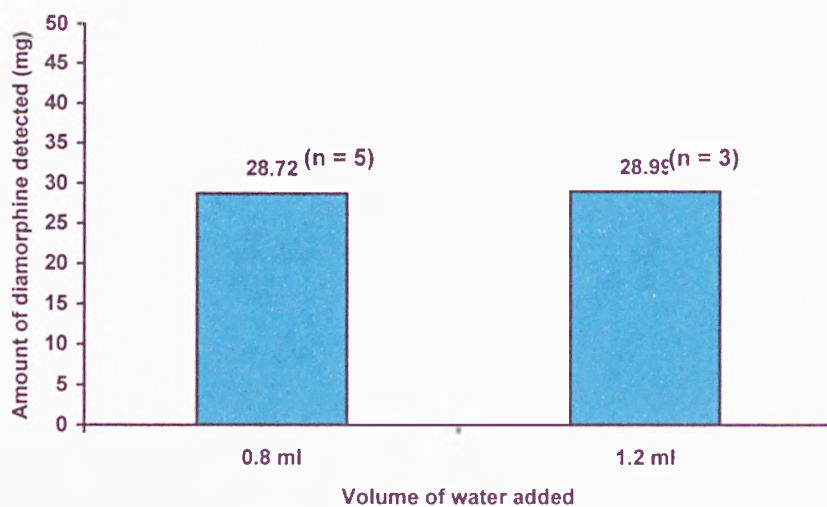


Figure 4.12 Effect of varying quantity of water on amount of diamorphine detected in resulting injections.

The spoons, the washings from the watch-glass and the needle sheaths all tested positive for diamorphine.

4.9 Chapter summary

The methods used to conduct the laboratory investigation into aspects of the injection preparation process have been described in this chapter, followed by the results from these experiments. The results showed that the Acrodisk[®] syringe filter achieved much greater reductions in particle content of the injections than the makeshift filters. There was no statistical difference between the amounts of drug in the Acrodisk[®]-filtered injections and any of the injections filtered with the makeshift filters. Although the amount of drug removed from the used Acrodisk[®] filters was statistically greater than that removed from any of the makeshift filters, observation suggested that the Acrodisk[®] 'sucked up' drug that remained on the spoon when the makeshift filters were used. These results suggested that the Acrodisk[®] might be more appropriate than the makeshift filters used by IDUs. The next stage in this study was to establish the acceptability of the Acrodisks[®] to IDUs. This work is presented in the next chapter.

Chapter Five

The user acceptability pilot study

5.1 The initial research concept

As said in chapter one (1.3.1), at the beginning of this project, it was proposed that after the laboratory study, the work would continue to establish whether the most effective filter in the laboratory was acceptable to IDUs. If it proved to be acceptable, the work would then go on to establish the health outcomes from its supply. It is also explained in chapter one (1.3.2) why it was not possible all this work to be done. The importance of undertaking a small pilot study where the supply and use of the filters was tightly controlled during their initial distribution, for safety reasons, became evident to the researcher as more experience was gained in the field. With the time and resources available it was possible to undertake this pilot work as part of this study, leaving the full-scale user acceptability study and health outcomes work for future research. What follows is a description of the pilot study that was carried out.

5.2 Methodological considerations

5.2.1 Legal approval of filter distribution

As said in chapter two, section 2.7, the distribution of filters to IDUs is illegal. Therefore, permission had to be obtained from the Procurator Fiscal (PF) in Grampian to allow distribution with exemption from prosecution. Details of the proposed study, including the pilot study, were submitted to the PF's office, who referred the matter to the Crown Office in Edinburgh. The Crown Office liaised with the Chief Scientist at the Scottish Office. Initially, permission to conduct the pilot study was applied for, with the aim of extending this application to allow a full-scale study once the pilot study results were available. Eleven months after the initial contact, the PF was able to grant approval for the pilot work. A copy of the approval letter is given in appendix 12.

5.2.2 Study design

The pilot project was designed to contain several safety precautions. Although the laboratory data suggested that the SF would remove large amounts of particulate matter without significantly changing the amount of opiates in the prepared injections, this data related to one quantity of heroin tested. The researcher could not control the quantity, purity and content of heroin and amount of acid used in the IDUs environment. For this reason, safety precautions were in-built into the pilot study recruitment process, to minimise the risk of any harm resulting from the use of the SFs. At later stages in a large-scale evaluation these could be relaxed, if appropriate. These safety measures are described in 5.3.2, where participant inclusion criteria are discussed. In-building the safety precautions influenced the study design. The participants had to be heroin injectors, recruited from somewhere where the researcher could access information on their self reported drug use and gauge their reliability in providing follow up information. The researcher also had to spend time with potential recruits to confirm their suitability for inclusion. On this basis, sampling for inclusion had to be done on a quota rather than random system. For these reasons, the collaborating agency on this project, Drugs Action, was chosen as the base for this study. Details of self reported drug use is recorded on clients needle exchange cards and private rooms are available for consultation. Anonymity of participants was not considered acceptable as follow up could not be initiated by the researcher, if the participants failed to report in the allotted time. Therefore, the researcher had to be explicitly clear regarding the confidentiality of the personal information provided and what action would be taken in the event of failure to report. Data collection from the participants had to be quick and simple. It was not practical for the researcher to be present at DA during all opening hours after the filters were distributed, to await the client's return. Therefore, a paper-based questionnaire was chosen as the method of data collection. Completion of the questionnaire was overseen by the needle exchange workers, therefore the participants had to be clear that the workers would be aware of their inclusion in the study, and that this information would be kept confidential by the researcher and DA. The notional target number for inclusion in the pilot study was ten.

5.2.3 Ethical approval

The study design and proposed procedures were submitted to and approved by the Joint Ethical Committee of Grampian Health Board and the University of Aberdeen. The remit of the committee has been previously described in chapter 2. A copy of the submission

form and approval letter is given in appendix 13. All relevant paperwork, including the participant information sheet, study protocol, participant instruction sheet and consent form was included with this application. They are discussed in detail in further sections of this chapter, where referral is made to the appropriate appendices in which they can be viewed. The Ethical Committee raised three questions relating to the application, which were (i) clarification of the proposed method of filter disposal, (ii) the position of RGU on project audit by external bodies and (iii) inclusion in the participant information sheet of a statement to say that participation or refusal to participate would not impinge on the services received from Drugs Action. These issues were addressed, disposal of the filters is described in the methods section, and the final approval granted, as shown in appendix 13.

5.3 Methods

5.3.1 Drugs Action staff team approval

The DA staff team approved the proposed study design during a team meeting, where the researcher explained the study and discussed relevant issues with the drugs workers.

5.3.2 Criteria for inclusion

5.3.2.1 Not be under medical care for drug problems

Ethically and for safety, it was decided that the people recruited to test the filters were not to be under medical care for a drug problem i.e. not receiving a prescription for substitute medication. The Ethical Committee require that if a person is included in a study that may affect their health, other health care providers who provide them with care should be informed of the study. This notification would mean client confidentiality could not be maintained. Also, the risk of overdose is higher if heroin is used in addition to prescribed substitutes such as methadone, so for the pilot study such people were excluded to avoid any implications for the researcher.

5.3.2.2 Agree not to use other drugs at the same time

Again for safety reasons, the participants had to agree not to take other drugs at the same time as they administered the heroin injections filtered with the SF. They also had to agree only to use the SFs for heroin injections.

5.3.2.3 Have an established dependence on heroin

The laboratory study showed that the SF removed the majority of particulate matter from the heroin injections without causing any significant change in the amount of opiates present. However, only one scenario could be tested in the laboratory and the preparation methods used by the participants could not be controlled. To minimise the risks from any significant difference between the amount of opiates in the SF injections compared with the participants usual filters, especially any significant increase and to exclude new injectors who potentially may be using on a more recreational basis and not have an established opiate tolerance level, the following criteria were set. The participants had to have been injecting heroin for at least three months, they had to be habitual users, defined as injecting at least twice a day and using at least one £20 bag of heroin per day. Participants also had to agree not to test all filters on consecutive injections, but to use the SFs for one in every four injections or less frequently.

5.3.2.4 Agreement to adhere to study requirements

The participants had to be willing to follow the given instruction sheet (5.3.4) and dispose of the filters in the cin bin provided. They also had to agree to provide feedback on their experiences with the filters including notification if they withdrew from the study. They also had to agree not to give the filters to anybody else, as they may not meet the safety requirements. Lastly, they had to agree not to reuse them, as this had not been investigated in the laboratory and may be unsafe.

5.3.2.5 Frequent attendees with good return rates at the DA needle exchange

To maximise the chances of receiving participant feedback and ensuring safe disposal of the injecting equipment and filters that were distributed, the clients had to be frequent attendees of the DA NX with a good record of returning used equipment. This was

defined by the researcher as visiting at least once a fortnight and returning at least 50 % of the number of needles with which they were issued. This percentage was an arbitrary choice of value that the researchers considered indicated an acceptable level of reliability to return used equipment. Also, clients had to be current users of the NX, which was defined as having visited in the past two weeks. The maximum number of sets of injecting equipment allowed to be issued under the Lord Advocate's guidelines is fifteen per visit, so in practice, a regular heroin injector may attend the NX every two or three days if they do not use pharmacy NXs.

5.3.3 Identification of potential recruits

Explaining the outline of the study to every DA NX client, asking if they were willing to be considered for inclusion, then going through the protocol with them to assess suitability was not considered an appropriate way to recruit the quota sample for the pilot study. The reason for this was (i) It was known that a large-scale study could not follow on immediately from the pilot study, as the time span for this project was almost finished. Informing all NX clients that filters were being distributed for investigation may have created a false expectation amongst IDUs that filters were or would shortly be available from DA. (ii) The time involved in doing so would be unreasonable from both the researchers point of view and the use of the private rooms at DA. Instead, clients were identified who could be targeted for inclusion, using two methods.

5.3.3.1 Identification by drugs workers

DA workers were told of the inclusion criteria, asked to consider their client case load and inform the researcher if they knew of any potential recruits. If the client was known to use the NX, the drugs worker gave their card to the researcher. If the client was not known to use the NX i.e. if they received home visits, the researcher gave the worker an information sheet for potential recruits and asked them to discuss with their client whether they would be willing to meet with the researcher to discuss the study further.

5.3.3.2 Identification by the researcher

Clients who use DA are identified only by their initials and date of birth. These are marked on their NX card. The cards are filed alphabetically, according to surname first initial and

then by first name first initial, in two drawers of a large filing cabinet. A copy of one side of a blank NX card is given in appendix 14. Non-numerical information is recorded using a coding system. From a client's record, details of the drugs they use by injection and a history of their attendance and return rate at the NX established. The researcher reviewed the DA NX cards and identified all clients who fitted the inclusion criteria described in 5.3.2, which could be established from the cards. A yellow adhesive label with the words *'Possible for Filter Study'* written on it, was attached to the card.

The marked cards were replaced in the NX cabinet. When a client with a marked card attended, the NX worker gave the client an information sheet on the study, described in 5.3.4. The sheets were stored in a pocket attached to the side of the filing cabinet. The worker marked the adhesive sticker to indicate that this had been done. The next time the person presented, they were asked by the worker if they were interested in participation. If they indicated they were, contact with the researcher was arranged, as described in 5.3.5

5.3.4 Information sheet

The double-sided information sheet for potential recruits detailed the purpose of the study, explained who was carrying it out and summarised the inclusion criteria. It assured confidentiality within the agency and that inclusion or refusal to take part would not alter the service received from Drugs Action. A copy of the sheet is given in appendix 15. This was included in the Ethical Committee submission (5.2.3).

5.3.5 The recruitment process

All worker activity and DA appointments are recorded in the agency diary, which has a day per page divided into a section for each worker plus one extra anonymous slot. With the agreement of the team, the researcher used this anonymous slot to indicate whether she would be present or absent at all sessions over the four week period allocated for the study. This allowed staff to give potential recruits details of guaranteed times when the researcher would be in the agency.

On meeting, the researcher outlined the study and explained that the inclusion criteria would be checked by asking a series of questions. The IDU was discreetly asked if they were comfortable reading and following printed information, to identify difficulties in following the instruction sheet and highlight that instruction had to be followed. It was

explained that name and contact details were required for safety, and emphasised that this information would be kept confidential to the researcher and not shared with the DA staff or any third party. Assurance was given that this information would be destroyed once the person had made a further visit to DA and returned their filters, either used or unused. It was also explained that knowledge of who was included, in terms of initials and date of birth, would be known to the NX workers using the cabinet. It was ensured that at this point the option to decline was given, in case the IDU felt uncomfortable with this. It was ensured that it was clear that the researcher had special permission to distribute filters for the study and explained it was still illegal to distribute filters, so the results from the study would not mean that filters could then be given out by DA. It was also stressed that detachable syringes would have to be used, to again give the IDU the opportunity to decline if this was unacceptable. It was explained that a short questionnaire would have to be completed the next time the participant attended the NX and emphasised that this could not be taken away. If the person was keen to participate, the flow-chart '*Inclusion criteria for volunteers*' shown in appendix 16 was used to determine suitability. This chart was included in the Ethical Committee submission.

If the person fitted the inclusion criteria, they were asked if they wished to test a filter with water to help them decide if they wished to participate in the study. This allowed them to assess the filters for possible ease of use within their injecting procedure, including the use of detachable syringes.

IDUs who remained keen to test the filters were then asked if they were prepared to test the filters according to the instruction sheet, and given a copy to read (appendix 17). This sheet was included in the Ethical Committee submission. If they agreed, they were told to keep the sheet for reference.

5.3.6 Informed consent

A consent form, which complied with Joint Ethical Committee requirements, was designed. It is included with the ethical application in appendix 13. A copy was signed by each recruit and kept in a locked cabinet until the study was over, then destroyed by shredding. A blank copy was included in the Ethical Committee submission.

5.3.7 Filter distribution.

The name by which the participant was known and their contact details were recorded by the researcher. Their initials and date of birth were noted to allow their NX card to be located. Each participant was assigned a number. The researcher emphasised that an honest evaluation of the filters was required, therefore, if the participant did not like them, it was important to say so and that this was just as important as knowing if they were liked. It was stated that the recruit did not have to agree to test all four SFs given. Both used and unused filters had to be put into the cin bin provided and returned to DA. They were told they would be asked to confirm this on return.

The opportunity to ask questions was given. Recruits were reminded that they were free to withdraw at any time without giving a reason. All that was asked was that they reported on their next visit that they had withdrawn so this could be noted by the worker on the sticker on their NX card. Recruits were given four packaged SFs of the type tested in the laboratory, four detachable barrels and four needles, in the size of their choice. Four swabs and two cin bins, one for filters and one for needles, were offered. If the recruit stated they already had a cin bin, they were given one for the returned filters. Recruits were also offered a copy of the booklet *'The Safer Injecting Handbook'* by Derricott and Preston (1997).

5.3.8 The data collection tool

5.3.8.1 Questionnaire design

A copy of the questionnaire is shown in appendix 18. It was important for the questionnaire to be short and uncomplex to encourage accurate self-completion, as advocated by Bailey et al (1995). Closed questions were used to establish facts, followed by open questions to gather opinions on the SF experience.

Firstly it was established what kind of filter was usually used by the recruit. Next the number of SFs that were tested was asked. If not all the filters were used it was asked why this was so. Next it was asked what injecting sites were currently used. This was important, as users of deep veins may already use two-piece equipment, as longer needles may be required, so the SF may be less disruptive to their current practice. To check this, they were next asked if they usually use insulin syringes. If they did, they were asked if they found detachable needles a problems and if so, to explain the problems.

Next the participant was asked to state any problems they had using the SF. It was then asked if the feeling experienced from the injection were any different when the SF was used, and if yes, to explain. Next, volunteers were asked to compare the SF with their usual filter for ease of use. They were then asked to decide whether they thought the SF or their usual filter was better or if there was no difference and to comment on why they thought this. They were then asked if they thought other users would require practice to get used to using the SF. Finally, they were asked whether they would prefer their usual filter or the SF to be distributed by NXs, if the law was changed. The opportunity to make further comments was given.

5.3.8.2 Validation

The completed questionnaire given had the recruit number on it so validation using one question could be carried out. After the questionnaires were completed, the researcher accessed the clients NX record to establish whether or not insulin syringes were the predominant type collected and this information compared to their response to Q. 4.

5.3.8.3 The data collection process

After a volunteer was recruited into the study, the researcher attached a numbered questionnaire (5.3.9) in an envelope to their NX card. This number corresponded to their recruit number. The envelope had the client's recruit number written on it, in case it became detached. The next time the recruit came to the NX they were asked by the worker to complete the questionnaire in one of the adjoining rooms. Recruits put the completed questionnaire back in the envelope, sealed it and gave it to the duty worker who put it in a collection pocket in the NX filing cabinet. The worker asked for the cin bin used to dispose of the filters or the unused filters and noted on the adhesive sticker what was received. Unused filters were left with the completed questionnaires.

5.3.8.4 Data analysis

The closed question responses were quantified. The open questions analysed to identify the opinions expressed, noting any similarities and differences. Although no conclusions can be drawn from a pilot study, and indication of the feasibility of future research could be gained and the need for modification of the methods used.

5.3.9 Appreciation of involvement

Before they left the NX, the duty worker gave the recruit a sealed envelope that was attached to their NX card. This contained a £5 gift voucher for a local supermarket and a university compliments slip, thanking them for their participation.

5.4 Results

5.4.1 Recruits

The recruitment period lasted two weeks. Fourteen information sheets were distributed to potential recruits during this time. It was not recorded how many people with marked NX cards were told about the study but did not wish further information. Seven people who considered themselves suitable for inclusion expressed an interest in participation so discussed recruitment with the researcher. Of these six people were recruited into the study. One person declined to participate as she did not wish to use detachable needles and syringes. Recruit details are given in table 5.1.

Recruit number	Sex	Age
1	Female	33
2	Male	22
3	Male	38
4	Male	36
5	Male	26
6	Female	25

Table 5.1. User evaluation of filters: participant demographics

All recruits except no. 5 tested the filters at DA with water prior to inclusion. No. 5 did not wish to do this as he considered handling needles would make him 'rattle' which means bring on feelings of wanting to inject. All recruits asked questions about the filters when given the opportunity, these included questions about whether the filters were known to retain drug and questions about why they could not be distributed by NXs.

All recruits returned to the needle exchange within two weeks, so the researcher did not have to initiate contact for follow up. All recruits were reported by the NX worker as having disposed of their filters in their cin-bins, which included the unused filters and other injecting equipment.

All the recruits showed an active interest in the study and were keen to offer suggestions on the types of filters that they perceived would be acceptable to IDUs. For example, one drew diagrams of his 'ideal' filter, including dimensions. Others described the concept of providing filters as welcomed, expressing a desire for something to reduce the number of injecting injuries experienced and help preserve veins. Some of the recruits were reported by drugs workers to have discussed their participation in the study with them further.

5.4.2 Questionnaire results

5.4.2.1 Usual filters used and injecting sites used with the SF injections

All six recruits reported usually using a cigarette filter to filter their heroin.

Six different injection sites were reported by the recruits to have been used when they tested the SFs. Users of peripheral veins (arms, hands and feet) reported using more than one site. Users of larger veins (groin and neck) only used one site. The sites and number who reported using them are given in table 5.2.

Recruit number	Sites reported
1	neck
2	arms and hands
3	arms and feet
4	groin
5	arms and hands
6	groin

Table 5.2 Injection sites reported to be used when administering SF injections

5.4.2.2 Validation question

All six recruits reported usually using insulin syringes usually (Q.4). The needle exchange records confirmed this to be the case for all recruits. Recruits nos. 1, 2, 4 and 6 had in

addition received detachable needles and barrels, but the quantities of insulin syringes received were greater.

5.4.2.3 Use of detachable needles and syringes

When asked if it was a problem to use detachable needles and syringes, three people stated it was not a problem, with no further comment. One person (No. 3) stated it was not a problem but added they had a preference for insulin syringes because they considered there to be a greater risk of detachable needles being inadvertently left lying around. Two people said using detachable needles and syringes was a problem, for two different reasons. One person (No. 1) said detachable needles were difficult to attach and they worried they may detach in use. The other person (No. 2) said he found it more difficult to access smaller veins as he believed the orange needles to be thicker.

5.4.2.4 Use of syringe filter

Four people used all four SFs and two people used two SFs. The four who used all SFs reported they had no problems using them in Q.6. The two people who used two filters only (recruits No. 3 and 5) reported they did have problems. For explanation of the problems, both respondents referred to their answers given under the reasons why they did not use all the SFs (Q.2). The reason given by both for this was that the filters retained too much fluid. This is illustrated by the statements given:

'I found it difficult to draw all the gear up into the works. [I] lost 2 out of 5 units which necessitated blowing it back out of the dirty end back into [the] spoon'.

Recruit no. 3

'they kept in too much fluid'

Recruit no. 5

When asked if they considered the effects experienced from the injection to be any different when filtered through the SF (Q.7), three people stated they did not think there was any difference, without further comment. This included no. 3 who said the filter retained too much fluid. One person did not mark an option but inferred from his response written underneath the question that he did not experience any differing effects. He wrote:

'I never noticed any physical difference but I felt better knowing that most of the impurities had been removed which would probably be more noted over a longer period of use'

Recruit no. 2

Two people stated they did feel different effects. One wrote the injections felt *'stronger/cleaner'* (no. 1) and the other, who reported that the filters retained too much fluid, felt there was less drug in the resulting injection (no. 5).

When asked how easy the SFs were to use compared to the person's usual filter, which was the cigarette filter in all cases, four people selected the option *'A bit more difficult'*. One person, who was one of the people who reported the filters retained too much fluid, reported them to be *'much easier'* to use. One person said there was *'no difference'*.

5.4.2.5 Comparison of syringe filter with usual filter

When asked to compare the SF overall with their usual filter, the two people who used only two filters, stated they preferred their usual filter. One person said the reason for this preference was that there was more involved in the preparation stage when using the SFs (recruit number 3). The other person (recruit number 5) stated two reasons for his preference for cigarette filters. The first was that a cigarette filter can be broken down to release trapped drug, so used to prepare further injections. The second reason was the repeated statement that the SFs retain too much fluid, equated with retaining drug. Three people stated they preferred the SFs. Two people gave one reason and one person gave three reasons for this preference. All stated they thought the resulting injection was a lot *'cleaner'*. This term is used amongst drug users to refer to the removal of materials perceived to cause adverse effects and injury. The person who gave other reasons stated they felt the SF will *'keep injecting sites better'* and *'last longer'*. One person (recruit number 2) circled both *'The syringe filter is better'* and *'There is no difference'*. Although this was unclear, under the comment section he referred to his response quoted in 5.4.2.4 as his reply to Q. 7.

When asked if users would need a bit of practice with the SFs to get used to using them, three people said no. This included respondent number 5. Three people said yes, one added he thought this because of the length of time required to draw the liquid into the syringe.

5.4.2.6 Distribution preference

When asked to say which kind of filters they would prefer to be available from needle exchanges if the law changed and it became legal to give out filters, four people said they would prefer the SFs to be available. Two people, the respondents who reported problems using the SFs, said they would prefer cigarette filters to be distributed.

5.4.2.7 Additional comments

Three people added additional information under the further comments section as follows:

'The filters are a good idea I think, because they would, in my opinion, drastically cut down the risk of getting a 'dirty' hit'

Recruit no. 2

This recruit also expressed difficulty with the SF because it obscured his view of the spoon. He described it as *'too bulky'* and suggested it may be better if a filter could be found which was the *'width of a finger'*. He gave further detail by suggesting it would ideally be *'around 1.5 times the size of a cigarette end'*.

'I think the filters I used [were] very good..a lot better than cigarette filters'

Recruit no. 4

'I have been using detachables to draw up [the injection] and then transferring to 1 ml insulin to inject. To prevent injuries and losing limbs they [syringe filters] should be supplied. [It] does seem to take some concentration/time to use them correctly'

Recruit no. 1

5.5 Chapter summary

This chapter has described the methods employed to conduct a pilot evaluation of user acceptability of the SFs and given the results from this work. The next chapter provides a discussion of all the work conducted for this part of the thesis, which has been presented in chapters three, four and five. Conclusions from this part of the thesis are also presented.

Chapter Six

Discussion

6.1 Chapter format

Each stage in the part one study is discussed chronologically in this chapter. Critique of the methods and discussion of the findings are both undertaken, but have not been separated. This was considered necessary to achieve continuity in the chapter format.

6.2 Selection of the drugs for the laboratory investigation

Heroin was proposed as the main drug for this work as it was perceived to be the most common drug injected by IDUs. However, in order to confirm this, information had to be established on illicit drugs used by injection. Data was also sought on other drugs used by injection by IDUs, as it was anticipated that it would take time to arrange supplies of street heroin for this study. The basis for selecting these other drugs was their popularity and the identification of specific factors of interest. As it transpired another factors that emerged in their selection were the ability to identify specific strengths and formulations used.

6.2.1 Use of the 1994/5 Scottish Drug Misuse Statistics

Data had to be identified that would allow the researcher to establish the popularity of drugs injected by IDUs. The Scottish Drug Misuse Statistics (SDMS) were considered to be the most suitable source of information as the route of administration is recorded.

6.2.1.1 Limits of the SDMS

The limits of the SDMS are that they only report data collected from IDUs who have contact with services, so those not in contact with services will not be represented.

Furthermore, they only record information from new contacts on drug use in the preceding month. Therefore, any changing patterns in use that occur in existing service contacts, for example due to interventions made by the service providers, will not be shown. Also, it may be that drug use in the month preceding contact is particularly chaotic, prompting the IDU to seek help. Given these facts, the SDMS may not represent injecting drug use in the population overall. However, the clear popularity nationally of heroin as the main drug used by injection over other drugs (81.4% against the second most popular main drug, buprenorphine at 8.5%) suggests that the limits of the SDMS may not be significant in confirming the drugs popularity. Also, in the 1996-7 statistics bulletin, a summary of the previous 5 years data showed popularity of heroin injecting by age group (ISD, 1998). Although a decline in injecting has been seen in all groups since 1994, coupled with an increase in heroin smoking since 1993, overall, injecting is still the main route of heroin use reported by those who stated the drug to be their main drug used. Data from SDMS statistics over several years were not pooled together to establish popularity as trends in drug use are known to change so the researcher wanted to use the most recent figures. For example, temazepam was the main drug used by 1% of new contacts in 1995/6 but popularity diminished to give a non-returnable figure in the 1996/7 statistics (ISD, 1998).

6.2.1.2 Lack of consultation with IDUs who use pharmacies only.

A further criticism of using the SDMS is that data is not gathered from pharmacy NXs, so IDUs who access only pharmacy services will not be represented in these statistics. However, Tucker (1997) conducted interviews with users of pharmacy NXs in two locations. He found that 62 % of the pharmacy NX users were in contact with other drugs services. New contacts with services reported in the SDMS are likely to include information on the drugs used by some pharmacy NX users. Consideration was given to gathering information from users of pharmacy NXs and identifying those who do not access other services. The local NX pharmacies were not suitable for private consultation with IDUs and use of remote locations was not permitted by RGU and although attempts were made to contact people through methadone services who had not used an agency NX, this wasn't pursued for the reasons in 3.1.4.2. It is a criticism of this work that further attempts were not made to contact IDUs who only used pharmacy NXs, for example through NXs with private facilities in other regions of Scotland.

6.2.1.3 Accuracy of the SDMS

It was established after this information was used that there is bias in the SDMS. In Aberdeen, Drugs Action returned statistics, on all new contacts, including needle exchange users. However, discussion with the leader of the ISD drug misuse information strategy team established that DA was the only agency to do this. Other reporting agencies do not include data from clients who only use their NX service, so this group will be under reported (McWalter, 1998).

The accuracy of the SDMS relies on both accurate self-reporting from IDUs and accurate recording by service providers. As reported by Maddux and Desmond (1975) and discussed in chapter 3, section 3.1.4.1, there may be a tendency by drug users to withhold information which is considered unpleasing or will result in their detriment. Given that some data in the 1994/5 statistics was gathered by services that are likely to have power to influence outcomes for the drug user, for example GPs and penal establishments, there may be inaccuracies reported. However, data from years after 1994/5 reports the data collected from penal establishments separately, but heroin still remains the main drug used by injection (ISD, 1998). Also, the drugs used may be considered less sensitive information than other questions on the SMR22/23 forms such as involvement in drug related crime. This may mean data on drugs used is subject to less inaccuracies in reporting (Maddux and Desmond, *ibid*). The significance of any recording errors by service providers is unknown.

6.2.1.4 Defence of the use of the SDMS

Despite these limitations, the SDMS were considered the most appropriate source of information on drugs used by injection. The Addicts Index, which was still actively used at the start of this work only gave information on the use of certain notifiable drugs, not all drugs used by injection, and only in those who sought medical help. In comparison the SDMS offered a broader range of information since there is the freedom to include all drugs, data is collected from a range of services including doctors, and reporting distinguishes injecting drug use. Also, it was mistakenly thought that to access this information the researcher would have to travel to London. It is a criticism of the researcher that this was not investigated, as it is now known that selected data can be requested and sent by post. Other sources of such information on injecting focus on studies done in particular localities or with particular groups, such as young people, so do not represent the general injecting population and do not usually distinguish main drug

from other drugs or quote statistics for the route of administration. The benefits of using the SDMS were that they allowed route of use and main drug used to be distinguished, which were important for this work. Also, the SDMS allowed data from 2040 IDUs to be considered whereas local studies represented smaller numbers. Local data was considered from the SDMS but the emphasis was placed on the national statistics.

6.2.1.5 Tablets used by injection

The overall popularity of injecting tablets as the main drug of misuse was seen to be small from the SDMS, however experience of having injected tablets at least once in the month preceding contact was large. Data on formulation was not available, so consideration could only be given to drugs where there was either only one formulation or there was information from other sources i.e. drugs workers and IDUs. For example, although morphine showed relative popularity compared to many other drugs (except heroin), it was not studied due to the great range of formulations. Information collection from drugs workers and IDUs is discussed below.

6.2.2 The role of data collected from IDUs and drugs workers in informing the choice of drugs for this work

Less emphasis was placed on the data on drugs used by injection collected from the drugs workers and IDUs than the SDMS data, as the SDMS provided information on a national level from a greater number of people. The worker data was mainly used to help the researcher become familiar with the drugs 'scene' and inform decisions in the absence of information from elsewhere. The IDU information was mainly used to give information on formulations used, which is unavailable from the SDMS and the injection preparation process. The SDMS report the main drug injected, but do not report the frequency that this represents, although this information is collected on the SMR form. The interviewees reported a range of injecting frequencies (3.3.4.6) from once or twice weekly to six times a day. A criticism of the interviewee schedule is that although frequency of injection was asked, in people who reported currently injecting more than one drug, the frequency for each drug cannot be assumed, as the frequency for each drug was not explicitly asked. People with the greatest length of time since first injection had injected a greater number of drugs, although the sample group is too small to conclude that this would apply in the whole IDU population. The data gathered from the drugs workers and IDUs did give support for the decision to select heroin as the main

drug on which this study focused, as they also reported it to be the most popular drug used by injection.

Information on the strengths and formulations of pharmaceuticals injected came from the interviews with IDUs. Since this number was small ($n = 20$) in comparison to national statistics, it cannot be taken to be representative of all IDUs. Some IDUs interviewed reported that the type of tablets used by injection is influenced not only by the IDUs preference but also by availability, so this may be subject to frequent change. It cannot be assumed that the tablets used for this study, Diconal[®], Physeptone[®] and Temgesic[®] 0.2 mcg, are the most popular tablets used by injection. What has been established is that they are used by IDUs, making their investigation applicable. It is a criticism of this work that the strength of the tablets injected was not explicitly asked in the IDU interviews, so the selection of the 0.2 mcg strength had to be based on the assumption that since it was prescribed to a greater extent, more may be available for injection and its reported use by one interviewee.

6.2.3 The quantities of drugs used in the laboratory

6.2.3.1 Heroin

As explained in chapter three, section 3.4.2.1, difficulty was experienced in establishing the actual weight of 'a quarter G' of heroin, the most commonly reported amount used to prepare injections. Use of the actual weight of 250 mg was considered the best option for this work, since it was within the range of quantities thought by the police to be used for single doses. The weights seized by the police ranged greatly and the interviewees indicated that the quantity used may vary depending on the desired effect and the amount of drug available for the person and those whom they shared drug with (i.e. a partner). The weight used for this study represents one of the weights likely to be used by IDUs. Had a greater amount of heroin been available for this study, investigations using a range of weights used to test all four filters would have been undertaken. Information that has since come to the attention of the researcher on the World Wide Web from the National Criminal Intelligence Service (NCIS)¹ details the selling prices of heroin per gram in many UK cities. Contact with the NCIS established that these units are approximate but the range of weights of a '£20 bag', which is another term for 'a quarter G', has a mode of approximately 200 mg (Silver, 2000). This suggests that the weights used in this work may have been above the most common weight for a 'quarter G', however both the NCIS

¹ <http://ramindy.sghms.ac.uk/news/prices.htm>

and the local police forensic information suggested that 250 mg was still within the range of weights packaged for injection.

6.2.3.2 Tablets

The quantities of tablets used in the experiments represented the most commonly reported amounts used by the interviewees, but the sample size does not allow generalisation. Furthermore, given the varying factors identified that influence use and the nature of illicit drug use, it was considered impossible to establish any overall consistency in amounts injected. All that can be said is that the amount investigated in the experiments represented one possible scenario in the injection of these tablets.

6.3 Collection of information to inform the injection preparation simulation process

6.3.1 The role of safer injecting information and drugs workers

The safer injecting information and discussions with drugs workers allowed the researcher to become familiar with the stages involved in the preparation of illicit injections but did not provide any specific details such as quantities used. The stages identified from all safer injecting information and workers were consistently the same. However, to confirm their use it was considered prudent to collect information from those with first hand experience of preparing illicit injections.

6.3.2 The role of the data collected from IDUs

The data collected from IDUs allowed the stages in injection preparation process identified previously to be confirmed, which supported their use. There was no variation in the stages of heroin preparation reported by all the interviewees. However, greater variation was seen amongst those who injected tablets. The interviews were also necessary to confirm specific details of the injection preparation process. However, it can be questioned whether data from the numbers interviewed was sufficient to confirm these details, but further questioned whether with such a variable and uncontrolled process any

consensus could ever be reached, even if much greater numbers were interviewed. This of course is unknown.

The analysis of injections prepared by IDUs, the use of ex-IDUs as observing advisors on the preparation process and non-participant observation of the preparation process were rejected for the reasons stated in chapter 3 (3.1.1 and 3.1.4.1). However, consideration was not given to using a simulation technique to establish the preparation processes used. Placebo tablets, 'fake' heroin, 'fake' acidifiers and other paraphernalia could have been provided within the drugs agency setting and the researcher could have asked IDUs to simulate the preparation techniques they used and made notes and measurements of the processes. This is supported by the fact that some interviewees used the clean injecting equipment they had obtained prior to interview to demonstrate points, for example how much water was added or how the mixture on the spoon was stirred. Some used the soil from a plant pot to illustrate their use of citric acid. Although there are issues that would have to be explored before such a simulation could be used, this would be the choice of the researcher for future work.

6.3.3 The use of the semi structured interview format to collect data from IDUs

6.3.3.1 Data collection tool design

A semi-structured questionnaire format was chosen to allow specific areas to be explored with the interviewee, however after piloting the schedule, the researcher chose to ask general open question on preparation and fill in any perceived gaps by using the schedule questions. Inclusion of the pilot information in the final analysis was considered appropriate since the actual data collected did not differ, just there was less repetition after amendment of the interview style. The researcher needed to have some knowledge of the approximate methods that may be reported, to allow her to understand the types of information that would be required for the laboratory work and to ensure the information she was collecting was understood. Without this understanding, the questionnaire and probes could not have been designed or used in a manner that conveyed familiarity with the subject, a factor reported to be important in interviewing (Moser and Kalton, 1971). Due to the lack of information on known preparation methods reported in the literature, safer injecting leaflets were used. A criticism of basing the data collection on safer injecting information is that the questionnaire may have appeared as a test of safer injecting and influenced a bias in response, especially since they were conducted within the setting of a harm reduction-based agency. Interviewees were assured of

confidentiality from the researcher and asked to be honest, in an attempt to reduce the incidence of biased response. Fifteen of the 20 interviewees reported having received safer injecting advice, so exposure to such advice was high in the interview group. However, the purpose of the interviews was to establish the preparation techniques used, so awareness of safer injecting information was not a barrier in this study. One example that shows a bias did not exist towards reporting safer injecting information is that of filters: All nineteen heroin injectors reported using a filter, however, fifteen of these had also injected tablets and only two used a filter with these. Had there been a bias towards reporting safer injecting information, it may have been expected that the use of filters would have been reported with all drugs, as recommended in safer injecting information.

The main criticism of the data collection tool is that correlation was not possible between the quantities of water and acidifiers used and the amount of drug injected. For example, if someone said they injected 'a quarter G' bag of heroin it cannot explicitly be assumed that the quantity of acid relates to this amount of drug, as this was not asked. In many cases the interviewees did state the quantity of heroin that the amount of acid related to, but it is a criticism that this was not explicitly explored. This also applies to the quantities of water.

A further criticism is that when asking about the mixing of drugs together in a syringe, only tablets were referred to so there may have been under-reporting of powders mixed together. This did not however, impact on this study. Similarly, prior to establishing filtration methods, questions were asked on whether the IDU worried about bacteria and particles. This information was not reported, as it was not used for this study. It may be criticised that this may have biased the filter questions, however again the lack of filtering reported with tablets suggests this not to be the case.

The willingness of the IDUs to engage in conversation with the researcher after taping had stopped indicates a rapport with the researcher had developed. This was considered important by Moser and Kalton (1971). It may also suggest the interviewee relaxed more once taping stopped and for this reason relevant information reported after interview was noted and included in the data analysis.

6.3.3.2 Reliability and external validity

The reliability and validity checks were performed on four interviewees, the results of which suggest the questionnaire was reliable, as all respondents gave the same answer

to the reliability checks as they gave when the questions were originally asked. The validation checks suggest that the questionnaire was also valid. Age matched exactly for all respondents. Age when first injected varied for two respondents by two years each, with the time reported in the interview since first injection being 8 years and 31 years respectively. For the interviewees where age since first injection matched exactly, the length of time since first injection was shorter (2 years and 4 years). Since the interviewee is not likely to be asked to recall this information as commonly as they are asked their age, and the difference in the responses that did not match exactly is relatively small, these responses were considered acceptable to suggest external validity. All drugs reported to be injected at initial contact with DA were recalled by the interviewees, except one interviewee who did not mention one drug that he reported at initial contact. However, five drugs were reported to have been used by injection, so the omission of one was considered to be an omission on recall, not a sign of invalidity.

Reliability checks were performed on data relating to the preparation methods and validity on facts relating to the interviewee. It may be criticised that data on both areas should have been collected for both the reliability and the validation checks. However, since no externally collected information on preparation methods used by the interviewees was known to exist, in practice only further checks on reliability could have been performed. In future work this should be done.

6.3.3.3 Recruitment of IDUs and the sampling method

Consultation with IDUs only recruited from one source i.e. Drugs Action, is a limit of this study, as discussed in 6.2.1.2. Quota sampling was the only realistic option in IDU recruitment for interview as explained in 3.1.4.2. A criticism of the sampling method is that the number of people who declined to participate and their gender was not recorded. Had this information been recorded it would have given an overall indication of the willingness of DA clients to discuss their injecting practices with the researcher. For example, women were under represented in the sample, but it is unknown whether the refusal rate for participation was higher amongst females than men. The use of a quota sample may have meant that IDUs who were aware that their preparation processes did not follow the safer injecting information given by DA refused to participate. However, potential interviewees chosen using a random sampling method would also have had to be given the choice to participate, so this factor could not be avoided.

6.3.3.4 Offering of caffeine and tobacco

The offering of caffeine containing drinks and nicotine containing cigarettes to the interviewees may be criticised as these substances do not promote health and are subject to dependence. It was observed by the researcher during her time at the agency prior to the interview period, that many of the clients drink tea or coffee and smoke cigarettes when they spend time at the agency. The researcher considered it appropriate to make these items available to assist in the creation of a relaxed atmosphere. The decision to accept them was that of the interviewee, they were not pressured to accept them. Some may view this as inappropriate, however the researcher did not consider this to be so in the circumstances.

6.4 The simulated preparation techniques used in the laboratory

6.4.1 The heroin preparation simulation

Six stages in the heroin preparation process were identified from the safer injecting information and the drugs workers (fig. 3.1). No variations were found at all. The preparation methods for heroin reported by the interviewees identified the same six stages. This suggests that the use of these six stages in the simulation process was appropriate. However, the interview data found variations in the specific details of four of these stages, reported by the interviewees. It may be criticised that if a greater number of IDUs had been interviewed, a consensus on the most commonly used factors would have been reached. Conversely, such variation may be expected, given the clandestine nature of drug misuse and freedom of individuals to use such variations. Practices used are unlikely to be exact and, as reported by many interviewees, subject to variation depending on the perceived strength of the heroin obtained. In a sense, when developing a simulation that tries to make an exact process out of an inexact one, there will always be the criticism that the simulation does not represent what is done in practice, because it cannot. Where a choice in what could be done in the laboratory was presented, the decision on which method to use was made by selecting the most popular option from the interviewees. This was necessary since a standardised method had to be used to test the filters to allow the results to be compared and not enough heroin was available to allow all options to be tested with all filters. Again, the small sample number may be criticised but the counter argument being that a greater number of interviewees may have led to greater variation. What the simulation technique used can be taken to represent is one method that is used in some situations by IDUs, but the specific quantities used are not

universal so the simulation results cannot be applied as universal. The exact effects of the different filtration methods are likely to vary with these variations in practice. For example, using a different shaped spoon may achieve different shearing forces when stirred with the needle sheath. These in turn may affect the particle size before filtration, which in turn could affect the number of particles in the filtered injection. To determine these exact effects, more heroin for further study would be required to establish whether the results from this study remain true for all scenarios.

A further matter that requires discussion is the mixing of the different heroin samples obtained to give one batch to use for this work. Although the limitations on the amount of heroin available for this work justify the need to mix the samples together, it may be criticised that the resulting mix was not tested for homogeneity. Visually, the mixture was inspected for a homogenous appearance but no further tests were performed. Therefore, in further work that required small samples to be mixed more attention to the mixing process would be given by consulting powder technology literature. It is not known whether the mix of the sample would have influenced the results. However it is suspected that the level of attention paid to the mixing process in this study would be no less than that given to the mixing process by drug dealers, although this cannot be confirmed.

6.4.2 The tablet preparation simulation

The preparation techniques used for tablets was found from the interviews to vary with the type of tablets used. For example coated tablets were reported to be crushed or have the coating 'chipped off' prior to mixing them with water. Formulations perceived to be more readily soluble such as Temgesic[®], which is designed for sublingual use, were merely shaken with water in the syringe. Even for the same drugs there appeared to be no consensus on whether the tablets were crushed prior to dissolution. For this reason, the laboratory investigation studied both options. Similar criticisms apply as for heroin (6.1.3.1) and what can be said is that the simulations used are likely to represent scenarios that apply to IDUs at some point, but they cannot be assumed to apply universally.

6.4.3 Source of water used

The source of the water used for the experiments performed was the tap. In Scotland, the water supply is described as 'soft' in that it does not contain large amounts of lime, unlike

other areas of the country. Water for injection was used during the control tests, illustrating that there was little difference in the particle count of control injections made using tap water and water specifically prepared for injections. However, in other areas of the country where the amount of limescale deposits in the tap water is large, there may be a difference seen between the particle content of 'blank' injections prepared using tap water and water for injections. Therefore, in further work it would be prudent to investigate this matter using tap water obtained from different areas of the UK.

6.5 The laboratory investigation

6.5.1 Equipment used

The equipment used for this work was largely dictated by availability within the School of Pharmacy. Although the validation of the Coulter Multisizer showed acceptable particle sizing (6.1.4.2), the equipment was difficult to optimise, for example, the pressure within the system was difficult to set. Pressure loss did occur during analysis on some occasions, this is seen by failure of the orifice tube to fill with saline. If this occurred, the sample had to be discarded. Similarly, if the orifice blocked, the sample had to be discarded. This however, only happened occasionally. At times, error occurred in establishing the current and again the analysis had to be discarded. When this occurred with the heroin work this led to loss of what was already a limited amount of material. The researcher became more familiar with the equipment over time and although not recorded, it is perceived that the incidence of analysis failure was more common with the initial tablet analysis work when the equipment was new to the researcher. A newer model of Multisizer that would allow downloading of results to a PC would have been an advantage as with the system that was used, results cannot be stored, so data recording all had to be done manually. A further criticism is that validation of particle counting cannot be carried out in the laboratory, since it is impossible to introduce a fixed number of particles into the system. Therefore that manufacturers assurance in the operating manual that up to 20,000 particles will be counted accurately within the 12-second counting period has to be taken as acceptable.

Some of drug was again wasted in the attempts to use the HPLC system. The CZE equipment was again dictated by availability. If a choice had been available, there would have been clear advantages in the use of automated equipment, as the results could have been stored and the inbuilt drug libraries could have been used in peak identification. However, the system used was found to be reliable. Dr Ann Low and Mr Raymond Reid gave some assistance in operation, for which the researcher is grateful.

6.5.2 Validation of the Coulter Multisizer

6.5.2.1 Reliability

For the reliability checks the RSD values were all below the acceptable limit chosen (4%) and were all less than 2 % (table 4.2), suggesting the results from the Multisizer to be reliable. The mode particle sizes were however higher than the stated label size of the latex (mean =14.24 μm , stated latex size = 13.7 μm). This was also observed for the precision checks and is discussed in the next paragraph.

6.5.2.2 Precision

From table 4.3 it can be seen that the RSD values for the mode particle size and the distribution were less than 3 %, and considered acceptable for this work. The mode particle sizes were higher than the stated label size of the latex (mean =14.06 μm , stated latex size = 13.7 μm). This was also observed in the reliability checks. The mode particle size represents the midpoint in the channel within which the greatest number of particles was detected. Therefore, the actual size of the particles will be anything within the channel size. The width of each of the 256 channels was 0.24 μm , so the actual size of the mode particles could be the quoted value \pm 0.12 μm . However, this adjustment only brings the precision check at 15 minutes to the latex stated label size. Although a small distribution would be seen when the latex was sized by the manufacturer, the accompanying information shows that the stated label size is the peak height in the sample distribution, so should be the same as the measured peak height (mode \pm 0.12 μm). Possible reasons for a measured latex size greater than the stated label size could be some coalescence or agglomeration has occurred amongst the latex particles. This could happen if the latex suspension became unstable. At the time of manufacture and of this work, the storage requirements recommended by Coulter Electronics were *in a cool, dark place*². The researcher stored the latex standards as instructed in a cool, dark drawer, and care was taken not to leave them exposed to sunlight. However, since this time, the new manufacturers Beckman Coulter have changed the recommendation to storage in a refrigerator above 4 °C. The latex standards used were several years old and cost restrictions prevented new standards being purchased for this work². Although latex suspensions are usually stable for many years, the lack of refrigeration and the unknown storage conditions prior to this work, may have caused instability in the suspension, leading to an increase in the size of the particles and hence some slightly larger

² Latex standards are made to order by the manufacturer. The approximate cost of one bottle is £100

measured sizes. However, the Multisizer was shown to be accurate, so this suggests some conflict, which would require further investigation to be explained.

6.5.2.3 Accuracy

All the stated label latex diameters fell within the mode channel sizes measured for the accuracy experiments. This demonstrates accuracy within the Multisizer measurements.

6.5.2.4 Within day and day-to-day variation.

The within day and day-to-day variation was investigated as a further test of reliability over a range of sizes. The results shown in table 4.5 show acceptable RSD values for the within day tests. Had latex standards been available that covered the whole size range of interest for this project i.e. up to 50 μm , these would have been used. However, 19.1 μm was the largest size available. Table 4.6 shows the day-to-day variation test results. The RSD values were again considered acceptable.

6.5.3 Particle size analysis results

6.5.3.1 Data recording

Direct comparison between filtered and unfiltered samples from the same injection was not done for the reasons given in 4.3.7.4. At the time this decision was made the researcher was concerned that if the orifice continued to block frequently with the unfiltered injections and many injections were discarded, there would not be enough heroin to perform all the experiments. In the case of the tablets, solid material remained dispersed so large amounts were sucked into the pipette tip. As it transpired, the heroin injections were less heavily contaminated and the solid material sank to the bottom of the spoon on heating, so this may not have been a problem with the heroin. However, it was considered important to do the same comparisons for the tablet injections as the heroin, so the results could be considered in similar terms, so the method was not changed. The concern about the removal of liquid from the unfiltered material reducing the volume of the final injection is now not considered a problem, as all filtered injections would have been subject to the same sample removal. However, the difficulty of one researcher performing 'before' and 'after' analysis on the un-automated machine was another reason

in defence on not making this comparison. Consideration must be given to whether the method of comparison used was acceptable. The particulate contamination in injections will vary greatly, so the purpose of this work was to identify trends in the results, not to take the results as absolute. The results that were compared were from injections that had been prepared in exactly the same way, under the same conditions and for this reasons were considered acceptable in providing information to identify trends.

It must be remembered that the actual particle numbers recorded represent what was counted from the sample in 12 seconds, not the total count in the injection. The stirring and addition of the sample to the relatively large volume of saline may have caused some particles to dissolve that were present in the injection. It is unknown whether this effect would be seen when the injection is administered as the components of blood could cause precipitation of materials in the injections, hence increasing the risk of blockage, or dissolution of particles, depending on the interaction between the injection materials and the blood. These effects are unknown. In vitro experiments examining the effects of the injections in blood would be needed to establish such information, however, since blood cannot be used as the analysis medium for the Coulter Multisizer, such work may not achieve any greater representation. The variability between different batches of heroin again would make the actual situation in practice variable.

6.5.3.2 Controls

It must be remembered that the exact particle counts obtained from the Coulter Multisizer analysis are meaningless since they will be subject to great variation. Instead, the data is considered by looking for trends in the particle counts, as shown in figures 4.2 to 4.5.

Unlike standard scientific experiments, the controls were not performed to show that in the absence of the material under investigation the equipment does not give a result when a 'blank' experiment is performed. In this work that would be impossible since some particles will come from the operator, environment and equipment. Instead, the controls were performed to see how the contribution made to the particle load by all factors involved in the injection preparation process, except the drug, compared to the particle load seen with the drug. The controls were also performed to find out whether the filters added to the particle load when water was passed through them i.e. by shedding particles. Both water for injection and kettle water were used to find out if using water specifically prepared for injection made any difference to the particle load in the controls or whether the contribution from the operator, environment and equipment over-ruled any possibility of benefit.

From figures 4.2 to 4.5 it can be seen in comparison with the unfiltered drug injections, both the kettle water and water for injection controls, contained a much smaller particle load. The filters were not considered to contribute to the particle load as significantly as the drug. The Water for Injections (WFI) blank performed with the cotton bud and the kettle water blanks with the hand rolling filter and syringe filter appear on fig 4.4b to be raised but when compared to both waters when shaken in the syringe they are seen to be similar (fig. 4.4a). This suggests that the contribution from the filters cannot be distinguished from that of the background. Again, the WFI did not show consistently less particulate load compared to the kettle water, suggesting that the background contribution cancels any benefit from the WFI. It must of course be remembered that there are likely to be microbiological benefits from WFI being used by IDUs.

6.5.3.3 Impact of filters on the particle load of the heroin injections.

Table 4.9 and fig. 4.5 show the results from the heroin injection analysis. Here it can be seen that all methods of filtration caused reasonably large reductions in particle load. The greatest reduction was seen, as hypothesised, with the syringe filter where the greatest proportion of the total number of particles were removed. Of the makeshift filters, the cigarette showed less reduction than the hand rolling and cotton bud filters.

Figure 4.6 shows the effects of the filters on particles in the two smallest size ranges of interest. The larger sizes were not included as the differences in numbers were small and not considered distinguishable from background effects. In the size range 5 to < 10 μm all the filters removed the great majority of particles. In the smaller size range, the SF performed best. Although the particles in this range are smaller than the SF pore size, the insoluble material itself may have acted as a filtration bed, as it coated the filter surface.

These results suggest that large levels of particle reduction in heroin injections can be achieved through the use of all types of filters, although the SF conveyed the greatest benefits.

It is not possible to distinguish the nature of the material of the particles measured with the Coulter Counter. Therefore, it cannot be said whether the particles measured were due to the drug, the filters or the environment. Analysis of the injections under a microscope could have been performed to establish whether the nature of the particles could have been identified. Future work would include this in the experimental process.

6.5.3.4 Impact of filters on the particle load of the tablet injections.

The Physeptone[®] experiments were not pursued as they could not be filtered using a process which the researcher considered would be acceptable to IDUs. The unfiltered injections showed particularly high levels of contamination (table 4.10 and fig.4.2). Confidence in the result from the sample that was crushed and mixed on the spoon must be low, as this far exceeds the suggested maximum particle load for the orifice, which is approximately 20,000 particles per 12 second count (Coulter Electronics, 1988). The Diconal[®] and Temgesic[®] injections were able to be satisfactorily filtered. As shown in fig. 4.3, the makeshift filters brought about some reduction in particles. However, the SF produced a much greater reduction in the level of particles than the makeshift filters. When the size range data is considered for Diconal[®] (fig. 4.7) it can be seen that in the 2 to < 5 μm range, only the SF produced any benefits. Similarly, in the 5 to < 10 μm range, only small reductions in load were caused by the makeshift filters, although the SF again produced very large reductions. The makeshift filters performed better in the 10 to < 20 μm size range although the SF was clearly better. Only in the 20 to 50 μm range did the makeshift filters convey benefits close to those of the SF. For Temgesic[®] (fig. 4.8) the SF results are comparable to those it produced with Diconal[®]. However, the makeshift filters showed poorer results.

6.5.4 Drug quantification equipment validation

6.5.4.1 Linearity

The CZE experimental method was shown to give a linear response over the concentration ranges of interest, as shown in table 4.13 and figures 4.9a and 4.9b. This meant that the ratios of the experimental peak heights to the standard peak heights could reliably be used to calculate the concentration of diamorphine, 6-MAM and morphine in the injections.

6.5.4.2 Within day variation and day-to-day variation

For the validation experiments performed for this work, the average peak heights and average migration times from the within day variation checks all had an RSD value less than 3.5 % (table 4.14). For the day to day variation checks the RSD values for the average migration times and peak height ratios were also below 3.5 % (table 4.15). This

shows that the CZE method used was sufficiently rugged to allow results to be compared that were collected over a period of time.

6.5.5 Drug quantification results

6.5.5.1 Controls

No peaks were found when the controls were analysed on the CZE system, illustrating that any peaks seen in the experiments are due to the heroin and not the preparation process.

6.5.5.2 Effect of filtration on the drug content of injections.

Table 4.16 shows the results of the amount of drug detected in the filtered injections. When compared statistically, the injection filtered with the hand-rolling filter was found to contain significantly less diamorphine than the other injections. This may be attributed to its greater size than the other filters, as it will have the capacity to retain larger volumes of fluid, which will contain dissolved drug. On examination of the results in table 4.16, the amount of 6-MAM in the injections filtered with the hand-rolling filters also appears reduced. This suggests that dissolved 6-MAM is retained in the filter also. If the reduced diamorphine quantities had been due to greater decomposition in the hand-rolling filter injections, it would have been expected that the amount of morphine detected would have been higher in comparison to the other filtered injections. This does not however appear to be the case. The SF did not differ statistically from any of the makeshift filters, suggesting that it may be acceptable for use by IDUs.

6.5.5.3 The amount of diamorphine retained in the filters

The average weights of the hand-rolling filters and the syringe filters after use were much greater than those of the cigarette and cotton bud filters. The results discussed in 6.5.5.2 suggest that the hand-rolling filter retained some of the drug that went into solution on the spoon. When the content of the filters were analysed, the syringe filter contained significantly greater amounts of diamorphine compared to the other filters. The reason for this is thought to be because not all the solid material dissolved when the injection was prepared, i.e. some of the basic diamorphine was not converted to salt. This was shown

by the detection of diamorphine in the remains on the spoon (4.7.7.4). This happened because the quantity of citric acid used was not enough for this conversion to take place completely (see 6.5.5.5). The SF was observed to act like a vacuum cleaner, sucking up all the solid material from the spoon into the filter casing. In the case of the makeshift filters, some of the solid material remained on the spoon and some stuck to the filter. Therefore the fluid retained in the filters will have contained dissolved drug and undissolved drug will be present in the solid that the filters retained. Additionally, the solid material may possibly retain fluid, which could contain dissolved drug, although the sucking of air through the filters into the syringe to indicate complete filtration may have minimised this. The SF appeared visually to contain much more solid and it was found from the filter analysis to hold more drug. The volume of fluid that the SF is quoted by the manufacturers to retain is 50 μ l (Gelman Sciences, 1991). Further work could be done to establish the amount of diamorphine retained if complete conversion to solution was achieved. The practice of IDUs retaining used filters to break down at a later date to prepare injections is known (Koester et al, 1990). This was also reported in informal discussions with IDUs and ex-IDUs. The donation of remains on the spoon to someone in the IDU's group who did not have money for drugs was also identified from these discussions.

The experimental analysis of the filters shows their capacity for retaining some of the drug and highlights why there may be difficulties faced by drugs workers trying to persuade IDUs not to retain filters for further use. As said, this practice is associated with 'cotton fever'. The solid material held in the SF could potentially be removed quite easily as the material forms a plug in the nozzle of the filter. Flushing the filter with water in the opposite direction to which the injections were filtered released the solid and returned the filter to a 'clean' appearance. Potentially, if this was known by IDUs it may encourage the sharing of the filter contents with others. The IDUs who took part in the user evaluation pilot study were not asked whether they found this out. This would be a useful point for investigation in further user evaluations.

6.5.5.4 The influence of the variables

Great care was taken in ensuring that the variables involved in the preparation process were kept constant to enable the results measured to be meaningful, as described in 3.4.3. However from tables 4.16 and 4.17 it can be seen that the standard deviations of the concentration of diamorphine measured ranged between 0.96 and 4.21. Heating is considered to be the most difficult variable to control since only indirect controls could be

used e.g. the length of time of heating and distance of the spoon from the flame could be measured and controlled, the quantity of energy input into the mixture could not be directly measured. Variations in the amount of energy input into the injections may have influenced the diamorphine concentration as more would break down if exposed to more energy. Smaller deviations that follow similar trends to the diamorphine standard deviations (table 4.16) can also be seen in the standard deviations of the 6-MAM and diamorphine concentrations shown in table 4.16. However, for single results where the diamorphine and 6-MAM contents seem to follow similar trends, but the morphine content did not always do so. This suggests that the lower diamorphine content found in some experiments could have been either due to increased diamorphine breakdown or less diamorphine being present initially, perhaps due to inconsistent mixing as discussed in 6.4.1. In table 4.17, only diamorphine content was measured so the speculation extends to these results but cannot be proven. Further work could investigate the effects of heating on drug content in injections more closely.

6.5.5.5 The acidifier investigations.

The structure of citric acid is shown in figure 6.1. One possible theory for the interaction between diamorphine and citric acid is as follows: When this acid is mixed with diamorphine, the three carboxylic groups dissociate and form complexes with the diamorphine molecules at each group. Alternatively, the acid may form a salt with the diamorphine. If full dissociation occurs, for every one molecule of citric acid, three molecules of diamorphine will complex with it. The extent of this dissociation depends on the amount of acid added (which will reduce the pH) and the pKa values of the groups and the pKa value of diamorphine. pKa is the log of the dissociation constant for the group, it indicates the 'willingness' of a reaction to happen. Because it is a log value, the lower the pKa, the higher the Ka and hence the stronger the acid. For example, the three carboxylic groups of citric acid have the pKa values 3.1, 4.7 and 6.4. Diamorphine has a higher pKa value (7.6) so the acid is 'willing' to dissociate and form complexes with the diamorphine, or conversely, the diamorphine is able to remove the H⁺ from the acid.

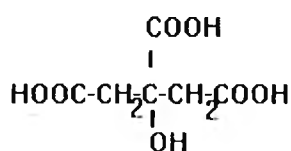


Figure 6.1 Two-dimensional representation of the chemical structure of citric acid.

The structure of ascorbic acid is shown in figure 6.. The pKa values of the two hydroxyl groups are 4.2 and 11.6 respectively. The 4.6 value shows that this group will dissociate and form a complex with the diamorphine. However, the 11.6 value won't as the diamorphine (pKa 7.6) is not strong enough to remove the H⁺. This means that only one diamorphine molecule will complex with one ascorbic acid molecule.

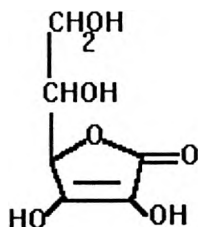


Figure 6.2 Two-dimensional representation of the chemical structure of ascorbic acid.

When the effects of acids are considered in molar terms, it can be said that for every mole of diamorphine, one third of a mole of citric acid will be needed for complete dissociation. For the ascorbic acid, one mole of diamorphine will complex with one mole of ascorbic acid. When this is transferred into weight, the quantity of acid required for complete dissociation can be calculated. In terms of street heroin, if the diamorphine content of the heroin is known, the amount of acid required can be calculated

For the heroin used in this work, a diamorphine content of 55.68% was found. This means that in 250 mg, as used for the experiments, the diamorphine content will be 139.2 mg. To convert 139.2 mg of diamorphine to salt form, the following calculations can be applied:

Citric acid: 1 mole of diamorphine requires 0.333 moles of citric acid. The weight of one mole of diamorphine is 369.4 g. The weight of one mole of citric acid is 210.1g.

$$210.1 \times 0.333 = 70.03\text{g}$$

By simple proportion, it can be calculated that for 139.2 mg of diamorphine, 26.39 mg of citric acid would be required.

Ascorbic acid: 1 mole of diamorphine requires 1 mole of ascorbic acid, which weighs 176.1g. The quantity required to convert 139.2 mg of diamorphine would be 66.36 mg.

The weight of citric acid used for the filter comparison experiments was based on the information collected from the IDUs in interview. As said, consideration was not given to the use of simulation to establish the quantities used. As it is illegal to give citric acid to IDUs, and as it is known that some IDUs have difficulty in obtaining acidifiers for this reason, it would be unwise to actually use acids in a simulation process, as the IDUs may want to keep the acids. This would put the researcher in a difficult situation. However, an inert substance which looks similar to citric or ascorbic acid could be used, such as sodium chloride. As long as it was identified which type of acid the IDU was basing his or her simulation on, the weight of the sodium chloride could be used to calculate the weight of acid used. This could also be done to establish the approximate amount of heroin to which the quantity of acid relates, using a material such as fine grade sand, which is similar in appearance to brown heroin. It is regrettable that this was not considered when the preparation processes were being established.

However, this does not mean that the results from the filter experiments are meaningless. The diamorphine content of the heroin will vary, and the IDU has no way of knowing this quantity. The amount of acid to add will be a process of 'trial and error' by the IDU. It is unknown from this work whether the amount of acidifier reported in the interviews was underestimated or whether IDUs do not achieve complete dissolution of the diamorphine when preparing injections. Of course the diamorphine content of street heroin will vary, a 'purity' of around 50 % is considered average for UK heroin (Gossop, 1995). It is unlikely, on the basis of so many variables that an accurate simulation process that represents the practices of the majority of heroin injectors could be achieved, given that the scientific analysis required strict control of variables. If large amounts of heroin were available, experiments using heroin of different purities and a range of preparation practices could be undertaken. However, arranging enough heroin may take some time, since the willingness of police forces, destruction procedures used locally and availability of drugs from closed cases all dictate what is available. As an illustration, after the heroin for this work was obtained, no further samples were available from the police in the time scale of the laboratory work. An approximate simulation is probably as accurate as this kind of work can be. As established through informal discussion with IDUs, diamorphine remaining in filters and on spoons may be used to prepare further injections. It does however, highlight the difficulties in trying to transfer an inexact process such as heroin injecting into a scientific analysis procedure.

From the acidifier experiment results (fig 4 10 and 4 11) it can be seen how the amount of diamorphine in the resulting injection increases with the quantity of acid added. The injection prepared with no acid could not be filtered as the solid remained flocculated on

the spoon. This illustrates the need for acidifiers when preparing base heroin for injection. Figure 4.12 shows how the addition of more water is ineffective in promoting the solubility of more diamorphine. It can also be seen from 4.10 and 4.11 that quantities of acid close to those calculated to be required for complete dissociation were tested in the laboratory, however, the resulting amount of diamorphine in the injections was much less than the 139.02 mg of diamorphine known to be in the injections. When the filters used in these experiments were analysed they contained an average of 12.55 mg of diamorphine for the citric acid experiments and 7.49 mg for the ascorbic acid experiments. The qualitative work showed that diamorphine was lost during the preparation process in the vapour on the watch-glass and on the needle sheath used to stir the mixture on the spoon.

pH

Table 4.21 shows the average values of the pH measurements recorded for some of the injections. It can be seen that, as expected, pH gets smaller as more acid is added. The physiological effects of these injections on vein walls have not been investigated and the buffering effects of blood is unknown, so it is not confirmed if pHs in these ranges will be damaging. The injection of ascorbic acid has been shown to cause haemolysis in individuals with underlying blood disorders such as glucose-6-phosphate dehydrogenase deficiency, but has not been a problem in healthy individuals (Parfitt, 1999). The pH of pharmaceutical diamorphine is 4.0 (Evans Medical, 1998), presumably because this is within the pH range (3.8 – 4.4) at which it is most stable in solution (Parfitt, 1999). This illustrates that low pHs can be administered intravenously. The damage to veins anecdotally attributed to citric acid by IDUs and drugs workers may be augmented by frequent administration, using excess or leakage from the veins. However, further work is required to investigate this. In the mean time, the recommendation to rotate injecting sites can be endorsed. At this stage, it is known that the addition of acidifiers is necessary as injections could not be prepared without it. However, when acids are added, the pH of the injections decreases (the pH of street heroin mixed only with water was 7.5).

When injected, diamorphine salts are rapidly converted to the active metabolite 6-MAM then morphine. Citric acid is metabolised to carbon dioxide and water whereas ascorbic acid is metabolised to dehydroascorbic acid, which in turn is converted to ascorbate-2-sulphate and oxalic acid. The latter is known to be toxic in large quantities, causing ionisable calcium to be removed from the blood and tissues and deposit in the kidney forming calcium oxalate calculi. However, this has not been shown from the injection of ascorbic acid (Parfitt, 1999). The daily human requirement of ascorbic acid is 30 to 60mg and any excess is excreted unchanged in the urine. Further investigation would be

needed to be sure that there were no cumulative or prolonged effects in IDUs who use ascorbic acid to prepare injections

6.5.6 Considering all laboratory results

An important lesson learned from this work is the difficulty in transferring such a variable process into a scientific laboratory experiment. The lack of access to all analysis equipment at the same time and availability of manual equipment also created difficulties. It is regrettable that the quantity of acid required for complete conversion of the diamorphine was not checked after the weight of 'a small pinch' of citric acid was found, at the time that the percentage content of the street heroin was established. The use of a simulation technique to establish information on preparation methods may be more useful and would certainly be used again in further work.

The results suggest that in terms of reducing the number of particles, if the paraphernalia laws changed, syringe filters may be beneficial if used by people who inject tablets, as they caused large reductions in the particles in the injections. However, care would need to be taken in how this harm reduction intervention was actually conducted, as it would have to be made explicitly clear that the SF would not make the injection of tablets 'safe', only it may reduce some of the risks. The makeshift filters did not produce a reduction in particle load to an extent close to that achieved with the SF.

For the heroin injections, the picture is less clear. The SF produced the greatest benefits in terms of particle load reduction. However, the makeshift filters did also reduce the load quite significantly. The hand rolling filter injections contained significantly less diamorphine than the injections filtered using other means and the syringe filter retained the most drug. However, it was found that not all the diamorphine in the street heroin was in solution. Solid drugs as well as liquid was retained in the filters, so in practice with differing quantities of drug in solution these results may change.

The results suggest that there may be health benefits for IDUs if they were to use syringe filters in the preparation of their injections, in terms of reducing the incidence of health problems that relate to the injection of particulate matter. Such benefits would depend on enough filters being available so they could be used for every time an injection was taken by an IDU. In order to measure the existence and extent of such benefits, further studies of the clinical outcomes of filter use in practice would be necessary and should be a future stage in this work.

6.5.6.1 Issues around the supply of makeshift filters

Although there did not appear from the controls to be a large amount of particulate matter contributed from the filters, the issue of advising on the use of something not specifically designed for the purpose is still pertinent. If the paraphernalia laws changed and needle exchanges chose to supply filters, many issues would exist. The syringe filters would be much more expensive than makeshift filters, for example the hand rolling filters. The health benefits and treatment savings would have to be determined to allow the total costs of the filters to be established i.e. the direct and indirect costs would have to be known. The makeshift filters are not however, designed for the purpose for which the NXs would be distributing them. Although the hazard sheets for cellulose acetate and triacetate, which were obtained from Filtrona, do not show any toxicity risks from these chemicals, should any harm result i.e. from shed fibres, the needle exchange would be in a difficult situation, in terms of legal responsibility.

The makeshift filters were tested in this work according to the methods described by the IDUs and drugs workers. The hand rolling filter was used complete. However, it could also be cut down in size and a smaller amount used, as is done with the cigarette filter. This may potentially reduce the amount of drug retained. This could be investigated in further work.

6.5.6.2 Issues around the supply of acidifiers

This study has shown that the addition of acidifiers is necessary in the preparation of base heroin for injection. However, the long term effects of citric and ascorbic acid, when used in this way require further investigation before their safety can be established. In the mean time the recommendation that injection sites should be rotated can be endorsed in an attempt to maintain vein patency. Also, the fact that the long-term safety of acidifiers is not known should be made clear to IDUs.

6.6 The user acceptability pilot study

6.6.1 The study design

6.6.1.1 Recruitment method

The recruitment of participants for the pilot study through the DA NX was appropriate because of the need to safety-screen potential recruits. The records held in the NX allowed this screening to be undertaken and the availability of counselling rooms allowed private discussion. Some potentially suitable clients may not have been identified if (i) they had recently been issued with a new NX card i.e. their previous card was full or had been misplaced, as they would have appeared from the NX card not to have an established attendance record. (ii) There had been an error in the code recording of information on the NX card. It is regrettable that the number of potential recruits that were identified through the NX card screening was not recorded, so the proportion that was recruited in the study period cannot be calculated. However, the limit on the time for recruitment prevents such a figure being meaningful in terms of identifying recruitment success of this method. It is the feeling of the researcher that a significant proportion of the NX clients were not considered acceptable for recruitment because it was noted on the card that they were taking methadone. The number of information sheets distributed was 14, seven of whom presented for consideration for inclusion in the recruitment time. six of whom were recruited. No follow up was made of those who received a sheet but did not present for inclusion.

6.6.1.2 Criteria for inclusion

The strict safety criteria imposed on the pilot study was considered necessary to safeguard the participants, DA and the researcher. Control over the amount of diamorphine in the heroin used to test the filters was impossible, so other safeguards to minimise the risk of adverse events were important. Also, at the time of this work much media attention locally was focusing on drugs services. Both DA and the researcher were keen that, in the event of attention being focused on filter distribution, safety precautions and accountability of the study could be demonstrated.

If the criteria for inclusion hadn't been as strict, it may have been possible to recruit greater numbers of people into the study in the given time. However, ethically this would have been unacceptable.

6.6.1.3 Anonymity and confidentiality

Participation in the study was not anonymous and ethically this has to be justified. The need for the first or nick names and contact details of the recruits was considered necessary as the researcher wanted a means of following up the recruits if they did not return to DA within the given time. This was to allow her to ensure that no harm had come from the filter tests. The names and details were kept confidential to the researcher and participants were assured of this. Several did ask to confirm that this would be the case before they agreed to participate. Once this was assured, the participants gave details, suggesting trust of the researcher.

Names of the participants were not revealed to the DA workers, however knowledge of who was participating, in terms of initials and dates of birth was known to those who saw the needle exchange card stickers and distributed the questionnaires. This system of identification was explained to the participants before they agreed to take part. In all cases the participants stated that they had no concerns about DA staff knowing they were taking part as they felt trust in the workers.

6.6.1.4 Trust

Trust was a key component of the pilot study. The researcher trusted the recruits not to give the filters to anyone else and to dispose of them as instructed. The recruits trusted the researcher not to expose them to harm and to keep their personal details confidential. Responsible disposal of the filters was measured in so far as all recruits returned a cin bin, which they said contained the SFs. Opening of the bins to confirm this was not considered safe for the researcher. The bins with transparent bottoms did not have wide enough openings to allow the filters to be disposed of in them. Therefore, the disposal information was taken on trust. In further studies commissioning the design of clear bottomed wide mouthed bins may be appropriate, although wide mouthed bins are not favoured by the DA workers as they allow the removal of their contents, encouraging reuse of injecting equipment.

6.6.1.5 Number of syringe filters tested

The number of SFs given to the recruits was four. From the researchers experience in the laboratory, this was considered enough to allow the recruits to become familiar with their

use. The two recruits who did not find the SFs acceptable did not test all four filters. It was not considered ethical or manageable to make it compulsory for recruits to agree to test all four filters at the outset. It is unknown from this work whether further experience with the remaining filters would have influenced the opinions of those who reported their use of the SFs to be unfavourable.

6.6.1.6 Questionnaire design

The questionnaire was short and quick to complete. There were no issues of ambiguity raised from the pilot group. The main criticism of the questionnaire, which was identified after it had been administered, was that details of the preparation methods used for the injections filtered with the SF were not gathered. For example, the amount of heroin, type and approximate quantity of acid and water added and duration of heating should have been asked to inform the researcher of the circumstances under which the filters were used. Also, it was not confirmed whether the filters were tested as detailed on the instruction sheet. Further work would include the collection of this information.

6.6.2 Discussion of the pilot study results

The pilot study group included both males and females with an age range of 22 to 38 years. This was considered appropriate as it represents both sexes and a wide age range. Although it was known from the inclusion criteria that all participants had been injecting for at least 3 months, the length of time since they began injecting was not recorded. Such information would be useful for a larger evaluation as it would allow the data to be investigated for a correlation between injecting experience and opinion of the SFs.

The recruits used a range of injecting sites when they tested the SFs. This is significant because larger detachable needles are used when access to deeper veins such as the femoral vein is necessary, for example when surface veins are collapsed. This may in turn influence the acceptability of the filters. Although the use of detachable needles and syringes were a problem for two recruits, both gave favourable reports of their use of the SF. One of these people added in the additional information that she had overcome her dislike for detachable needles and syringes by transferring the injectable liquid into an insulin syringe for administration. On wide scale distribution, if this proved to be seen in a significant proportion of SF users, there would be issues around the need for greater

amounts of injecting equipment. There are limits on the number of sets of needles and syringes that can be collected at any one time from a NX in Scotland, as stated in the Lord Advocate's Guidelines (The Scottish Office, 1998), so more frequent visits to NXs would be needed, which carries implications for workload, resources and practicalities such as disposal and client convenience.

The pilot evaluation showed that the syringe filter was acceptable to four of the six IDUs in the pilot group, with three showing definite preference for it compared to their usual cigarette filter. Two of the IDUs had difficulties with the SF that related to it retaining fluid. One of these declined the offer to test the filters with water at DA before he agreed to participate. A larger study could investigate whether demonstration of filter use contributed to filter acceptability. One of the IDUs who was interviewed in the work reported in chapter 3, mentioned that he wet his filters before use. He gave a detailed explanation of the reason for this, the conclusion of which was to reduce the amount of drug-containing fluid retained. Since this practice was not explicitly asked about in the interviews reported in chapter 3, it is unknown whether this practice is done by other IDUs. Further work to establish injection preparation techniques could be combined with data collection on the testing of SFs. In this work the incidence of filter wetting should be addressed. Filter wetting may be an unknown factor that contributed to the difference in opinion seen in the pilot group.

Two people expressed an opinion that the effects from the injection were different, with one stating the injection felt stronger and cleaner and another stating the effects from the drug was reduced. The quote from recruit no. 2 (5.4.2.4) suggests a perception that the impurities in a heroin injection are those that do not dissolve. It is of course possible that soluble impurities may also be present in injections. From analysis studies it appears that common adulterants are soluble inert sugars such as lactose, but soluble active impurities may also exist such as caffeine (Kaa 1991, Chiarotti et al 1991, Chaudron-Thozet et al, 1992, Kaa 1994). Further investigation of users perceptions of the benefits of SFs should include questions to establish whether there is a perception that filtering makes injections 'pure'. It would also be prudent to establish other perceived benefits of filtering, especially in relation to health.

Although no conclusions can be drawn from a pilot study, this work suggests that a larger scale investigation into user acceptability and use of the SFs would be worthwhile to establish whether filter acceptability or unacceptability predominates. Details of the preparation methods used would be collected to identify whether any differences in

preparation method contributed to the IDU's opinion on the SFs and to gain more information on the range of preparation methods used.

The inclusion criteria would be relaxed for further studies in stages, as safety information emerged. The recording of participants contact details would be necessary for further work initially, until an indication of the safety profile for the SF had emerged. If nothing happened to question safety, further participation could be anonymous. As the study expanded, the number of participants lost to follow up may increase. However, this would be affordable once it was known that the filter did not increase the incidence of adverse risks. The return of used filters could be checked if a clear disposal bin was used. However, the risk of not getting back all filters that were distributed is likely to exist.

A final comment on the pilot study from the researchers viewpoint is that all the pilot group showed an active interest in the study. This may be expected since they agreed to participate, but the researcher felt that there was an interest in being listened to and an interest in helping with the development of this work to benefit IDUs as a group. This came from the participants' provision of further comments, including the drawing of diagrams of possible ideal filters and discussion around the legal status of the provision of filters. The drugs workers also reported additional comments made at a later date, which showed interest. Given the difficulties found in establishing accurate information on the injection preparation process and the ethical and legal barrier that prevent non participant observation, as discussed in chapter 3, there may be a case for continued studies having a user involvement component. User involvement is advocated in the development of drugs services (The Scottish Office, 1999, UK Government, 1999) and anecdotal information suggests the number of users groups in the UK to be growing (Anon, 2000). This work suggests user involvement may also be appropriate in research. Areas that could be explored are user recruitment of participants into the SF study and using participant observation to record information on the SF tests and testers opinions.

For further evaluation, the questionnaire would be expanded to establish how the filters were used, including details of approximate quantities. The testers would also be asked about issues around reuse of the filters. A user information leaflet summarising the laboratory findings in clear and understandable language would be needed in order to explain both the evidence on which the decision to distribute the filters was made and the limitations of the filters e.g. be explicitly clear that they will not prevent the transmission of blood borne viruses if equipment is shared. Long-term health gains would take time to measure.

6.7 Conclusions and further work

The research questions that this study aimed to answer will now be returned to, to briefly give the conclusions of this work.

The first question was: can a simulation of the injection preparation process used by IDUs be developed, which can be used to conduct representative investigations in the laboratory setting?

A simulation process was developed that allowed controlled reproducible conditions of investigation in the laboratory. The extent to which large variables exist in the preparation of illicit heroin injections means that the process did not and could not represent the practices of all IDUs. Further work could be conducted to establish preparation techniques by asking IDUs to simulate their preparation processes using 'fake' drugs and acids. The quantifiable aspects of the process could be recorded. One person in the user evaluation pilot study did not wish to test the filters with water as he said using the equipment would make him crave heroin. If this was the case for many users, there may be an unwillingness amongst some to participate in a simulation process.

The second question was: can a measure be made in the laboratory of the effectiveness of makeshift filters at removing insoluble particles?

This was done using particle size analysis, performed on injections prepared with heroin and with Diconal[®] and Temgesic[®] tablets. For the tablet injections, the makeshift filters showed some success in the size ranges of interest, however contamination levels remained high. However, for the heroin injections a larger decrease in the particle content was seen.

The third question was: are commercially available syringe filters more effective at removing insoluble particles from injections than makeshift filters?

For both heroin and tablets, using a 5 µm Acrodisk[®] syringe filter, this was found to be the case for all drugs tested. The syringe filter was able to cope with heavy contamination as was seen with the tablet injections, whereas the makeshift filters exceeded their capabilities so were relatively less effective.

The fourth question was: can the extent to which makeshift filters retain drug be established? And the fifth question was: how does the amount of drug retained by syringe filters compare to the amounts retained by makeshift filters?

This work was only conducted for the heroin injections. Because not all the diamorphine was converted into its soluble form in the injection preparation process, there are difficulties in drawing conclusions from the results of this part of the work. Some drug remained in the solid material left after filtration, some of which attached to the filter. The extent of this attachment was variable. Also, although the syringe filter retained the largest amount of drug, this was probably only because it removed most of the solid material from the spoon whereas the makeshift filters did not. The solid material was easy to remove by flushing water through the filter in the opposite direction to filtration. This raises issues around the reuse and sharing of syringe filters. However, if a greater quantity of acidifier had been used so as to cause all the diamorphine in the street heroin to go into solution, differing results may have been seen as the volume of fluid quoted by the manufactures to be retained by the Acrodisk[®] is small.

The sixth question was: is the most effective filter, according to the laboratory work, acceptable to IDUs and does it produce health benefits?

This aim was found to be over ambitious and work could only be begun to answer it. A pilot user evaluation was conducted that provided valuable information on the design of a larger scale evaluation. Measurement of the health benefits from filter distribution would take time and resources greater than those available for this project, a factor that was not recognised by the researcher at the start of this work.

The last question was: does laboratory investigation support the need for acidifiers in the preparation of brown heroin for injection?

The results from this investigation illustrated in practice the chemical theory behind the use of acidifiers. They showed how the quantity of diamorphine in the resulting injections increased as the amount of acid increased. It was also shown that when the approximate quantities of citric acid and ascorbic acid necessary to dissolve all the diamorphine were used, similar amounts of diamorphine were found in the resulting injections. However, these quantities were still much less than expected. Diamorphine was shown to be retained in the filters used for this work. Qualitative work showed diamorphine to be present on the spoon in which the injection was mixed, on the needle sheath used as a

stirrer and in the vapour that evaporated from the spoon, indicating the loss of some drug in the preparation process.

In view of the answers to the research questions discussed above, it can now be considered as to whether the original hypothesis set in has been upheld. In chapter two the hypothesis was defined as follows: Through development of a simulated injection preparation process and analysis using laboratory-based experiments, it is possible to gather information on the effectiveness of injecting paraphernalia to inform harm reduction practice. In chapters three it is shown that a simulated injection preparation process can be developed and in chapter four it is shown that this can be used in the laboratory to gather information on the effectiveness of some injecting paraphernalia, namely filters and acidifiers. The limits of the simulation have been discussed. These can be summarised as mainly being that the laboratory study requires an exact process whereas in 'real life' the process appears from the interviews with IDUs and safer injecting information to be inexact. The clandestine preparation methods of the street drugs also means results in practice are likely to vary depending on the nature and composition of the drugs used, so exact replication of the results in practice cannot be expected. However the trends seen in the laboratory are considered to represent trends that would be seen if similar preparation methods are used in practice. Hence information has been gathered to inform harm reduction practice and further study, which was not available previous to this work being undertaken.

Further work has been highlighted in this chapter. To summarise, a more accurate correlation between the quantities of acidifier added and the quantity of heroin used could be established by asking IDUs to simulate the preparation techniques they use with 'fake' materials. These materials could then be quantified and the weights of acidifier and heroin that they represent calculated. As the weight and density of heroin will vary, this would still be an approximate value. Further detail of the preparation processes used could also be observed.

Working using a bigger range of tablets with quantification of the effects of filtration on drug content in the injections is also desirable. Similarly, if further commercially produced filters that are cost effective and user-friendly can be identified, they could also be tested, using a range of quantities of drug, if available. The development of an effective, user-friendly virus filter should also be considered.

Physiological investigation into the effects of acidifiers on the body is important to establish whether there is any long-term harm from their use. Similarly, the long-term benefits from commercially produced and makeshift filters should be assessed. The identification of long term risks from using makeshift filters is also vital to establish. This is important in the light of recent calls for the paraphernalia laws to be abolished.

Once such information is established a large-sale user evaluation study could be undertaken. Using the information established, the health and economic effects of supplying effective paraphernalia to IDUs could be predicted. Such information would be necessary for purchasers of services for IDUs if the paraphernalia laws were changed.

PART TWO

Investigation into the role of a pharmacist
at a non-statutory drugs service

Chapter Seven

Background, literature review and aims of this study

7.1 Background

The initial stimulus for this study came from the researcher's experience whilst conducting the work described in chapter three. The collaborating establishment for this project, Drugs Action (DA), is a non-statutory drugs service, in Aberdeen, Scotland. At the time of this work, the staff came from a range of backgrounds, including social work, sociology, community and youth work, but none came from health-based professions such as medicine, nursing or pharmacy¹. A funding bid made by the agency to establish a nurse-led health clinic in 1996 was unsuccessful. The researcher, who is a pharmacist, found that whilst she was on the DA premises attending the client drop-in and conducting interviews, she was increasingly being asked by the staff and clients for her opinion and advice on a range of health and pharmaceutical issues. She therefore considered that there might be a role for a specialist pharmacist in providing information and advice at DA. If this was found to be the case, further investigation could go on to explore whether such a role also exists in other non-statutory and statutory drugs services. If so, this could potentially open up another extended role opportunity for pharmacists and benefit the clients and workers of drug services. The work presented here began exploring these proposals by undertaking a feasibility study to examine whether an information and advice giving role exists for a specialist pharmacist at Drugs Action.

Before the study is described, background information will be given, to set in context the number of people seeking help for drug problems in the UK. Then the literature will be examined to describe previous work that has studied the provision of information and advice on drug misuse by pharmacists and the possibility of developing an extended role in this area will be highlighted. Following on from this the hypotheses will be defined.

¹ Since this study was undertaken, the agency has employed team members from nursing backgrounds.

7.2 Literature review

7.2.1 Trends in problem drug use in the UK

There are difficulties in accurately quantifying the extent of problem drug use in the UK, as explained in 1.1.4.3. Data on the number of people presenting for care at drugs services is shown in figures 7.1 and 7.2. Figure 7.1 shows the trend in the number of new contacts or re-contacts after a period of at least six-months absence reported by service providers in Scotland for each financial year between April 1992 and March 1999. The collation of such statistics and their limits has previously been described (3.2.1 and 6.2.1.1.).

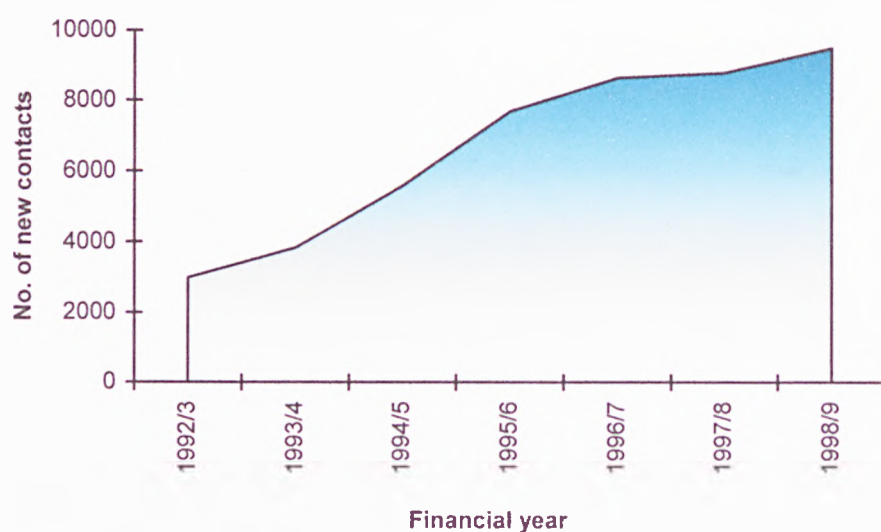


Fig. 7.1 Trend in the number of new contacts presenting for care in Scotland between April 1992 and March 1999. Source: Drug Misuse Statistics Scotland (ISD, 1999).

Figure 7.2 shows the trend in starting agency episodes reported by service providers in England and Wales for each financial year between April 1993 and March 1999. Note, the Welsh figures were taken from a summary in the English statistics and have not been viewed directly.

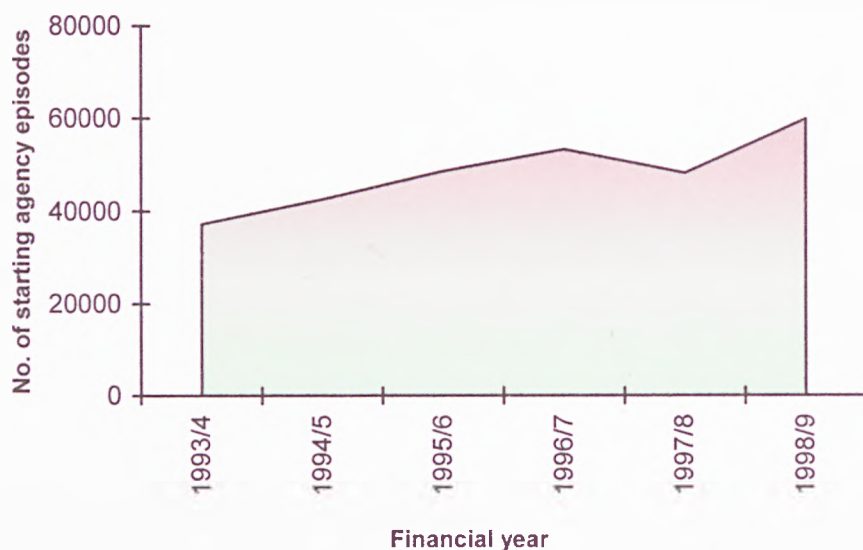


Fig. 7.2 Trend in the number of agency episodes for all reporting agencies in England and Wales between April 1993 and March 1999. Source: Statistical Bulletin (Government Statistical Service, 1999)

The data in figs. 7.1 and 7.2 cannot be taken as an absolute representation of the prevalence of drug use in the UK. Not all drug users will present for care. In the time periods accounted for, the number of reporting drugs services and extent of service provision may have changed, consequently influencing opportunities to present. Although, the reporting agencies are similar in England and Wales to those in Scotland, the data should not be compared, even when adjusted to population percentages, since the Scottish statistics are adjusted to take into account presentation of an individual at more than one service whereas the English and Welsh statistics do not. The English statistics may therefore include several new contacts made by one person. Despite these limitations the data does show that the number of drug users presenting for care has increased over time.

7.2.2 The provision of pharmaceutical services to drug users

It may be assumed that some, but not all, of the people represented in figs.7.1 and 7.2 will require pharmaceutical services, for example the supply of substitution therapy. Similarly, there may be users of pharmacy needle exchanges not represented in the data because they do not use other drug services². Therefore, the data cannot be taken as an indicator of the extent to which pharmaceutical services are required. No such work has been conducted. However, the extent to which pharmaceutical services are provided to drug users has been investigated.

² Pharmacy needle exchanges do not submit information to the drug misuse statistics databases.

The most up to date English and Welsh statistics come from the work of Sheridan et al (1996 and 1997), who conducted a postal questionnaire of a random 1 in 4 stratified sample of community pharmacies (CPs), with a response rate of 74.8% (n = 1984). They found 50.1% of CPs surveyed to be dispensing controlled drugs for dependency, 34.5% to be selling injecting equipment and 18.9% participating in NX schemes (Sheridan et al, 1996). Their questionnaire was based on that used seven years previously by Glanz et al (1989), who also conducted a one in four postal survey of CPs with a response rate of 79% (n = 1946). A weighting was applied by Glanz to predict service provision from all community pharmacies. They concluded that 23.0% of CPs were dispensing controlled drugs for dependency, 28.0% were selling injecting equipment and 3.0% were participating in needle exchange (Glanz et al, 1989, Sheridan et al, 1996). Sheridan et al did not apply a weighting and advise caution in making direct comparisons between their results and those of Glanz. However, the authors conclude that the differences in the findings do show a sizeable increase in the provision of CP services. No such comparison data exists for Scotland, as only one national investigation has been conducted (Matheson et al, 1999). They surveyed all CPs using a postal questionnaire with a response rate of 79.1% (n = 864). The authors found 53.2% of respondents were dispensing methadone for drug dependency and 8.8% were providing NX.

The work of Sheridan et al (1996 and 1997) and Matheson et al (1999) illustrates that pharmacists have a significant level of contact with drug users. If these pharmacists are already providing information and advice to drug users and drugs services, it may be unnecessary to develop a specialist service from within drugs services. Similarly if the current drug information network in the UK is fulfilling such a role it may be unnecessary to pursue this matter. These factors require exploration before it can be decided whether there may be an opening for a specialist pharmaceutical information and advice service at drugs services.

7.2.3 The pharmacist as a source of information and advice

Advice giving and information provision are inherent features in the role of pharmacists. Those who receive the advice or information may be professionals or members of the public. The process can be formal or informal, proactive or reactive (Stewart, 1998). In the UK, a network of drug information (DI) centres is in place. This network comprises local DI centres, supported by regional centres. The centres are staffed by pharmacists and largely operate out of hospital pharmacy departments. Many regional centres specialise in particular areas, for example the regional centre in Newcastle specialises in drugs in pregnancy and poisoning and toxicology. The centres primarily operate a service for

health professionals working in primary and secondary care, although some provide a help-line for patients recently discharged from the hospital where the centre is based (UKDIPG, 2000). Pharmacists working in community practice also provide information to health care professionals and routinely give information and advice to members of the public (Stewart, 1998). The easy access of community pharmacists makes them a frequent point of contact for information and advice by the public (Blenkinsopp et al, 2000). As the availability of information to the public increases, for example with access to the internet becoming more widespread, community pharmacists are likely to see an increasing number of patients seeking professional opinion on materials they have retrieved from other sources such as web sites (Blenkinsopp et al, *ibid*).

7.2.4 Recognition of a role for pharmacists in the provision of information and advice on drug use

A role for pharmacists in the provision of information and advice relating to drug use has been suggested in several key documents. The Advisory Council on the Misuse of Drugs, in part one of their report '*AIDS and drug misuse*', recommended a role for pharmacists in providing health education to drug users (Advisory Council on the Misuse of Drugs, 1988, Anon, 1988). The Task Force that reviewed services for drug misusers in England in the mid 1990s also endorsed the role of the pharmacist in undertaking health promotion (Polkinghorne, 1996). On an international level, a joint statement from the World Health Organization (WHO) and the International Pharmaceutical Federation (FIP) in 1997 highlighted the accessibility of pharmacists, their training in public health and contact with decision makers as key reasons why pharmacists should embrace an active role in HIV prevention. The statement gave guidance on how pharmacists should be involved. The provision of health education, multidisciplinary working and the development of inter-professional networks were amongst the functions listed (Nakajima and Steinbach, 1997). The importance of the community pharmacist in advice giving and delivery of care is also highlighted in current clinical guidelines (The Scottish Office, 1996, Department of Health, 1999). The report of the RPSGB working party, which reviewed pharmaceutical services for drug misusers, identified pharmacists as an under utilised knowledge source for both drug users and professionals (Working Party on Pharmaceutical Services for Drug Misusers, 1998).

7.2.5 The involvement of UK pharmacists in providing information and advice to drug users and professionals in the field

7.2.5.1 Community pharmacists

The extent of the provision of written and verbal advice to drug users by community pharmacists was investigated in the studies described in 7.2.2. Sheridan et al (1997) found the percentage of respondents who said they supplied information leaflets on HIV prevention and drug misuse to be 55%. This figure is less than the 68% identified by Glanz et al (1989). The percentage of pharmacists who said they gave verbal advice on HIV and drug misuse was also reduced slightly in the 1995 study (20%) compared to the 1988 study (23%). Both studies did not separate HIV prevention and drug misuse, so it is not known whether the reductions reflect less information on drug misuse, or less information on HIV as respondents who gave a positive response may have only provided information on one of these areas. At the time of the work of Glanz et al, HIV was relatively new in its discovery and high on the public health agenda. The reductions found by Sheridan et al may have been due to HIV having a less prominent status in campaigns being run at the time of their work. However, as said (7.2.2) Sheridan et al did not apply a weighting to their results whereas Glanz et al did. Given that the percentage of non-respondents in the Glanz et al study represented one fifth of community pharmacies in England and Wales and involvement in service provision might influence the decision to respond to the questionnaire, the accuracy of the weighted results may be queried. Since the differences found in the two studies are not large, the significance of these is open to question. When Matheson et al (1999) asked about information and advice provision, the authors separated the subjects of HIV and drug misuse. They also asked whether information provision was made '*always*', '*sometimes*' or '*never*'. However, the authors only asked the respondents who dispensed methadone about their involvement in information and advice provision (53.2%, n = 460). Therefore, pharmacies providing information and advice, but not involved in dispensing methadone will have been omitted from the results. Matheson et al found the majority of pharmacists who were dispensing methadone never gave information leaflets on drug misuse (61.9%) or HIV (60.2%), but it is unclear whether this means leaflets were not available for self-selection. Face to face advice on drug misuse was provided '*always*' by 5.5%, '*sometimes*' by 45.9% and '*never*' by 48.6%. The figures for face-to-face advice on HIV were less, with 2.6% reporting they '*always*' gave advice, 28.0% reporting they '*sometime*' gave advice and 69.6% reporting they '*never*' gave advice.

The extent to which the studies by Sheridan et al and Matheson et al give a true reflection of the activities of community pharmacists will depend on the accuracy of the reported information. This is the case with any method of self-reporting where validation of the information by other means is not or cannot be undertaken. Both authors sampled large numbers of pharmacists and achieved good response rates. Also, the questionnaires used were piloted prior to use. This will mean that ambiguity in the questionnaire will have been tested for. This suggests that overall the incidence and impact of errors in self-reporting will have been minimised.

No work could be found investigating the extent and nature of the involvement of community pharmacists in providing information to other professionals, despite such a role being identified in reports (7.2.4).

7.2.5.2 Hospital pharmacists

Drug information departments may receive enquiries from professionals and to lesser extent members of the public on drug misuse issues. However, information on the national incidence of such enquiries and responses could not be found. In 1987, Gerret et al reported the findings of their study into the provision of a specialist pharmacist information service on drug misuse, open to professionals from statutory and non-statutory drugs services. The service was based in a hospital drug information centre and contact made via the telephone. In a 12-month period, the service dealt with 68 enquiries from professionals. It was not a public service, however calls from members of the public were responded to ($n = 7$). The authors concluded that specialist pharmacists might make a valuable contribution to the work of statutory and voluntary sector drugs agencies, especially in a drug information capacity. However, no evaluation of the usefulness of the service was undertaken. The opinions expressed are those of the pharmacist who provided the service and not those of the information recipients.

In a paper by O'Connor et al (1995) describing the role of specialist addictions directorate pharmacists at the Maudsley hospital in London, the authors highlight information and advice provision to both clients and staff as being part of the role of these pharmacists. The researcher also became aware of anecdotal evidence of secondary care pharmacists working in drug dependency outpatient clinics and inpatient units. Contact with one pharmacist established part of her role was to supply information and advice to colleagues and clients (Robb, 1998). Such roles are identified in the report by the Working Party on Pharmaceutical Services for Drug Misusers (1998) and have been

outlined in a specialist bulletin (Anon, 1998). However, published information on the nature and extent of this work could not be found.

7.2.5.3 The nature of the information and advice provided and outcomes

Although the extent to which community pharmacists are involved in the provision of information and advice has been explored (7.2.5.1), no study could be found investigating the nature of the information and advice given on drug misuse in any detail, or the outcomes from the provision of such information and advice. Similarly, the only investigation conducted in hospital appears to be the study by Gerret et al (1987), which reported statistics on the use of the service and the service providers opinions on it's benefits. The authors do not describe the nature of the enquiries received or their outcomes.

7.2.6 The benefits of examining the role of the pharmacist in the provision of information and advice at drugs services.

7.2.6.1 Demonstrate whether a potential specialist role exists within drugs agency teams

As said in 7.2.5.2, Gerret et al (1987) considered that specialist pharmacists might have a role in the provision of information and advice to those working in drugs agencies. However, the service they studied was remote from the agency environment and not open to members of the public. A service in the location where it is required and open to the public might be better more accessible and allow opportunistic provision of health education, pharmaceutical information and advice. Although community pharmacists have a substantial amount of contact with drug users, there may be barriers to conducting an investigation in the CP setting. Sheridan and Barber (1996) conducted a pilot study (n = 9) and Matheson (1998) a larger study (n = 124) exploring drug users opinions and experiences of community pharmacy services. They found the role of pharmacists in drug misuse perceived by drug users to be largely that of supply e.g. needles and syringes and substitute drugs. Matheson found that a large proportion recognised the pharmacist as an appropriate source of information and advice on general health matters, but only a few saw the pharmacist as a source of advice on matters relating to illicit drug use. For this reason, it may be difficult to explore the provision of advice and information from the CP setting if such information and advice is not sought in the first place. An alternative to this

would be to place the pharmacist in a specialist drugs service, building on the recommendation of Gerret et al (1987) and explore the nature of the enquiries referred to the pharmacist by drugs workers and directly from clients. The findings could then be used to establish if an extended role for pharmacists, providing information and advice within the drugs agency setting, exists. In addition, the attitude of the drugs workers towards this service could be examined to establish the compatibility of the pharmacist within the agency team, an important factor in a climate where the emphasis is on multidisciplinary working (UK Government, 1999, The Scottish Office, 1999). The nature of the enquiries could be used to inform the development of training materials as suggested in 7.2.6.1. This assumes that drug users who use specialist services and those who use community pharmacies require similar information. Although this is unknown, it is known that many drug users use both pharmacy and specialist services so the client groups overlap (Tucker, 1997).

7.2.6.2 Inform the design of pharmacists education and training packages

The education and training needs of specialist pharmacists providing an information and advice service to drugs services could be examined through the implementation and study of such services. There is also evidence to suggest that pharmacists in general require specific training in drug misuse and working with users. In 1991, the Council of the RPSGB identified a need to address the education of pharmacists at both undergraduate and postgraduate level to enable pharmacists to provide a full service to drug users (Anon, 1991). In a study published by Sheridan and Barber (1993), exploring the attitudes of final year students ($n = 85$) and pre-registration graduates ($n = 56$) to drug misuse and HIV, the authors found 88% ($n = 75$) of undergraduates and 95% ($n = 53$) of pre-registration pharmacists thought that the time spent teaching about drug misuse should be increased in the degree programme. When asked about competence in counselling about drug misuse, 74% ($n = 63$) of undergraduates and 67% ($n = 37$) of pre-registration pharmacists stated they did not feel competent. Those questioned were from one school of pharmacy only, so the opinions on education cannot be taken to apply to all schools of pharmacy. However, a survey of all schools undertaken for the Report of the Working Party on Pharmaceutical Services for Drug Misusers (1998) found a lacking in the areas of social aspects of drug misuse, harm reduction, treatment and drug policy. Sheridan et al (1994) found that student confidence in counselling could be increased by the provision of education. In the study by Sheridan and Barber the respondent's interpretation of the term 'counselling' may have varied. It is likely to have been interpreted as the provision of information and advice on health and the effective use of medicines, as this is the

common meaning in relation to the work of pharmacists (Moody, 1998). However, it is possible that it may have been interpreted as the provision of psychological support through motivational interviewing, as undertaken by members of the British Association of Counsellors, so there is some ambiguity in interpreting the results. Despite these limits, the studies show that the group considered education at undergraduate level about drug misuse to be important.

At post-graduate level, a need for education and training has also been identified. In a survey of community pharmacists around the London area (n = 268, 74.4% response rate), Harding et al (1992) report 40% of respondents did not consider themselves to have the knowledge to deal with injecting drug users. The attitude statement to which this figure relates was *'Pharmacists do not have the knowledge to handle problem drug users'*, illustrating that the response may not be limited to injectors as the authors suggest. Also, the authors do not explore the type of situations to which the respondents were interpreting the question to apply. However, the phrase implies the handling of the behaviour of people rather than handling their enquiries or problems. In the study described in 7.2.5.1, Sheridan et al (1997) found 72.6% of respondents agreed with the statement *'I need training on how to deal with drug misusers who may visit my premises'*. However it is again not known what situations the pharmacist's interpretation of the statement was referring to i.e. responding to enquiries from drug users or handling difficult behavioural situations. The authors considered training to be essential in order to capitalise on the opportunities pharmacists have to deliver information and advice to drug users. A paper from one NX pharmacy reports that the pharmacist felt medical and drug related enquiries from service users to be *'beyond her knowledge and experience'* (Hollyoak and Wardlaw, 1992). Although this cannot be assumed to apply universally, it suggests there may be training needs in this field. The report of the Working Party on Pharmaceutical Services for Drug Misusers (1998) identified specific areas for education and training. It suggested that pharmacists might be the only contact some drug users have with health care, so should be equipped to respond to their health care needs. It may be assumed that this would include providing information and advice. From the researchers experience of providing training to pharmacists it is perceived that training in both matters relating to drug use and the handling of drug users is required.

The Council statement and the above studies and reports have identified a need for education and training of undergraduate and postgraduate pharmacists on drug misuse issues. As shown in 7.2.4, pharmacists are perceived to have a role to play in the health education to drug users. The extent to which this role is undertaken is unknown. The provision of information and advice on matters relating to drug misuse may be inhibited,

possibly due to lack of confidence and knowledge, but also due to attitudes towards drug users (Sheridan et al (1997), Matheson et al (1999)). Matheson et al suggest that providing training may influence attitudes and possibly increase the level of service provision.

The report of the RPSGB working party (7.2.4) outlined general areas where training is required. It is not known whether pharmacists self-opinion of training needs reflects actual needs so work is underway to establish this and develop assessment tools (Cunningham, 1999).

Information gathered from studying specialist information and advice services could not only inform the education and training of these specialists, it may also be useful in informing the education and training of pharmacists in general, since, as discussed a large number of community pharmacists (the area where the majority of pharmacists are employed) have contact with drug misusers.

7.2.7 Statutory and voluntary sector drugs agencies.

The work of modern drugs agencies has already been described (1.2.2.5). The structure and skill mix of the agencies will vary. As said (7.2.5.2) pharmacists have been identified who are based within statutory sector drugs services, providing a supply and information service. Statutory sector agencies are funded by the regional health board/authority and the workers are employees of either a community or hospital trust. Drugs agencies may also be part of the voluntary sector. These take various forms but are often registered charities that receive funding from a range of sources (Taylor, 1998). There appears to be little suggestion of pharmacists working for voluntary agencies in the literature. One American study, reported in 1982 by Powell et al examined the role of a pharmacist in a voluntary sector, multidisciplinary, community health education project. The project offered advice on four areas: nutrition, hypertension, drug use and misuse and alcohol and substance abuse. However, the term drug use and misuse referred to what in the UK is called compliance or concordance with prescribed treatment. The term substance abuse covered illicit psychoactive drug use. The pharmacist involved in the project only participated in the arm of the study that related to drug use and misuse. It is not clear from the paper why the pharmacist was not involved in the other aspects of the study, as they are all areas in which pharmacists have knowledge. The paper did not therefore have relevance to this work, other than indicating that an investigation had placed a pharmacist within the voluntary sector. Although the authors report the input of the

pharmacist was welcomed, there is no description as to how this information was ascertained. No information in the literature reported pharmacists to be working in voluntary drugs services. Pharmacists are known to work for non-governmental organisations such as Voluntary Services Overseas (VSO) and Pharmaciens san Frontières (PSF). The organisations' web sites³ do not suggest that work is done with drug users. Therefore, this project aimed to undertake investigation in a field that pharmacists have not previously been reported to work in. For this reason and the reasons in 7.2.6.2, it was considered important to establish the opinions and attitudes of the agency staff towards having a pharmacist included in the team. As funding is a pertinent issue for voluntary services (Taylor, 1998), it was considered useful to establish the approximate cost of providing a pharmacist-led information and advice service.

7.3 The hypotheses of this study and research questions

As shown above, the review of the literature found that several researchers and expert bodies have suggested that there is a role for pharmacists in providing information and advice to drug users and limited work has explored the nature and extent to which this is done by community pharmacists. Furthermore, it has been suggested that there is a potential role for pharmacists in providing information and advice from within specialist drugs agencies, supporting the proposal by the researcher described in 7.1. From the literature, no previous work could be found that had explored this suggestion, so it is unknown whether such a service could be implemented or what the benefits of such might be. As said, the first stage in exploring whether an extended role might exist for specialist pharmacists at drugs services, is to conduct a feasibility study in one agency. It is this work that is presented here. Two hypotheses were set for this feasibility study as follows:

1. It is possible to implement a pharmacist-led information and advice service within a voluntary sector drugs service.
2. The pharmacist-led information and advice service would be of positive benefit to its users.

Based on these hypotheses, the following research questions were generated:

³PSF: <http://www.psf-pharm.org/frame.htm> VSO: <http://www.vso.org.uk/> [Accessed: 10.05.2000]

1. Is there a role for a pharmacist in the provision of information and advice within a voluntary sector drugs agency?
2. What is the nature of the information and advice sought by people who consulted the pharmacist?
3. What knowledge and skills were required to provide the service?
4. What were the agency client outcomes from the service?
5. What were the opinions of the other agency staff on the service received?
6. What was the attitude of the other agency staff to the service?

Chapter Eight

Methods

8.1 Design and implementation of the pharmacist's service

8.1.1 The location

The location for this case study was Drugs Action (DA), 48a Union Street, Aberdeen. This agency was chosen because: (a) it was the only non-statutory drugs agency in the area. (b) anecdotal experience as described in 7.1 had suggested there might be a role for a pharmacist at this service and (c) it was the collaborating agency for this project.

DA is a registered charity, which receives funds from a range of sources including Grampian Health Board, Aberdeen City Council, Aberdeenshire Council, The National Lottery Fund and Comic Relief. The DA philosophy is based on a non-judgmental harm reduction approach to drug use. A management committee oversee the agency, with day-to-day running undertaken by the co-ordinator. When this study began there were fourteen drugs workers, including part time staff, from a range of backgrounds including sociology, community work, social work and health promotion.

The agency is based in the city centre, but service provision extends into urban communities through the use of outreach teams. The aim of the city outreach team is to take services to drug users in urban areas of high socio-economic deprivation who may not otherwise access services. At the time of this study a rural team was also funded. They took services to drug users who may not travel to the city from Banff and Buchan. This is a large rural area containing several small communities, approximately spanning a 50-mile radius to the North and West of the city. Both teams liaised with community pharmacists to support and encourage service provision.

DA clients are drug users, family members and friends of users and other professionals who work with users. Among the drug-using clients, heroin predominates as the main problem-causing drug (Drugs Action, 1998). The agency is open to the public for nine 3-hour sessions per week. Outreach work is carried out during this time and at other times,

including evenings. Services for drug users and their families and friends include the provision of information and advice through a telephone help-line, an appointment system for one-to-one support, a brief contact drop-in service and a HIV/Hepatitis C session run by a specialist worker. The Family Support Group, which has a fund-raising arm, The Hope Group, provide self-help for relatives of drug users. A women's service focuses on issues specific to women. These include street-work with female prostitutes and joint working with Aberdeen Maternity Hospital and the Substance Misuse Service to provide a one-stop antenatal clinic, known as the 'Golden Square Clinic'. At the time of this work a Criminal Justice worker provided support and after-care for offenders, working in Craiginches Prison, Aberdeen and the DA base. Incite, the recreational drugs team, deliver an outreach service in nightclubs and at dance events. Needle exchange is provided for injecting drug users. There is no prescribing or medical service at DA. A bid to establish funding for a nurse-led injection site injury clinic was unsuccessful. Services for professionals include the provision of information, training on drugs issues and advice on working with drug users.

Drugs Action was established in 1986, initially as an information and support agency for solvent users and developed in responses to need. The needle exchange opened on 20 January 1993. In the first full financial year of operation, there were 1917 visits to the exchange, 202 of which were new contacts (Drugs Action, 1994). The most recent annual report states for the 1998/9 financial year there were 8005 visits to the exchange, 429 of which were new contacts (Drugs Action, 1999).

8.1.2 The pharmacist

The pharmacist who operated the service was the researcher. At the time the service commenced¹ she had been registered as a pharmacist for 25 months. Her pre-registration year was split equally between the pharmaceutical industry and hospital pharmacy. As a registered pharmacist she had worked 9 months full time as a basic grade hospital pharmacist prior to beginning this research. Since registration she has also worked regularly as a locum community pharmacist.

¹ September 1997

8.1.3 Consultation with the Drugs Action staff team

The initial proposal for this project was discussed with the DA advisor to the project and the co-ordinator. However, it was not discussed with other members of the team, as the researcher wished to measure their attitudes to the proposed service before she discussed the details or sought team approval. The researcher attended a DA team meeting. The attitude of the staff to a pharmacist being part of the team was measured as described in 8.3.3. Following this, the proposed study was discussed. Approval of the team was necessary to allow the service to be able to be implemented. It was also necessary to establish that the pharmacist could work as an independent professional within the team. This largely related to the handling of ethical dilemmas discussed in 8.1.7.5. There were initial concerns amongst the team that pharmacists may operate on an abstinence-only approach to drug use. As discussed in chapter one, harm reduction does not preclude the attainment of abstinence, but works to achieve hierarchical goals, realistic to the individual's present situation. Strategies other than the promotion of abstinence are therefore necessary. On explanation of the professional responsibilities of pharmacists to care for the health and well being of individuals and the public, and the researchers' belief that moral values should not hinder this, the DA team were satisfied that the service had potential for exploration. They also agreed that the pharmacist required freedom to exercise her professional judgement. The pharmacist and the team agreed that if either side felt there was a conflict of professionalism the matter would be discussed and the option to terminate the service made available to both parties. The team also asked for clarification of the confidentiality which pharmacists are ethically required to uphold. On discussion it was established that this was compatible with the confidentiality policy of the agency. This is further discussed in 8.1.7.

In accordance with DA practice for new staff, the pharmacist undertook the in-house training package '*An Introduction to drug use*', which was part of the DA induction programme. The pharmacist had undertaken safer injecting training, which was also part of the induction, when she first began this research. The pharmacist shadowed each of the outreach teams for one day to become familiar with their working practices. She attended one in four team meetings, which was the required attendance of staff working less than 16 hours per week. The DA advisor was designated the pharmacist's supervisor. It was usual practice for new staff to shadow an existing team member and then work under observation during an induction period. However, the team did not consider this requirement necessary for the pharmacist's service.

8.1.4 The pharmacist's service structure

8.1.4.1 'The pharmacist's session'

The service was designed to make the pharmacist as accessible as possible, within the constraints of time and other agency activities. The pharmacist was present at the agency for one 3-hour session per week. During this session, DA staff, members of the public and professionals could make contact for information and advice. This was known as the '*Pharmacist's Session*' (PS). When selecting the time to hold the PS, consideration had to be given to other agency activities and available space, as the pharmacist required a private room to be available. The potential for client contact had to be maximised, without compromising worker activity, e.g. by occupying a required counselling room. After discussion with the team, Tuesday afternoon was selected for several reasons: An afternoon was selected over a morning, as it was usual for client numbers to be greater in the afternoons. Tuesday was selected because both base and outreach work was carried out, so both could make use of the PS. The criminal justice worker was at the prison, so could refer enquiries. This also meant desk space was available for the pharmacist. Only one worker had one-to-one appointments, so a counselling room was free for use.

Members of the public and other professionals could make contact directly with the pharmacist during the PS, either in person or by telephone to the help-line. Additionally, drugs workers offered a referral to the pharmacist when they considered it appropriate. DA base workers could contact the pharmacist face to face, whereas the criminal justice and outreach workers could contact her by telephone. The pharmacist recorded all enquiries that she received on a purpose-designed form [form 1], shown in appendix 19.

8.1.4.2 The pharmacist's service outwith the session times

During all other working hours², the pharmacist was contactable by DA staff only, although enquiries could be made on behalf of others. This was similar to the traditional drug information structure whereby the pharmacist is remote from the enquirer. Enquiries that required an answer before the next PS were made by telephone direct to the pharmacist's office. An answer phone was used to collect messages if she was out of the office. This was kept in a locked drawer. For confidentiality reasons, client names or identifying details were not included in messages. Non-urgent enquiries could be made in writing on another form [form 2] (appendix 20). Blank copies were kept at DA in a marked

² This refers to the working hours of the agency staff: Monday 9 am to 8pm, Tuesday 9 to 1pm, (Tuesday afternoon PS), Wednesday to Friday, 9 am to 5pm.

box file, on a clip in the needle exchange and above the help-line desk. Once completed, forms were left in another marked box file and collected by the pharmacist when she was next at the agency. Both forms are discussed in section 8.2.1.1.

8.1.4.3 Service duration

The service commenced on 9 September 1997, for a six-month period. Service provision was continuous except for one break of one week in September 1997 due to annual leave and four days in December 1997 due to statutory holidays. This time was compensated for by extending the service for nine days after the six-month period had expired, to give a total duration of service provision of 26 weeks.

8.1.5 Publicity of the pharmacist's service and sessions

Several publicity methods were designed and targeted at prospective service users, to promote use of the service. Publicity was initiated during the week prior to the service commencing and continued until the last session had been held.

8.1.5.1 Publicity materials

Pharmacist's session leaflet

This aimed to provide relevant information and help readers make a decision as to whether the service may be useful to them. It explained the service was in place for a trial period only and could be accessed by drug users, family members and friends and people who work with drug users. It gave examples of types of information and advice that was considered relevant. The leaflet also stated that the service was free and confidential. The address of DA, a map and details how to access the service were given. A copy is in appendix 21.

Pharmacist's session posters

Posters summarised what was contained in the leaflet. One type, for use outwith Drugs Action, gave the agency address and PS times and another type, for internal use, only detailed times. Posters were produced in colour, A3 and A4 size and laminated. A black and white A4 version of the poster for internal publicity is shown in appendix 22.

8.1.5.2 Targeting of prospective service users

Drugs Action staff

The pharmacist attended the DA team meeting five days prior to the first session. Staff were reminded of the operation of the sessions, invited to use the service and refer others. Staff were given a written reminder and a sticker, detailing the day and time of the session and telephone number for contact outwith session times. It was suggested this was attached somewhere prominent e.g. telephone handset or diary cover. A3 posters were displayed throughout the agency, including staff-only areas, such as at the help-line desk and administration office. For the duration of each session, a flyer was attached to the front of the needle exchange filing cabinet. This reminded the duty workers that the pharmacist was on the premises. The sessions were also noted in the agency diary.

Drugs Action clients

Posters were displayed in the waiting area of the needle exchange, the meeting room and in each counselling room. Leaflets were displayed in the waiting area, needle exchange and corridor alongside other leaflets. A3 posters and leaflets were also displayed at all outreach team locations within Aberdeen City and at the rural team base at Ugie Hospital, Peterhead. Staff encouraged clients to use the service when they felt it appropriate.

Professionals and their clients

The service was promoted to selected outside organisations. Services that may be accessed by people affected by drug use and not known to be providing health or medical services were identified from the DA mailing list. For example, the Cyrenians hostels for the homeless and young peoples' projects. These selected groups were sent a letter outlining the service, stating that it was for a trial period only. They were invited to use the service and refer people if appropriate. Leaflets and an A4 poster were enclosed for display in client areas. The list of those who received publicity is given appendix 23.

Three groups providing health and medical services to drug users were informed of the service. These were the Substance Misuse Service, the Family Planning Centre and the genito-urinary medicine clinic. The first two were informed because they were working jointly with DA to provide a maternity service for drug users. The latter also has close links with DA and mutual clients. It was considered good practice to inform them the service was in place. In addition, the criminal justice worker informed the prison officer and medical team with whom he worked, of the pharmacist's service and telephone number.

The criminal justice worker and prison officer worked together to deliver an in-house drugs education package and supported prisoners with drug problems. The medical team offered a short detoxification programme on admission.

8.1.6 Resources

The pharmacist required access to certain resources to provide the service. Use of a telephone and photocopier was agreed and usage records kept so the costs incurred could be reimbursed to DA. The agency kept several key publications including the British National Formulary, The Data Sheet Compendium, The Patient Information Leaflet Compendium, specialist textbooks on drugs of abuse, drugs in pregnancy and UK legislation. It also kept *'Addiction'* and *'Druglink'*. The pharmacist also acquired specialist texts, including *'Drugs of abuse'* by Simon Wills (1997). Journal papers and Internet access were available through the University. Information leaflets held by the agency were available for distribution by the pharmacist. These included information on drugs and their effects, safer injecting, blood borne viruses, safer sex, legal matters, welfare rights, homelessness, rehabilitation, detoxification and advice for families and friends of drug users.

8.1.7 Responding to enquiries

When planning the service, attention was paid to legal and ethical guidance for UK pharmacists (RPSGB, 1997) and the UK Drug Information Procedure Manual (UKDIPG, 1997a and 1997b). Although these guidelines are intended for hospital based drug information services, the principles have generic application for all pharmacists involved in information provision. The procedures used will now be discussed.

8.1.7.1 Confidentiality

As required by professional ethics, information that became known to the pharmacist was treated confidentially. Enquirer identity and matters discussed were not disclosed to any third party without the enquirers' consent. Clients who discussed issues with the pharmacist in the presence of their drugs worker were assumed to be consenting to the matter being discussed between the pharmacist and the drugs worker. If the drugs worker wasn't present and the pharmacist considered it appropriate to discuss the matter with the

worker, permission from the client was sought. The pharmacist's code of ethics was in keeping with the DA policy on confidentiality, which is based on the British Association for Councillors guidelines. The policy declares clients have the right to confidentiality, which will be maintained unless the client has given consent for information to be divulged either in their absence or presence. The exception to this is given as instances where there is considered to be risk of serious physical or mental harm to the client or others, which can be prevented by breaching confidentiality.

8.1.7.2 Anonymity

In other settings where the public ask pharmacists for information and advice, such as community pharmacies, very often contact is on an anonymous basis. Being able to access pharmacists without an appointment or the keeping of records are factors thought to encourage the public to use their services (Blenkinsopp et al, 2000). The UKDIPG (1997a) recommend that all enquirer details are recorded. However, it was considered that this would discourage use of the service and was not in line with DA procedures. The researcher considered it important that contact with clients could be traceable, on the grounds of accountability. Therefore, complete anonymity, such as could be given in the community pharmacy setting was not offered. However, a minimum amount of information that would allow the details of a recorded contact to be found was kept. Client first name initial, gender and the date of contact were recorded on the enquiry form. The names of DA workers and other professionals were recorded.

8.1.7.3 Enquiry processing

The enquiry handling procedure used for this study was based on UKDIPG guidance (1997a). It is represented in figure 8.1 and will now be discussed.

Identify enquirer

First the status of the enquirer was established i.e. drugs worker, worker from outside organisation or client. Pharmacists are advised in the code of ethics (RPSGB, 1997 and 2000) that enquiries from the public can be handled, providing they ensure the wishes of the patient's medical practitioner or pharmacist are not compromised. Therefore, for enquiries that related to particular individuals, it was established whether the person was under medical or pharmaceutical care and what information they had already received. Care was taken not to undermine any established therapeutic relationships. Further

consultation with the medical practitioner or pharmacist was encouraged and discussion on the clients behalf undertaken, if agreed.

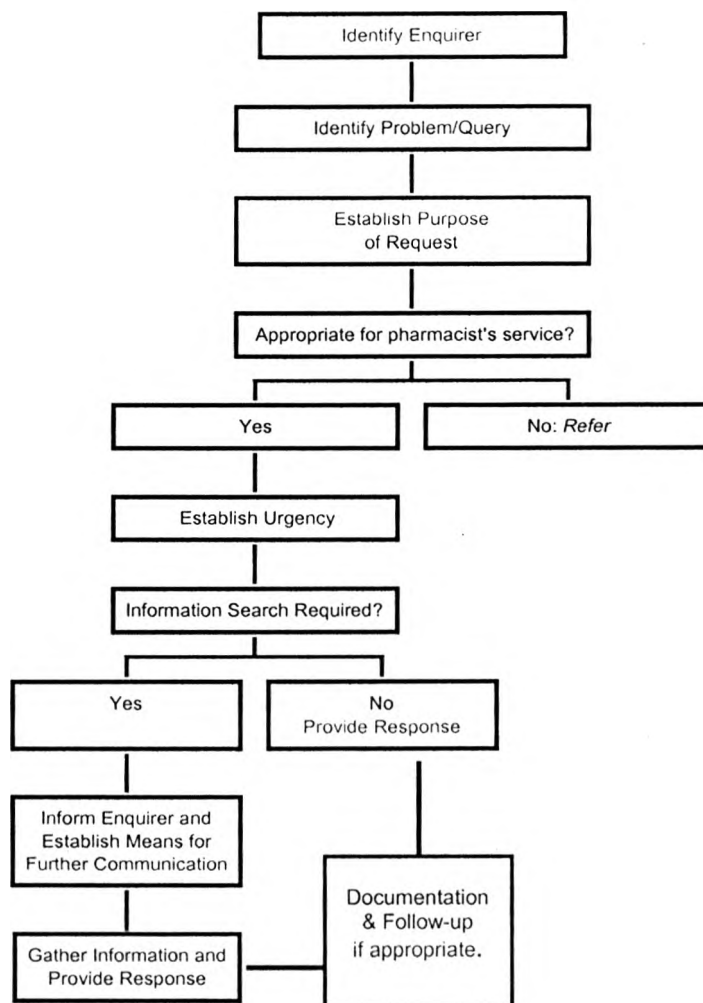


Figure 8.1. Enquiry handling procedure used for the pharmacist's service.

Identify problem/enquiry

The enquirer was questioned to establish the details of their enquiry and gather relevant information that the pharmacist considered necessary. As much detail as possible was collected, including why the information was needed and an assessment of what was already known. This helped ensure the response could be tailored to the individuals needs and existing knowledge. Before any response was given, the enquiry, as the pharmacist understood it, was relayed back to the enquirer for confirmation that it had been correctly interpreted.

It was made clear to the enquirer which type of response they were receiving. Where appropriate, the pharmacist translated technical information into a format suitable for members of the public and non-health professionals. Responses could be given verbally or in written form, including the preparation of information sheets or printed material.

Documentation and follow up

This is discussed in 8.2.1.

8.1.7.5 Ethical dilemmas

An ethical dilemma as defined by Kelly et al (1990) is:

'...a situation that presents a conflict in competing values or perceived obligations in which one value or course of action must be chosen and in which respect for one value or obligation necessitates violation of another'.

Pharmacists sometimes receive requests for information that pose ethical dilemmas. As Kelly et al (*ibid*) state, these often, but not exclusively, arise when members of the public request information. When a dilemma presents, the pharmacist has to identify the competing values or obligations and decide which will be respected and which will be violated. In making this decision, the pharmacist must establish all relevant facts and use his/her professional judgement to decide where priority should lie. The pharmacist must also be able to justify his/her actions. Identification of the existence of an ethical dilemma and consequent professional judgement will be influenced by, not only knowledge of professional and legal responsibilities, but by knowledge and interpretation of the given situation and the potential consequences of possible actions. Moral beliefs of the pharmacist will also influence the decision making process. Therefore, each situation has its own unique set of variables, so procedures for handling such situations cannot be formulated. Instead, each situation must be considered individually, with reference to professional guidelines and published literature.

Because of the illegal nature of drug misuse, the complex social and medical issues which can be involved and the professional and ethical responsibilities of pharmacists, it was considered possible that issues may present during the service that posed one or more ethical dilemmas. In handling these, the pharmacist had to be able to exercise her professional judgement freely, without any risk this freedom being compromised (8.1.3). General discussion about dilemma situations held between the pharmacist and the DA

workers led to the conclusion that both had the common aim of promoting the health and well being of the patient/client whilst protecting the public from harm. The workers supported the need for freedom for the pharmacist to exercise her professional judgement.

8.2 Monitoring of the pharmacist's service

8.2.1 Enquiry monitoring and data manipulation

8.2.1.1 Paper-based forms

The paper-based forms used to record enquiry information are mentioned in 8.1.4.1 and 8.1.4.2 and shown in appendix 19 and 20. They will now be discussed in more detail. The forms were different colours to allow easy recognition. Form 1, which the pharmacist used to record enquiries she received, was green and form 2, which was completed by the workers for non-urgent enquiries, was yellow. A separate form was used to record each contact with the pharmacist. They were based on the form published by Gerret et al (1987) and the guidance given by the UKDIPG manual, chapter 8 (1997a) and appendix E (UKDIPG, 1997c).

Front of recording forms

The front of the forms were used to record information about the enquiry and only varied slightly, so can both be discussed together. As each contact was made, it was chronologically assigned a number. The date the contact was made was recorded. Enquiries made by telephone were marked with the symbol (T) The close proximity of the DA base to the university meant information could be delivered by the pharmacist in person if required at times outwith the session. This also meant that face-to-face enquiries from workers might be presented to the pharmacist at times other than session times. Method of contact used by DA staff could therefore be classified, as one of four categories: 'During PS', 'At base, not PS', 'Telephone' or 'In writing' on form 2. Both 'During PS' and 'At base, not PS' refer to face-to-face contact made by the workers when the pharmacist was present at the base. However, they were separated to allow use of the service during the designated session to be distinguished from use at other times when the pharmacist happened to be on the premises.

Client initial and gender or worker first names and location if from outside organisation, were recorded. Enquirers were informed these and details of the enquiry would be recorded, and assured of confidentiality and anonymity in any service reporting. Details provided in the course of the service, such as names and addresses e.g. for posting information, were recorded on a separate piece of paper, kept with the enquiry form. After the response was sent the information was destroyed in a shredder. Workers were categorised according to the nature of their work at the time the enquiry was made, not their job title. This was to establish whether location of work affected use of the service. For example, if an outreach worker made an enquiry in relation to duty work when covering at the base, the enquirer was recorded as a base worker not an outreach worker, since they were not acting in their outreach capacity. The following codes were used to categorise workers:

WB = worker at the base	WP = worker when based at the prison
WO = worker in outreach location (city)	WR = worker in outreach location (rural)

Clients were categorised according to their status in relation to drug use e.g. primary drug user, or secondary to drug user, such as a parent or friend, and whether they self referred or were referred by a worker. This allowed investigation into whether clients using the service did so as their own decision or whether they were acting on the recommendation of a DA worker. Clients who were told about the service by an outside organisation worker were counted as having self referred since they had actively chosen to come to DA to seek out the pharmacist. The following codes were used to categorise clients:

C1S = Primary drug user, self referred	C2S = Secondary to drug user, self referred
C1W = Primary drug user, worker referred	C2W = Secondary to drug user, worker referred

Outside service workers were assigned the code OS. This included both self referral and referral by DA workers to the pharmacist. Although the prison officer who had a specialist remit for drugs worked closely with the DA criminal justice worker, he was included in the outside service worker category as he was not a DA employee.

Information on use of the service was determined for each of the categories described above. However, to allow collective information to be reported in chapter 9 for each group of service users the following terms have also been used (see fig. 9.1 for illustration):

DA workers': refers to the collective results for WB, WO, WP and WR, i.e. all contacts or enquiries from the DA workers, not distinguishing for location when enquiry made.

'Members of the public' refers to the collective results for C1S, C1W, C2S, C2W, i.e. all contacts or enquiries from users of the service who were not DA workers or professionals from other agencies, not distinguishing between drug user status or method of referral.

'Outside service workers' refers to the results for OS, i.e. all contacts or enquiries from professionals from other agencies.

'Last Date of Use if Applicable' or *'ASAP'* were recorded to allow the enquiry to be prioritised. For monitoring purposes, it allowed the number of immediate and non-immediate enquiries to be identified. Workers who used form 2 were given the option of stating their preferred method of reply from the following options: *'verbal'*, *'written'* or *'published info. requested'*. They were also reminded of the day of the PS and of the telephone number to call for a quicker response.

A summary of the enquiry was made. On form 1 this was done by the pharmacist. on form 2 the DA worker did it. In the case of form 2, if the pharmacist required further information, the worker was contacted. In the event of more than one enquiry resulting from a single contact, data and response information for each was recorded separately on the form.

The question *'Would you consider asking a chemist in a shop about an enquiry such as this?'* was asked to clients only (form 1) and the response noted. It was asked after the response to the enquiry was given and included to investigate whether the client would consider using a community pharmacist as a reference source.

A summary of the response given was made. References, written information and leaflets supplied were noted on the forms and copies of written materials produced were attached. This was in accordance with UKDIPG (1997b) guidance on copyright laws.

Back of recording forms

Table 8.1 was printed on the back of the forms and used to record details of the response mechanism. The approximate time taken to prepare the response was recorded. Immediate was defined as a response prepared just after the request was received or during the course of the session. Non-immediate was any response that required the pharmacist to conduct a further information search and respond at a time later than the end of the session.

Combined knowledge: Perceived to be largely based on core knowledge but requiring the addition of some further specialist information to enable the pharmacist to process the enquiry. It was considered that all pharmacists could process enquiries in this category if the necessary information was obtained. No specialisation in the area of drug misuse was considered necessary, but knowledge of and access to information sources would be required.

Sources of information recorded under '*further knowledge*', '*literature*' and '*other*' were listed to provide a reference source to describe how the pharmacist acquired her specialist knowledge.

Skills used for enquiry processing

The enquiry responses were subject to content analysis and the skills the pharmacist used to provide the service were highlighted. These skills were then defined as being '*Core*' which meant they were perceived to be gained at undergraduate or pre-registration level or '*Specialist*' which meant they were perceived to have been acquired specifically for delivery of the service. Again reference was made to the RPSGB undergraduate syllabus and the pre-registration manual. Sources from which the pharmacist learnt specialist skills were listed.

8.2.1.3 Data storage and manipulation

As enquiries were processed, information was transferred into a Microsoft Access® database for analysis. All computer-stored information was anonymous, so enquirers could not be identified from the database. The consecutive number assigned to the enquiry was used as the primary key, which identifies data in the database.

8.3 Evaluation of the pharmacist's service

8.3.1 Methods used to establish the benefits of service provision to DA clients.

The pharmacist's service was evaluated by establishing outcomes that were attributed by the client or the drugs worker, to the provision of information and/or advice by the pharmacist. Client contact was anonymous in so far as only first initial, gender and date of contact were recorded. In many cases, clients who saw the pharmacist could have been traced through the DA database because the pharmacist became familiar with more

identifying information during the contact. However, this was considered inappropriate and unethical, as it would invade client privacy and breach confidentiality. Instead, only clients who made further contact with the pharmacist or had had a three-way contact with the pharmacist and their drugs worker were followed up. This avoided any breach of confidentiality, since in the latter case, drugs workers were aware the pharmacist had given the client information or advice and clients were aware that both the drugs worker and pharmacist knew of their issue. These methods also allowed follow-up when client approached the agency, which is in keeping with the DA client-led service. The disadvantage was that not all clients who received information and advice from the pharmacist were followed-up and those who were did not come from a random sample.

8.3.1.1 Data collection

Clients who made contact with the pharmacist at a later date were asked to report on the issue that they presented initially to the pharmacist. In the case of three-way contact between the client, pharmacist and drugs worker, the drugs workers were asked to inform the pharmacist of further contact that related to the enquiry. The main points the pharmacist asked either the client or drugs worker were:

- I. Was the information/advice followed?
- II. What was the outcome?
- III. Is further information required?

After a three-way contact, if the drugs worker did not report follow-up, the pharmacist periodically asked if such had occurred. The pharmacist recorded the reported information on the form shown in appendix 24 [form 3], which was attached to the associated enquiry form. The enquiry number was used as identification on form 3. The key issues that were identified at first contact with the pharmacist and information/advice given in relation to them were recorded on the form. Then for each issue, the responses to the three points were recorded under 'outcome'. Time between pharmacist's input and reported outcome was recorded. If further information was required, it was provided to the drugs worker/client and the outcome from this again recorded. This method used informal information exchange, which Van Teijlingen and Huby (1998) note as being part of the information gathering process in evaluation. The pharmacist used the data on enquiries and follow-up to describe case studies that illustrated outcomes that may be attributable to input made.

8.3.2 Methods used to gather staff opinion on the pharmacist's service

Once the pharmacist's service had finished, staff opinion was investigated using a discussion group. The methods used to conduct this group were based on guidance given on focus group discussion by Greenbaum (1993). Group discussion was chosen to explore staff opinions as it can generate large amounts of information and has the benefit of group interaction. Matters raised could be discussed, endorsed or contested within the group to reveal differing opinions. Also, the agency structure was conducive to holding a discussion group, as staff are familiar with debating issues and expressing their ideas, opinions, concerns and criticisms to and of their colleagues.

8.3.2.1 Discussion group attendance and timing

A memo was circulated to all drugs workers and the DA co-ordinator one week prior to the group being held. This informed them of the intention to hold the group and that attendance was voluntary. Staff were informed that quotations used in the research would be anonymised. The discussion group was held one month after the pharmacist's service finished. It was conducted prior to a staff team meeting at the DA base, in the meeting room. This was done to enable as many staff members as possible to attend, as agency services were closed on the morning of the team meetings. A post-service attitude questionnaire, which is detailed in 8.3.3, was completed first and the discussion group followed.

8.3.2.2 Discussion group format and data collection

The questions

The discussions held with the DA advisor, co-ordinator and team prior to the service commencing (8.1.3) were used to identify the themes of the questions that guided the discussion group. Further points the researcher considered significant were also included. It was important that the discussion was not too long, to prevent participants from tiring or losing interest. Ninety minutes was the proposed duration, which was within the time suggested by Greenbaum. In this time it was estimated that six questions could be discussed, allowing 15 minutes per question. A list of questions for the discussion group were formulated and reviewed by the supervisory team. This was done to examine their clarity and purpose. The themes and exact wording of the questions as they were put to the group were as follows:

The researcher specifically endorsed the need for honesty, as it was acknowledged that familiarity with the researcher might prevent negative opinions being expressed. Therefore, participants were also asked to declare any opinions they felt unable to raise in the group, anonymously, in writing by post to the researcher. This was also stated in the memo circulated the previous week, giving contact details and a deadline of four weeks after the discussion group was held.

Round-table discussion was held first, whereby each person was given the opportunity to comment. This was followed by open floor discussion. The researcher brought about closure by asking for any further comments before moving on to the next question. The team gave verbal consent the discussion being recorded. This was done using a micro cassette recorder, placed on the central table of the meeting room. It was previously checked by the researcher that the device gave a satisfactory recording in a similar situation.

8.3.2.3 Data verification and analysis

Immediately after the discussion was held it was fully transcribed. Data was then processed using the technique described by Bailey et al (1995). This involved coding the statements made into identified themes. The themes were then subjected to progressive focusing, to produce key themes that were supported by quotes from the original statements.

After the final date for submission of written comments, a report was produced, listing the key themes and supporting quotes. A copy was given to each of the discussion group participants. In a covering memo, they were asked to make notes on the report if they considered any of its content to be inaccurate. If they were satisfied with its content they were asked to write '*approved*' on the top of the report. As this was a further opportunity to add comments on issues that were not raised in the group, it was done anonymously. Participants were given one week in which to respond. The researcher knew how many reports had been distributed, so in the event of reports being not returned, the DA adviser would remind all participants to return their reports until all had been collected.

8.3.3 Attitudes of the drugs workers to having a pharmacist attached to the team.

Attitude has been explored extensively in psychology and many theories and definitions of it appear to exist. Oppenheim (1992) offers a simple definition, satisfactory for the purpose of this study. He reports '*attitude is a state of readiness, a tendency to respond in a certain manner when confronted with certain stimuli*'.

Investigation was undertaken into the attitudes of the DA drugs workers towards having a pharmacist attached to the team. This was done before and after the period of the service, to identify if exposure had changed attitude. The investigation was based on the method described by Moser and Kalton (1971), Oppenheim (1992) and Coolican (1994) using attitude scales on a questionnaire format.

8.3.3.1 Content setting discussion

Content setting discussion was held with the DA adviser to the project and DA co-ordinator during the planning stage of the pharmacist's service. This was done to establish relevant areas concerning staff attitude towards having a pharmacist attached to the team. The four areas that emerged from the discussion were:

- I. The pharmacist working with clients
- II. Contribution of the pharmacist to the team
- III. The pharmacist's understanding of the psycho-social aspects of drug use
- IV. The attitude of the pharmacist to drug use/users.

These areas were used to form a bank of attitude statements, used in the design of the questionnaire. This design will now be described.

8.3.3.2 Questionnaire design

More attitude statements were generated around areas I and II as the adviser identified a greater number of issues relating to these. The statements were worded so some were 'favourable' and some were 'unfavourable'. A favourable statement was one whereby agreement with it would reflect a positive attitude to the subject and an unfavourable statement one where agreement with it would reflect a negative attitude to the subject. The number of favourable and unfavourable statements generated was equal. Neutral

statements were avoided, as were double negatives or statements perceived to be ambiguous. Checks for ambiguity were performed during the validation process (8.3.3.4).

Statements were randomised using random number tables, to establish the order in which they were presented. A summated ratings scale, also known as a Likert scale, was used to score the responses to the statements on the questionnaire. The scale allowed respondents to express their opinion by rating their agreement with a series of statements, as illustrated in the example below:

I think a pharmacist could contribute positively to the work of the team.

<i>Strongly Agree</i>	<i>Agree</i>	<i>Undecided</i>	<i>Disagree</i>	<i>Strongly Disagree</i>	<i>Not Applicable</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Statements were scored according to table 8.2. The total score for each respondent was achieved by adding up the score given to each response. Note how the scoring system was reversed for the unfavourable statements to ensure that attitude was scored in the same direction for all statements i.e. as attitude became more positive the scores increased.

Statement type	Response				
	<i>Strongly Agree</i>	<i>Agree</i>	<i>Undecided</i>	<i>Disagree</i>	<i>Strongly Disagree</i>
Favourable	5	4	3	2	1
Unfavourable	1	2	3	4	5

Table 8.2: Scoring method used for the attitude scales.

After the attitude statements, some questions were included in the questionnaire. Different questions were used for the pre-service questionnaire and the post-service questionnaire. On the former, the following questions were asked, leaving space for response to be written:

1. Please briefly describe what you see, if any, the main role of a pharmacist at Drugs Action to be:
2. Please briefly describe reservations, if any, you have about a pharmacist coming to work at Drugs Action:

On the post-service questionnaire, again leaving space for response, staff were asked:

1. Based on your knowledge, experience and opinion of the pharmacy sessions which were provided at Drugs Action, do you think there is a role for a pharmacist as part of the team?

Yes

No

If you answered yes to the above question, please expand by stating what you see the main role to be:

If you answered no, please expand by explaining why you think no role exists:

The open questions were analysed and categorised into themes. Responses to the closed question options were counted.

8.3.3.3 Validation

The questionnaire had to be validated to check it would measure what it intended, which was attitude of the DA staff team to having a pharmacist working as part of the team. A valid questionnaire would allow differences in the scores of individuals to be interpreted as differences in their attitude to the subject. The questionnaire could not be piloted on a large enough sample to test validity or reliability because the total population i.e. all the DA drugs workers, was not large ($n = 11$, at pre-service measurement). The investigation was unique to the particular agency, therefore using drugs workers from another agency would not have given data that could be assumed comparable to DA. For this reason validity and reliability were checked using other means.

The questionnaire was subject to content validity, as follows. A team of judges, consisting of the director of studies, the two project supervisors and the adviser from Grampian Health Board were asked to examine the statements and questions. They were told of the four areas that had been identified through content setting discussion with the DA adviser. They were then asked to check whether they considered a full range of attitudes to be covered. As a result of this assessment, an additional statement was generated on knowledge of drugs of abuse.

8.3.3.4 Piloting

The first draft of the pre-service questionnaire was piloted on two DA outreach workers to check that it was appropriate for the group under investigation. It was important to pilot the questionnaire on people who were part of the group. The purpose of the pilot was to review the statements for understanding and clarity. The workers were asked to respond to the statements, but when doing so they were also asked to write comments, thoughts or contradictions the statements generated in their mind beside the statements. The final pre and post service questionnaires are shown in appendix 25 and 26.

8.3.3.5 Reliability

It was important to check the attitude scale was reliable; meaning repeated measurement made under constant conditions would give the same results. Any statements not found to be reliable had to be removed from the scale. Reliability could not be checked by repeated measurement with the scale because constant conditions could not be controlled. For example, if the same respondents had been used to repeat the measure at a later date, they may remember their responses to the first test and repeat them exactly, thus indicating falsely high reliability. Alternatively, respondents may have considered the survey subject more in the interim period, for example the DA workers may have discussed the issues raised amongst themselves, with clients or another pharmacist, which may change their attitude and thus responses. Therefore, the pre-service questionnaire was administered and reliability checks performed subsequently.

Presenting three issues in both favourable and unfavourable forms checked internal reliability of the pre-service questionnaire. These were statement nos. 4 & 5, 9 & 13 and 10 & 16. The scores for each statement in the pair were compared. Reliability was assumed if these statement scores had no difference for the majority of respondents.

Internal reliability analysis was performed using SPSS version 6⁺ software (SPSS Inc. Illinois, USA) as described by Norušis (1992). The statistics requested were *Inter-item correlations* and *Summaries of correlations*, using '*descriptives for the scale if the item was deleted*'. This was to ensure the item was not contributing to the total with which its correlation was being calculated. The *Inter-item correlation* calculation returned a correlation matrix. Negative and low numbers indicate items with no or little correlation. Also returned were the *Item-total Statistics*. This is a table that details the *item-total correlation (Pearson's co-efficient)* and *Cronbach's alpha if item deleted*. Both these

statistics are indicators of reliability. Pearson's co-efficient should be above 0.2 (Streiner and Norman, 1989) to confirm correlation. The *Summaries of correlations* returned the *Cronbach's alpha* for the overall scale, which is a reliability coefficient, giving a measure of internal consistency. The higher the alpha value the greater the overall reliability. This value should be above 0.7 (Bowling, 1997). Statements that gave many negative or low numbers on the correlation matrix indicated they should be removed from the scale. Statements that gave *Item-total correlation* below 0.2 also suggested they should be removed. The values of *Cronbach's alpha if item deleted* for each statement also confirmed statements that on removal would increase the overall reliability of the scale. These checks were run and the relevant items removed from the scale. The value of Cronbach's alpha after statement removal was checked to ensure reliability had been increased to a satisfactory level.

Attitude scores were calculated using only the statements that remained after the reliability analysis had been performed. For statements pairs that remained after the internal reliability analysis, their combined score was halved, since both statements asked the same thing.

8.3.3.6 Investigation into the impact of the pharmacist's service on staff attitudes

Due to staffing changes, not all staff that completed the pre service questionnaire were available to complete the post service questionnaire. Attitude scores were calculated for staff that were able to complete both. A Wilcoxon Matched-Pairs Signed-Ranks test was performed using SPSS, to investigate if there was any significant difference between pre and post questionnaire scores. The test statistic, Z, was compared with the standard normal statistic, Z-score [one-tailed test at 95% confidence] to test whether there was any significant difference between the pre and post service attitude scores. If the test statistic fell outside of the Z-score on the distribution, the hypothesis that there was no significant difference between the pre and post service attitude scores could be rejected.

8.3.3.7 Administration of the attitude survey

Pre-service questionnaire

The pre-service questionnaire was completed by DA drugs workers and the co-ordinator prior to the meeting where the proposal for the pharmacist's service was taken to the team. Participation in the questionnaire was voluntary and anonymous. Care had been

taken not to discuss the proposal with any team members except the DA adviser and co-ordinator. These people were included in the respondent group. The team meeting setting was used because it allowed quick and co-ordinated distribution of questionnaires, ensuring discussion with fellow workers could not influence response. The researcher asked the participants not to consider her or any particular pharmacist they knew, but to consider their opinions in relation to pharmacists in general. The questionnaires were completed and immediately returned to the researcher, to maximise response. Two workers who were not present at the meeting completed the questionnaire three working days later.

Post-service questionnaire

The post service questionnaire was completed again prior to a team meeting, one month after the service ended. Participation was again voluntary and anonymous, with staff being given one week's notice. Respondents were asked to consider their attitude after exposure to the pharmacist's service.

Coding

The researcher made a list of the order that the workers handed in the completed questionnaires. The names and corresponding questionnaires were numbered. This enabled the researcher to identify the respondent's pre and post service questionnaires, allowing responses to be compared. The respondents were not made aware of this coding.

8.3.4 Cost of the service provision

No pharmaco-economic evaluation of the service was conducted. However, calculation of the approximate cost of the provision of the service was done to give an indication of the funds that may be required for such a service. This was done using the information recorded on the monitoring forms and on the sheets that recorded use of DA resources. The total time spent by the pharmacist providing the service was calculated by multiplying the hours spent providing the service by the rate that the School of Pharmacy charged for consultancy and locum work, which was £14.36 per hour. Ten percent was added for National Insurance. Photocopying costs were calculated at the estimated cost of 4p per sheet. Telephone call destination and duration had also been recorded. Costs were based on the current BT charges at the time the service ended, which were 2p per minute for

local calls and 10pm per minute for national calls. A list of the leaflets and quantities distributed by the pharmacist was given to a DA administration worker, who calculated the cost of these to the agency. Papers requested from the university inter library loans (ILL) service for use in enquiry answering were costed at £5:00 each, as quoted by the School of Pharmacy subject librarian.

Chapter Nine

Results

9.1 Pharmacist's service activity data

9.1.1 Number of contacts made with the pharmacist and enquirer categories.

A total of 77 contacts were made with the pharmacist during the 26 weeks that the service was in operation. Of the 77 contacts, 45 were with Drugs Action workers, 25 with members of the public and 7 with workers from outside organisations. Figure 9.1 shows these values as a percentage of the total number of contacts.

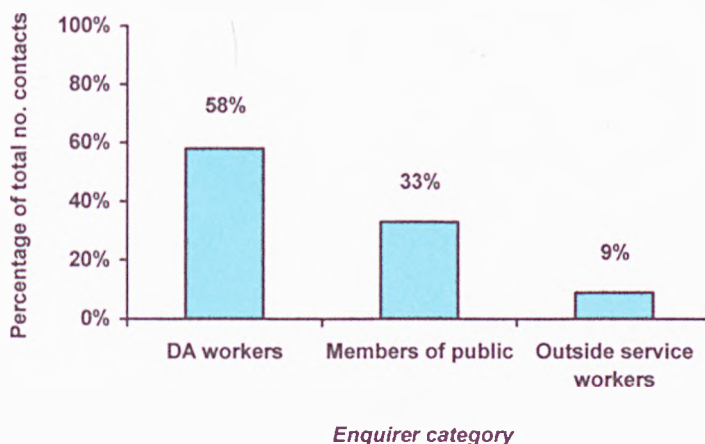


Figure 9.1 Percentage of total number of contacts ($n = 77$) made by each enquirer category

Use of the service by Drugs Action workers

Of the 45 contacts made by DA workers, 39 (87%) were made while working at the base, 5 (11%) were made from a city outreach location and 1 (2%) was made from a rural outreach location. None came from a drugs worker at the prison.

Use of the service by members of the public

Of the 25 contacts made by members of the public, 22 (88%) were with drug users and three (12%) were with people secondary to a drug user. Of these, two were made by family members and one made by a friend. Of the 22 contacts with drug users, 21 (95%)

were referred by a DA worker and 1 (5%) self referred. Of the 3 contacts with people secondary to a drug user, 2 (66%) were referred by a DA worker and 1 (33%) self referred. Overall, a DA worker referred 92% of the members of the public.

Use of the service by workers from outside organisations.

There were 7 contacts made with the pharmacist by people who worked for outside organisations. Of these, three were from a prison officer with a specialist remit for drugs education, one was from a police officer, two were from workers in care homes and one was from a nurse with a specialist remit for drug treatment.

Table 9.1 summarises the number of contacts broken down into each enquirer group and the percentage of the total number of contacts that these figures represent.

Service user group	No. of contacts (n = 77) (% of total)
Drugs worker working at the base	39 (51%)
Primary drug user referred by worker	21 (27%)
Outside organisation worker	7 (9%)
Drugs worker at city outreach location	5 (7%)
Person secondary to drug user referred by worker	2 (3%)
Person secondary to drug user who self referred	1 (1%)
Primary drug user who self referred	1 (1%)
Drugs worker at rural outreach location	1 (1%)
Drugs worker when based at the prison	0 (0%)

Table 9.1 Number and percentage of contacts that used the pharmacist's service, shown by category of enquirer.

Figure 9.2 shows the number of contacts each week, over the 26-week period. Note the pharmacist was on annual leave the week beginning 23.09.97, so this has not been included. Figure 9.3 shows same information as fig. 9.2 but broken down for each enquirer group.

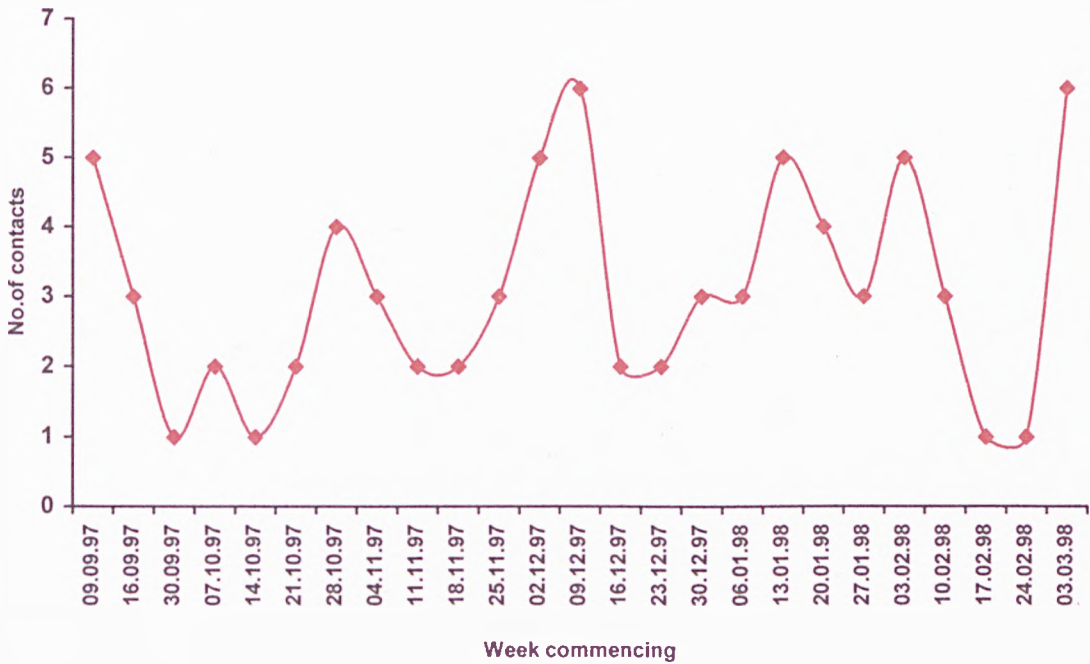


Figure 9.2 Number of contacts per week made with the pharmacist

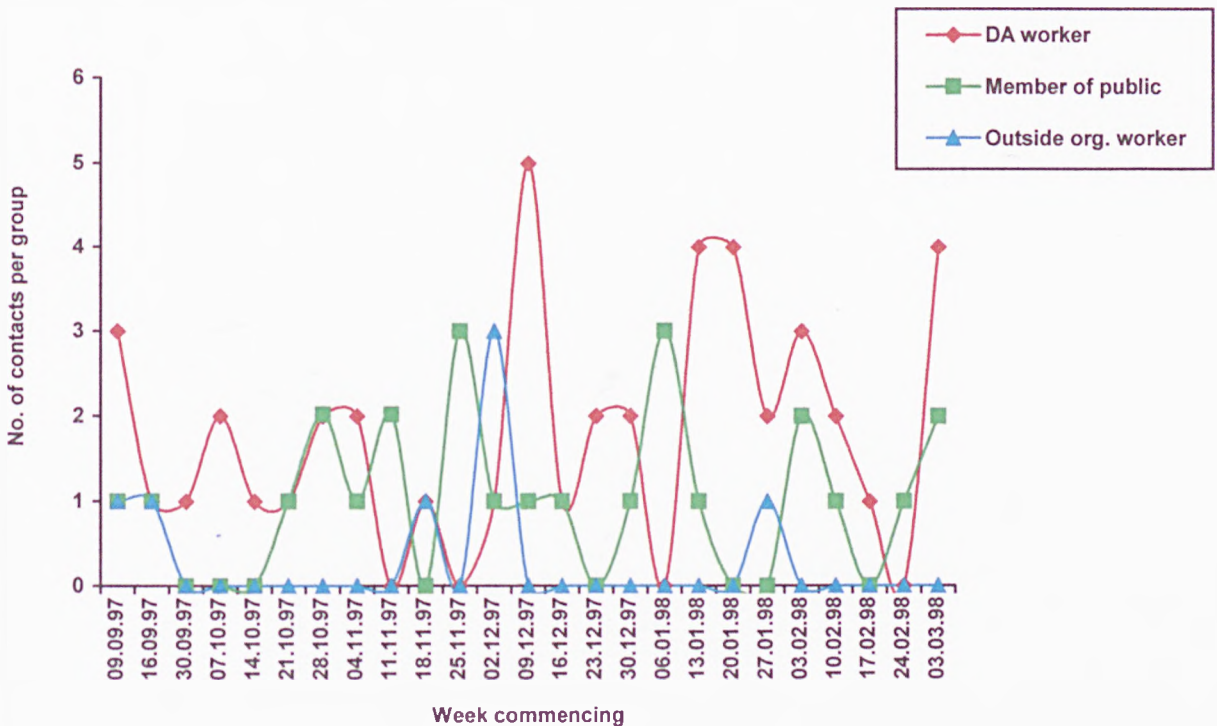


Figure 9.3 Number of contacts made per week by each enquirer group

9.1.2 Methods of Contact

Members of the public and workers from outside organisations could only access the pharmacist during the session on a Tuesday afternoon. DA workers could access the pharmacist during all working hours of the 26 weeks in which the service ran. The method of contact used by the DA workers is shown in table 9.2.

Method of Contact	No. of contacts (n = 45) (% of total)
During pharmacist's session	22 (49%)
At base NOT session	7 (15.5%)
Form 2	9 (20%)
Telephone	7 (15.5%)

Table 9.2 Methods of contact used by Drugs Action workers

9.1.3 Number of enquiries made

The majority of contacts presented one enquiry (n = 69). However, six presented 2 enquiries and two presented 3 enquiries. This gave a total of 87 enquiries received. Of these, 49 came from DA workers, 31 from members of the public and 7 from outside service workers. This is illustrated in figure 9.4.

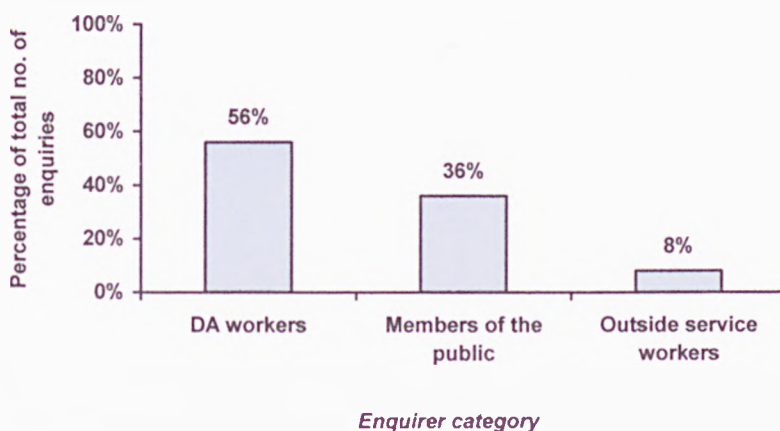


Figure 9.4 Percentage of the total number of enquiries made by each group of service users (n = 87).

9.1.4 Urgency with which contacts required a response

Forty-nine (64%) of the contacts presented enquiries that required a response as soon as possible. Of these, 24 were members of the public (49%); 3 (6%) were from outside organisations and 22 (45%) were DA workers.

Of the 49 contacts that required a response as soon as possible, 94% received a response immediately, defined as straight away or within the duration of the Pharmacist's Session or equivalent time frame. The remaining three received a response within 1 day, 3 days and 6 days respectively.

9.1.5 Consideration given to using a community pharmacist to obtain information

The members of the public who used the pharmacist's service reported in the main it would be unlikely that they would consider asking a community pharmacist a similar type of enquiry, although some said they may do so, depending on the nature of the question and their perceptions of the pharmacist. Some mentioned specific community pharmacists whom they perceived to have a positive attitude towards drug users, which may encourage them to ask for information. No one made any direct reference to perceived knowledge of pharmacists, although many indicated they associated Drugs Action with the provision of specialist information. The non-judgmental attitude of DA staff towards drug use was also cited as a reason for asking for advice at DA. Two people had consulted a community pharmacist but were not satisfied with the information they received, so they then contacted Drugs Action.

9.1.6 Categories of enquiry

From the 87 enquiries received by the pharmacist, a total of 11 different categories were identified. These categories and the number of enquiries in each are shown in table 9.3. This table also details the abbreviations used to refer to the categories later in the text.

Category	Abbreviation use for category	Number of enquiries	% of total (n = 87)
Drug Information (prescribed)	DI(P)	18	21%
Drug Information (not prescribed)	DI(NP)	14	16%
Drug Testing	DT	13	15%
Health Problem (drug related)	HP(D)	8	9%
Identification	ID	7	8%
Harm reduction techniques	HRT	7	8%
Other	O	7	8%
Medical Information	MI	6	7%
Pharmaceutical services	PS	3	4%
Adverse drug reaction (prescribed)	ADR(P)	2	2%
Adverse drug reaction (not prescribed)	ADR(NP)	2	2%

Table 9.3 The categories of enquiry dealt with by the pharmacist's service, abbreviation used, number of enquiries in each category and percentage of the total that this represents.

Although mostly self-explanatory, a brief description of the categories will now be given. 'Drug Information (Prescribed)'¹ relates to requests for information on prescribed drugs whereas 'Drug Information (Not Prescribed)' relates to requests for information on non-prescribed drugs. 'Drug Testing' relates to enquiries about the testing of body fluids as an indicator of recent drug use. Enquiries in the category 'Health Problem (Drug related)'

¹In all cases, the term prescribed refers to medicinal products taken under the direction of a medical practitioner or counter-prescribed by a pharmacist.

were about health problems that the pharmacist considered were attributable to the non-medical use of drugs. *'Identification'* was concerned with the identification of pharmaceuticals or street drugs. *'Harm Reduction Techniques'* refers to enquiries that advised on techniques to reduce injecting related harm. *'Medical Information'* was concerned with the provision of information on medical as opposed to pharmaceutical matters. Enquiries about services from community pharmacists were grouped under *'Pharmaceutical Services'*. Enquiries in the category *'Adverse Drug Reaction (Prescribed)'* related to adverse reactions to drugs that had been prescribed. Enquiries in the category *'Adverse Drug Reaction (Not Prescribed)'* related to adverse reactions to non-prescribed drugs. Enquiries that did not apply in any of the other identified categories and had no common theme between were placed in the category *'Other'*.

Appendix 27 contains two examples of enquiries in each category. These are given to assist with understanding of the categorisation and to provide an insight into the nature of the enquiries received. Further examples are used later in the text, when discussing ethical dilemmas and client outcomes.

9.1.7 Methods of reply

The pharmacist used a total of nine different combinations of methods of reply. Table 9.4 shows these methods of reply and the percentage of contacts in each group who were responded to using the method stated.

<i>Method of reply</i>	<i>Enquirer category</i>		
	<i>DA worker (n = 45) (%)</i>	<i>Member of the Public (n = 25) (%)</i>	<i>Outside service worker (n = 7) (%)</i>
<i>Verbal</i>	22 (49)	19 (76)	4 (57)
<i>Verbal & Leaflet</i>		3 (12)	
<i>Verbal & Published info.</i>	8 (18)		
<i>Verbal & Written info.</i>	6 (13)	2 (8)	
<i>Verbal & Written info. & Leaflet</i>		1 (4)	
<i>Verbal & Written info. & Published info.</i>	1 (2)		
<i>Written info.</i>	6 (13)		1 (14)
<i>Written & Published info.</i>	1 (2)		2 (28)
<i>Written & Published Info. & other</i>	1 (2)		

Table 9.4 *Methods of reply used to deliver information from the pharmacist's service, shown as the number and percentage of the total no. enquiries from each group that received replies in the stated format.*

9.1.8 Ethical and moral dilemmas

Four areas arose that presented ethical and/or moral dilemmas. They were:

- Provision of information to third parties (two dilemmas)
- Verification of information from another professional source (three dilemmas)
- Provision of information on drug testing (six dilemmas)
- Identification of unknown tablets/capsules (six dilemmas)

After consideration and consultation of the literature, all the dilemmas were responded to, to varying degrees. The competing value considered to be at the greater risk from harm was the one that was given priority. The pharmacist attempted to achieved a balance between the competing values as far as possible. Further details of the dilemmas and the handling procedures used are described in appendix 28.

9.1.9 Knowledge requirements and categorisation

Of the 87 enquiries received, 45 were answered using core knowledge, 20 used specialist knowledge and 22 used a combination of both. The proportions of the total number of enquiries that these figures represent are shown in figure 9.5.

There were two categories of enquiry where the pharmacist considered core knowledge alone was not used to respond to any of the enquiries. These were harm reduction techniques and adverse drug reactions to non-prescribed drugs. At least one enquiry in all of the other categories had been answered using core knowledge alone. Core knowledge was used to answer all the drug information (prescribed) enquiries and many of the non-prescribed.

Specialist knowledge was used when responding to enquiries that fell into six of the categories. These were: drug testing, harm reduction techniques, adverse drug reactions (non-prescribed), identification, medical information and other.

Eight categories contained at least one enquiry that required a combination of core and specialist knowledge. These were health problem (drug related), harm reduction techniques, drug information (non-prescribed), drug information (prescribed), medical information, identification, adverse drug reaction (non-prescribed) and other.

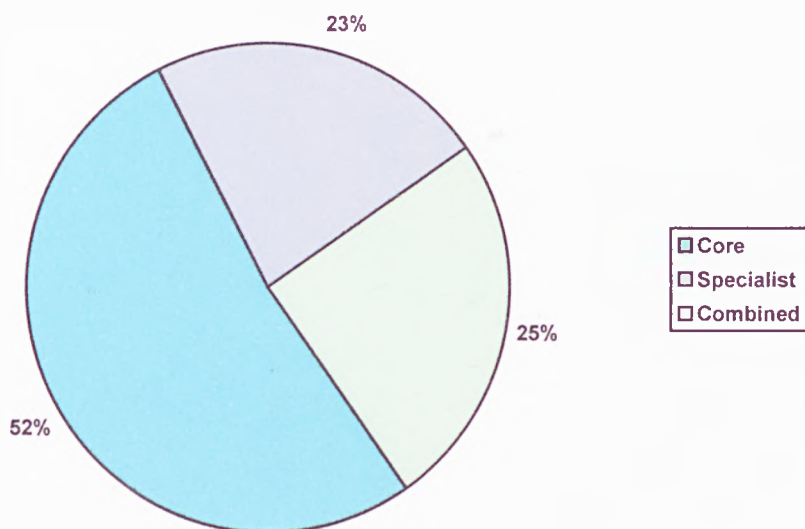


Figure 9.5 Knowledge requirements needed to answer to enquiries received by the pharmacist (n = 87).

The major topics of core knowledge that were involved in the enquiry answering process were:

- Knowledge of prescribed drugs
- Drug delivery routes
- Anatomy and physiology
- Therapeutics of substitute prescribing
- Assessment of presenting symptoms
- Ethics
- Pharmaceutical service provision
- Care planning
- Primary and secondary health-care systems

The major topics of specialist knowledge that were involved in the enquiry answering process were:

- Drug testing in body fluids
- Harm reduction principles and techniques
- National and local statistic keeping
- Social services and welfare rights

-
- 'Set and Setting': the psychology, social context and associated factors that impinge on drug use
 - Terms and expressions used by drug users
 - The drug-using sub culture

The major topics of combined knowledge that were involved in the enquiry answering process were:

- Pharmacology of street drugs
- Risks and complications associated with injecting drug use
- Health problems associated with the use of street drugs
- Legal implications of drug taking

Information sources used by the pharmacist to acquire specialist knowledge necessary for the provision of the service were:

- Text and resource books.
- Health Education Authority/Board publications.
- Specialist journals.
- Conference presentations and proceedings.
- Specialist services (inc. ISDD, HIT, Lifeline, Tic-Tac, National Poisons Unit).
- Data sheets and company literature.
- Postgraduate education packages and multidisciplinary seminars (e.g. SCPPE, Safer Injecting Training Day (HIT, Liverpool)).
- Drugs Action in-house training materials.
- Grampian Health Board.
- Home Office (Action Against Drugs Unit).
- World Wide Web.
- Discussion with drug users.
- Discussion with other professionals.

9.1.10 Skill requirements in the provision of the pharmacist's service

Core skills that were required when providing the service were:

- Information retrieval
- Information interpretation
- Patient and drug history taking
- Effective communication with other professionals.
- Effective, non-patronising communication with members of the public.
- Decision making with respect to the provision of information in the context of each situation.
- Relation of information to the individual circumstances and people concerned.

Specialist skills that were required:

- The ability to translate information into terms used in the drug culture.

This skill was learned by discussion with and observation of drugs workers in practice before the research began and through popular culture media.

9.2 Evaluation of pharmacist's service

9.2.1 Client follow-up

Of the 25 members of the public who used the pharmacist's service, nine (36%) were followed up at a later date when they made contact with the agency. Four were followed up through direct contact with the pharmacist and five were reported via drugs workers. The nine cases presented 13 different issues from which to establish outcomes. All the outcomes, with the exception of one, were considered by the pharmacist to be positive. The negative outcome was when consented divulgence of information to a Substance Misuse Service nurse led to the patient being discharged from care. Three of the cases received further input from the pharmacist at follow up: one directly relating to the matter concerned where the opportunity arose to give information and advice on warfarin and two where the clients presented for further unrelated assistance. These nine case studies including the outcomes are described in appendix 29.

9.2.2 Discussion group

Nine drugs workers and the agency co-ordinator were present when the discussion group was held. The group lasted 80 minutes. No written comments were received. The labelled themes, which categorised the expressed opinions from the group discussion, are listed below. Quotes from the participants, which illustrate the themes are given.

Question 1: *'To those who used the pharmacist's sessions, can you tell me what you thought of the service?'*

Theme 1: The pharmacist enhanced the service provided by the multidisciplinary team at Drugs Action.

Supporting quotes:

'It has really enhanced the service and given us more knowledge than we would've had..and [given us] knowledge about where to go if you need to find out things.'

(base worker)

'It really did help..it complements a multidisciplinary team'

(prison worker)

'It has been a luxury...it has been really, really helpful and useful....it's been a great service.'

(base worker)

'Lots of help, lots of information, especially having a lot of knowledge about drugs and it's just been brilliant to be able to come to yourself'

(HIV/Hep C worker)

'I found the responses very, very valuable and illuminating..'

(co-ordinator)

'Easily accessible, efficient, very thorough, user friendly information....[it] raised issues I hadn't thought of which were of benefit to the client'

(base worker)

Theme 2: The centre-based nature of the service determined the workers and clients who were able to make most use of the service. Workers based at outside locations were restricted in how much they could use the service because information has to be to hand when responding to clients.

'... 'cause it was a centre based service, I got less service out of you as a pharmacist as I did when you did cover with the outreach team².'

(outreach worker)

'...[I agree with] the point made by [name of outreach worker who made above comment] about not being centre based, but often I found information in my pigeonhole which I appreciated'

(prison worker)

Theme 3: The pharmacist played a role in resourcing information

'It's good to know there is somebody there who knows the stuff that you know and it saves us looking up reference books when you are the source of the information right there and we can just get hold of you and save us time and mucking about trying to find out bits and pieces'

(outreach worker)

'when we wanted to check details about the Release leaflet [information leaflet which was available from a youth project in Aberdeen, produced by the agency Release on urine testing for illicit drugs in schools].you contacted the National Poisons Unit. Also when trying to find a tablet, you contacted the Tic-Tac system..that was really useful.'

(outreach worker)

² This comment referred to times when the pharmacist had gone to outreach locations with the workers to experience practice.

Theme 4: The pharmacist increased drugs worker's knowledge and understanding of pharmaceutical and medical information

'It has saved us loads of time and not just time but really it has been easier to interpret information and I think it has been a brilliant resource.'

(base worker)

'Sometimes we know things but we don't know how we know them, you've given us a medical reason why certain drugs do things or why it's not right to prescribe whatever, it has been really good for us to challenge bad prescribing...we've got medical back up ourselves, so it enhances it [challenging prescribers]'

(base worker)

'..explaining to me what certain tablets do that I don't know..very useful'

(outreach worker)

'..you gave good feedback on intramuscular injecting. I thought the potential to develop an agency leaflet is there and I'd like to explore that with you..'

(co-ordinator)

Theme 5: The pharmacist played a role in discussing and explaining pharmaceutical care issues with clients and workers

'I was glad when you came into peoples' appointments, [gives name of a client described in appendix 28, case study 7 and described scenario]..he was really scared about the effects it would have on his body and going through these....and when the withdrawals would happen. Even though I was trying to say things to help him, for the pharmacist to come in as well and say the same kind of things but in more detail, was good and it was true what happened to him afterwards. He was shitting it that he'd have really bad withdrawal and you said he wouldn't and he didn't.'

(outreach worker)

'One of the things I found was that clients who had already seen you..I was picking up on chats they had already had with you, and I was able to talk to you about clients. It meant next time I saw the same client I was informed about it.'

(prison worker)

'It was very useful to have a pharmacist here, especially when I was dealing with a client and his partner, who I guess didn't really want to believe us and anything we were saying and the doctor was saying. But when Jenny was involved she sat and listened and instead of it being me or the male doctor-telling her how it was going to be, it was a woman speaking to her, a female pharmacist, who had the knowledge as well. That I found was incredibly useful for her to get a bit of understanding about her husband's situation'

(HIV/Hep C worker)

Question 2: *'Have your views and opinions on the skills of a pharmacist changed at all by having this service at DA?'*

It was asked if this question was specific to the pharmacist who conducted the sessions or if it was referring to all pharmacists, so the question was rephrased as follows:

'I would say all pharmacists. Do you feel there were interventions made, things discussed, topics covered, which you didn't think were part of a pharmacist's job or do you think you weren't suprised by the kind of service delivered?'

Theme 1: The work of an individual cannot be perceived to represent that of the profession.

'I wouldn't generalise about all pharmacists based on the service that you provided. Attitude, knowledge and standards are based on individuals skills and would have to be proved by individual pharmacists....what I'm trying to say is, I'd have concerns about pharmacists in general and would have to base my opinions on individuals and not the profession'

(base worker)

Theme 2: It was felt that a specialist pharmacist is likely to have a greater level of knowledge and understanding of the drugs field than a community pharmacist.

'I'd be suprised if most other pharmacists had the level of knowledge that you have in such a specialised subject, my experience is that they've not seemed to have that insight into users, or effect [of drugs] etc'.

(outreach worker)

'When you and Luan [the needle exchange worker] were doing training, things you were discussing and things they [community pharmacists who provide needle exchange] were coming out with [referring to questions raised] were things you knew, so there is a difference between you.'

(outreach worker)

Theme 3: The experience of the agency of having a specialist pharmacist was seen to have raised expectations of the workers from other pharmacists. However, it was thought that other pharmacists do have access to information and knowledge, but often drug users are discriminated against on the basis of morals.

'Knowing what Jenny knows, I think we can now expect them [community pharmacists] to tell us things and find things out..'

(outreach worker)

'All pharmacists should be able to put skills into practice, but they cannot be bothered [with drug users]'

(base worker)

'Even the basic stuff that pharmacists will know..they don't want to give information or, because of their attitudes, they don't want to enter into any conversation'

(HIV/Hep C worker)

'Without complimenting you, I think you're doing what pharmacists, I think, should be doing, which is work in a non discriminatory way, working actively, trying to look at a particular unsympathetic client group.'

(outreach worker)

Theme 4: Some health professionals, including pharmacists, were seen to have a lack of ability to view the person holistically, which was considered important.

'I think sometimes there is a tendency to generalise and maybe stereotype. Sadly sometimes the stereotypes or experiences are true. In the medical profession and other professions like that, often we come up against people who devalue the human component, you know they are very reductionist and look at bits of people, they are not looking at the person and they don't have the values of respecting people.'

(co-ordinator)

Question 3: *'One area of concern before the sessions started was about communication, pharmacist's communication with staff and particularly clients. Can you comment on communication with staff and clients?'*

It was confirmed that this was referring to communication during the pharmacist's sessions not community pharmacists.

Theme 1: Response to queries from workers was delivered quickly.

'You were always quick to respond'

(outreach worker)

'Quick, information you gave came in next day or next two days..'

(outreach worker)

'Quick to respond'

(base worker)

Theme 2: Workers were confident in the responses they received from the pharmacist.

'I was clear about how much something was checked and how clear you were about it, what was speculation and what was fact and what could be proved and what couldn't.'

(outreach worker)

'I always felt confident in the service you were providing, that it was always going to be good and the information you were providing was going to be accurate...'

(outreach worker)

'Communication with me, as a worker, was efficient and suited my needs'

(base worker)

Theme 2: Communication with clients was clear and appropriate

'When you were speaking to clients you didn't speak in the medical words, it was all really easy to understand and not done in a patronising way or condescending at all. It was all just straight forward and cut through all the jargon.'

(base worker)

'You can explain things to them (clients) without patronising them. That's really important.'

(outreach worker)

'Also, when you did speak to them, you took time to make sure they understood what you'd said, which I think is really important and necessary. Once clients started a dialogue, they felt comfortable enough to ask more questions.'

(HIV/Hep C worker)

Theme 3: If a query arose when the pharmacist wasn't present, sometimes the response was not used if the client made no further contact.

'The only difficulty was relaying info to the clients that I see sporadically. i.e. if the query wasn't on a Tuesday afternoon and was therefore written, the clients sometimes didn't return for the info.'

(base worker)

Question 4: *'The attitude of the pharmacist to drug users was expressed as another area of concern before the sessions started. Can you comment?'* [the group asked for further explanation, so the researcher added: *'..concerns were expressed about being judgmental and how clients might feel'.*]

Theme 1: The pharmacist was perceived to have a positive non-judgemental attitude appropriate for working with drug users.

'Your attitudes are obviously non-discriminatory and you have had a lot of positive contact with drug users'

(base worker)

'Your attitudes are good'

(outreach worker)

'You were seeing the person as a whole, not just these are all drug users, therefore everything that is wrong with them is to do with their drug use'

(base worker)

'When I told you a client you'd seen had been in to see me, you were very concerned to know how his health was, to follow through the information from me. That showed nothing but a healthy attitude towards the needs of the client and showed genuine concerns about his long term health ...'

(prison worker)

'What you were displaying was the possibility and potential for a non-discriminatory practice.'

(co-ordinator)

Theme 2: Clients may have had perceptions about pharmacists based on past experiences. However, the reputation that Drugs Action has with drug users, meant implicit trust was placed in the pharmacist.

'I've had to explain to someone that you're not here as a pharmacist in a chemists shop and you're not going to cut their 'script or things like that. I have had to do that. Once I'd explained it, they were all right, maybe a bit dubious because of their experiences with pharmacists from before, but once you show your actual attitude then they know you're all right'

(outreach worker)

'A lot of it [attitudes and how clients might feel] is based simply on the fact that folk will have 'blind trust' -the recommendation from someone they trust, e.g. the drugs worker introduces client to pharmacist....it's like, you are another Drugs Action worker and that has been people's perceptions, partly because they've been guided, but there haven't been any blocks, I haven't heard any fears. People have been kind of glad that there is something they can access'.

(outreach worker)

'I must admit I was a wee bit apprehensive as to how clients would be when we said we had a pharmacist and she can come and speak to you, I did wonder how that'd be..they were great. I think that is also a reflection on how they view our service as well'

(HIV/Hep C worker)

Question 5: *'How do you think the clients felt about talking to me? Consider any feedback you may have got and consider confidentiality, that was something that was expressed that clients may not feel comfortable with...that the service that was being provided was confidential.'*

Theme 1: It was felt confidentiality was perceived to be assured because of the reputation of the agency.

'..the fact you were a colleague, one or two needed reassured...[but] it was taken as read that the confidentiality thing of the whole agency was taken to mean the pharmacist as well.'

(HIV/Hep C worker)

'I don't think there were any problems with that [client's trusting the service to be confidential], not in my experience.'

(HIV/Hep C worker)

'From what folk are saying, the confidentiality thing was the odd exception, which is what happens with us. There is the odd person who needs reassurance e.g. 'is getting works here going to affect my script?'

(outreach worker)

Question 6: *'Do you have any concerns you want to express about the service?'*

Theme 1: It was perceived that the pharmacist's service had become an established part of Drugs Action services, withdrawing it because the study was over meant letting people down.

'The main one [concern] is that we've raised expectations of clients for you to be here.'

(needle exchange worker)

'..some clients who've come along and got a bit of information, come back for some more information or help and support 'cause they knew you were here and again, it's about for the agency and directly for our clients..'

(HIV/Hep C worker)

'If I could say, okay we've had our own pharmacist, but you'll get this somewhere else...but, I don't think people are connecting with that...I think they'd be foolish to. I think they're right not to think I'll be able to go into a pharmacy and feel comfortable speaking to the pharmacist...'

(outreach worker)

'I have no concerns, but I would like to see a service provided with more sessions, so that communication [of information] to clients was improved'

(base worker)

All participants approved the discussion group report as being accurate within the given time frame.

9.2.3 Attitude Measurements of DA workers

Eleven out of the fourteen drugs workers employed at the start of the pharmacist's service completed the pre-service attitude questionnaire. Of the three who did not, one was on long-term sick leave, one was on maternity leave and one worked only one evening a fortnight and did not attend team meetings.

9.2.3.1 Piloting

As a result of the pilot study, statements relating to the provision of information on mandatory drug testing in prisons to workers and clients were removed, as the respondents considered it irrelevant. The balance between positive and negative statements was maintained.

9.2.3.1 Reliability checks

Internal reliability.

The responses to the paired statements are compared in table 9.5. The difference in scores for each pair of statements was calculated for each respondent. These are shown by the number of respondents who achieved the stated differences (minimum 0 and maximum 4) and the percentage of the total number of respondents ($n = 11$) that this represents.

Statement Pairs		Difference between statement scores				
		0	1	2	3	4
4	I think the clients would feel comfortable talking to a pharmacist at DA.	6	4	1	0	0
5	I think the clients would not feel comfortable talking to a pharmacist at DA.	(55%)	(36%)	(9%)		
9	I think the clients would benefit from having a pharmacist at DA.	8	3	0	0	0
13	I think a pharmacist would not be much use to DA clients.	(73%)	(27%)			
10	I think a pharmacist would not be able to contribute positively to the team.	7	4	0	0	0
16	I think a pharmacist could contribute positively to the work of the team.	(64%)	(36%)			

Table 9.5. Difference in scores to paired statements, shown by number of respondents ($n = 11$) who achieved this score. (Percentage of the total number of respondents in brackets)

The majority of respondents scored both statements in the pair the same, suggesting the questionnaire had satisfactory internal reliability.

Reliability Analysis.

The statistical output from SPSS lead to the removal of some statements as explained: Statement number 1 was ignored by SPSS as all respondents gave the same response, so there was zero variance. Using the 19 statements that were left, the Cronbach's alpha achieved for the scale was 0.1807.

'Alpha if Item Deleted' indicated removal of number 18 would greatly improve internal consistency. This was done and Cronbach's alpha became 0.7902. Looking at the Corrected Item-Total Correlation, three statements had a correlation of less than 0.2. These were statement numbers 5, 6 and 11. These were removed and the analysis performed again. All statements now gave a Corrected Item-Total correlation above 0.2 and the value of Cronbach's alpha was 0.8327. However, the Correlation Matrix indicated some statements still had low or negative correlation with others, although their overall correlation with the scale was adequate. These statements were numbers 4, 2, 19 and 20. These were removed and again the analysis performed. The resulting Correlation Matrix indicated a positive correlation between all statements. All Corrected Item-Total Correlations were satisfactory and the value of Cronbach's alpha had been raised to 0.8641.

Table 9.6 summarises the statements that were removed and those that were kept for the attitude comparison.

Statements Used to Score Attitude	Statements Removed
3, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17	1, 2, 4, 5, 6, 11, 18, 19, 20

Table 9.6 Results from reliability analysis

9.2.3.2 Attitude scores

The minimum attitude score possible with eleven statements was 9. This would indicate the most unfavourable attitude. The maximum score possible was 45, indicating the most favourable attitude.

Nine respondents completed both the before and after attitude questionnaires, so their pre- and post-service attitudes could be compared. The scores of the respondents are shown in table 9.7. Note, no respondent chose the 'Not Applicable' option in response to any of the statements.

Respondent Number	Score before	Score after
1	35	37
3	47	37
4	27	41
5	33.5	43
7	44.5	43
8	31	43
9	39	40
10	33	43
11	37	39
Mean	36.33	40.67

Table 9.7 Respondent attitude scores before and after pharmacist's service.

Attitude scores before and after the service was implemented are represented in figure 9.6. Note, each coloured block represents the attitude of an individual drugs worker.

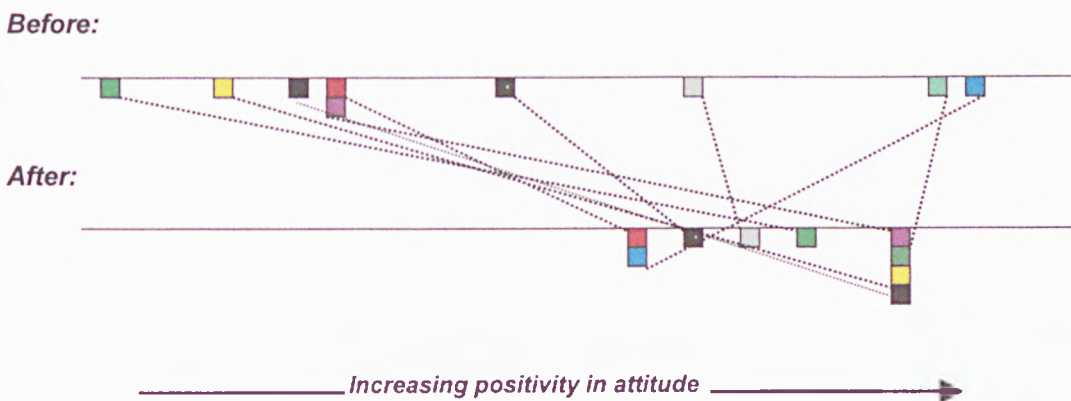


Figure 9.6 Changes in drugs worker attitude to having a pharmacist as part of the team based on attitude measurement made before and after the service was conducted.

From the Wilcoxon Matched-Pairs Signed-Ranks test, the test statistic Z was -1.661 ($p = 0.05$). For a one-tailed test at 95% confidence the Z -score is 1.645 . Because the test statistic is negative, it is compared with the negative Z -score. Since -1.661 is less than -1.645 (i.e. the test statistic is outside the critical value), the hypothesis that there is no significant difference between pre and post attitude score of the team can be rejected. In

conclusion, the attitude of the team as a whole significantly shifted in a more favourable direction after exposure to the pharmacist's service.

9.2.3.3 Responses given to open questions on the attitude questionnaire

Eleven workers completed the questionnaires before the service was implemented and twelve completed it after. The responses of all are included, as the pre- and post-service questions are not directly comparable.

Responses to questions asked before the service was implemented

The first question was:

1. 'Please briefly describe what you see, if any, the main role of a pharmacist at Drugs Action to be:'

Five themes emerged in response to this question. These are now listed with description of specific factors raised.

(1) Support and compliment the existing staff team

- provision of information to workers. Topics specified were drugs and their effects, medical information and services and health issues.
- provision of advice to workers.
- supplement the skills already available within the team
- add to the professionalism of the agency

(2) Provide information to clients

- Especially, the provision of health information to clients with no access to primary health care services.

(3) Provide training

- Training for both staff and clients, through both formal events and on-the-job support.

(4) Increase understanding of staff and clients of issues relevant to the pharmacy profession

- Raise awareness of problems pharmacist's have with drug users and drugs workers
- Raise awareness of staff and clients of the role of pharmacist's in the care of drug users, including pharmacist's position on confidentiality.

-
- Make staff aware of political issues relating to pharmacy.

(5) Provide a supportive link with other professionals

- Provide a professional link that enhances collaboration with and training of other pharmacists.
- Advocate harm reduction practices to other health care professionals such as doctors, and health board workers.
- Enhance communication with medical-based services

The second question was:

2. Please briefly describe reservations, if any, you have about a pharmacist coming to work at Drugs Action:

Five themes emerged around the team's concerns, which are listed with descriptions of specific factors.

(1) The attitude of the pharmacist to drug use and drug users would contradict the agency's philosophy.

- Specifically, concerns that the pharmacist may be judgmental
- A pharmacist may not support harm reduction within the agency or to colleagues from outside
- Concerns that the pharmacist may have a different ethical basis from the agency
- Concerns that the pharmacist may be afraid of drug users and treat them in a manner that showed this.

(2) Concerns that the pharmacist may not provide a confidential service

- Concerns the pharmacist may breach confidentiality because of knowledge about clients from other work (e.g. tell prescribers of substitute drugs if someone received a needle exchange).
- Concerns that clients may worry the pharmacist is not providing a confidential service and therefore not trust the service or be honest with the pharmacist

(3) Concerns about the pharmacist's understanding of drug use.

- A pharmacist may not understand the social issues around drug use
- Specifically, a pharmacist may not be able to deal with unrealistic expectations of clients

- A pharmacist may not challenge users about behaviour issues in an appropriate manner
- A pharmacist may make assumptions about client's feelings

(4) Must ensure that the pharmacist had adequate supervision and management when being integrated into the team.

- Concerns specifically underpinned by the above reservation
- Standard practice for any new member of staff

(5) Demonstration of a useful service may lead to service provision elsewhere but not at Drugs Action

- Concerns that if funders saw the service was useful to DA, they may fund such a service elsewhere instead of at DA.

Responses to questions asked after the service was delivered

In response to the closed question:

1. Based on your knowledge, experience and opinion of the pharmacy sessions which were provided at Drugs Action, do you think there is a role for a pharmacist as part of the team?

Yes

No

All staff said yes.

When asked:

If you answered yes to the above question, please expand by stating what you see the main role to be:

The staff gave several examples. From these, five themes emerged, which are listed with examples.

(1) Be a specialist on pharmaceutical/medical issues relevant to drug use, to compliments the team.

- Increase the holistic approach of the agency to deal with all issues around the person and their drug use by providing information and advice on health issues both related and unrelated to drug use
- Be a source of information for staff and clients on wide range of health issues
- Help staff interpret medical information relevant to clients
- Provide a credible pharmaceutical/medical aspect to the service

-
- Provide instant access to information on pharmaceutical/medical issues

(2) Strengthen the knowledge of the team on pharmaceutical/medical issues.

- Help staff keep up to date and aware of current medical based research and practice relevant to drug use
- Widen the knowledge base of staff on the physical effects of drugs, both illicit and prescribed.
- Provide staff with a necessary level of in-depth pharmaceutical/medical knowledge to understand specific situations e.g. prescribing issues.
- Increase knowledge of staff making them confident in challenging bad practice e.g. bad prescribing.
- Increase staff knowledge on general health issues

(3) Provide clients with pharmaceutical/medical information

- Provide information on both drug related health and general health issues
- Explain drug issues with a specific pharmaceutical/medical aspect
- Assist clients in assessing the risks and benefits of using specific drugs, in terms of health and lifestyle.
- Assist clients in understanding health issues around stopping using specific drugs
- Assist clients in understanding health issues around receiving a prescription for substitute therapy.

(4) Network and negotiate with medical based services and policy makers

- Defend harm reduction practice when working with other professionals
- Add credibility to DA practice and experiences
- Negotiate harm reduction strategies with medical-based professionals on behalf of clients

(5) Provide training

- Train staff formally and informally, through joint work with case load
- Train medical based professionals from other agencies and services

9.2.4 Cost of the service provision

Cost of pharmacist's time

The pharmacist spent 22 hours and 30 minutes outwith the session time dealing with enquiries. Therefore total time spent on service provision in the 26 week period was:

3 hour session x 26 weeks + 22 hours 30 minutes

= 100 hours 30 minutes.

Cost @ £14.39 per hour = £1446.20

+ 10 % National Insurance (theoretical)

= £ 1590.82

Use of agency resources

The pharmacist made 17 A4 photocopies at the agency during the 26 week period.

= £0.68

The pharmacist made three local rate calls, with approximate total duration of 4 minutes =

4 x 3.95 = £0.16. The pharmacist made seven national rate calls, with approximate total duration of 25 minutes = 25 x 7.91 pence = £1.98

The pharmacist distributed three safer injecting booklets at a cost of £1:00 each. The cost of other leaflets used was estimated at £6:00

Use of University resources

The pharmacist made 37 A4 photocopies at the University for use in response to enquiries = £1:48

The pharmacist made 4 local rate calls, with approximate duration of 25 minutes = 25 x 3.95 pence = £0.99

The pharmacist made nine national rate calls, with approximate duration of 90 minutes = 90 x 7.91 pence = £7.12

The pharmacist received 4 papers through inter library loans x £5:00 = £20:00

The total estimated cost of provision of the pharmacist's service was: £ 1630.23

For 87 enquiries, this averages at a cost of £18.74 per enquiry.

Chapter Ten

Discussion

10.1 Critique of method

10.1.1 Methods used to provide the pharmacist's service

10.1.1.1 The researcher as the pharmacist

The decision to use the researcher as the pharmacist who delivered the service should be criticised. It could be viewed that when the researcher was investigating the impact of the service, she may have had preconceptions of its benefits, since she delivered the service. However, there were also benefits to using the researcher as the pharmacist. It allowed greater understanding of the cases and eased interpretation of the findings, due to her first hand experience. It may also be criticised that the familiarity of the DA team with the researcher/pharmacist prior to this work being undertaken could have introduced bias when they expressed their opinions on the service, if they already had a favourable view of the researcher. However, there were also benefits of this familiarity, in that the researcher had an understanding of the policies and practices of the agency. This allowed the service to be designed in a way that was considered to complement the existing structure. Also, people who have drug problems and their families are seen as a vulnerable client group. New workers must be carefully introduced to this group to protect those concerned, for example by supervising practice for the first three months of employment. The familiarity of the DA team with the pharmacist and her prior research experience at the agency¹ meant that the team did not consider this necessary, so the service could be implemented without an induction period. Steps were taken to minimise the bias from these factors. The researcher was conscious that in order to be ethical she must be objective in her views. Cost restrictions prevented a separate pharmacist being employed to conduct the service, so the system that was used here where the pharmacist who delivered the service was also the researcher was the only option. However, it is not considered to be ideal. If further work were to be conducted in this area, provision would be sought to enable a separate pharmacist would be used. The fact the pharmacist was also the researcher and the potential for bias as discussed above, must be born in mind when considering the results.

¹ Observing practice and conducting the interviews with IDUs for the work in part 1.

10.1.1.2 Structure of the pharmacist's service

It may be suggested that the input of the pharmacist to the work of the agency was not maximised over the 6-month period since she was not present during all opening hours. Certainly, the results suggest that had she been present all the time, more opportunistic interventions would have been made. However, the purpose of having one 3-hour session was to use a situation that would be more likely to represent what could be provided in the current climate of partnerships and buying in of services. The provision of funding for specialist sessions was considered to be more likely than the funding of a full time post. For example, a community pharmacist with an interest in specialising in drug misuse could be bought in to deliver one session per week. It may then be criticised that allowing the pharmacist to be contactable by telephone at other times was contradictory. However, this aspect of the service was done to allow investigation of the suggestion made by Gerret et al (1987), that drugs agencies may benefit from a specialist pharmacist information service.

The pharmacist hand delivered information to the agency at times outwith the session times, when it was needed. Some opportunistic enquiries were received during these delivery times. This may be criticised as deviating from the defined structure of the service. A more rigid service would not have allowed enquiries to be received at other times and delivered all urgent information by fax. However, the pharmacist considered that this should be done, in order to make the service as accommodating as possible. She also felt ethically that she did not want to refuse assistance. Although the number of contacts made during these times was small ($n = 7$), this contribution to the total number of contacts made must be borne in mind.

10.1.1.3 Duration of the pharmacist's service

Given that no induction period was required and the previous familiarity of the pharmacist with the agency and vice versa, a six-month investigation period was considered to be adequate to allow the role of a pharmacist at Drugs Action to be explored. In this time a total of 87 enquiries were received, which was considered to be adequate to illustrate the role the pharmacist carried out. Had the pharmacist been unknown to the agency, a longer period of time would have been used.

10.1.1.4 Publicity of the pharmacist's service.

The publicity for the service was not released until one week before the service commenced. This was done so the workers were not made aware of the plans prior to their attitudes being measured. Also, it meant that anyone who responded to the publicity did not have to wait several weeks to receive the pharmacist's service. The effectiveness of the publicity was not investigated. Asking contacts from outwith DA, who self referred, what prompted them to use the service, could have done this. This would be considered if such a service were implemented in the future. However, since the number of self-referrals was low ($n = 2$ for members of the public and $n = 3$ for outside organisation professionals), this suggests that publicity alone was not very effective compared to worker recommendation. At the time the publicity was distributed, a decision was taken not to publicise the service to GPs and community pharmacists, as it was felt that they already had access to further information. However, on reflection this decision is not considered to have been correct and there may have been benefits to inviting them to use the service. If such a service were implemented in the future, it would be extended to include GPs and community pharmacists. The publicity materials gave examples of possible areas of enquiry. These examples may have influenced the nature of the enquiries made. Some examples given relate to areas of enquiries received e.g. the effects of drugs but others do not e.g. sexual health and contraception was an example given but no enquiries were received. However, since this was not investigated it cannot be said whether publicity affected the nature of the enquiries received or not. Given that the majority of enquiries received from members of the public were referred by a drugs worker, the perceptions and opinions of the drugs workers on the appropriateness of issues for the pharmacist is likely to have been a large factor in influencing the nature of the enquiries received.

10.1.1.5 Enquiry handling procedure

The enquiry handling procedure was based on the guidelines given to drug information pharmacists by the UK Drug Information Pharmacists Group. Where considered appropriate, procedures were adapted for the agency setting. The main modification was the extent of the client details recorded. These were minimised to provide as much anonymity as possible, to encourage service use. The pharmacist recorded enough information so that, had a case arisen where there was a need for her to be able to give an account of an enquiry, she could do so. Enquiries could be traced based on their date and the enquirers' initials, or in the case of workers, first names, being known. When

considering the need for accountability in information and advice provision on the basis of clinical governance, this raises the question of whether community pharmacists and others who provide information on an anonymous basis should do so. It can be criticised that providing anonymous information with no means of follow-up prevents the practitioner from being able to demonstrate and justify their actions or to audit their practice. However, this anonymous and informal system is known to encourage the public to use pharmacists as a source of information and advice (Blenkinsopp, 2000). Formalising the system might remove such opportunities, which could be detrimental for all concerned. However, this does raise a potential area for investigation in view of clinical governance. The UKDIPG guidelines were used for the pharmacist's service as they were considered to be the most appropriate guidance available in 1997. However, if a specialist role for information pharmacists developed at drugs agencies, it would be desirable for those involved to develop their own practice guidelines.

10.1.1.6 Monitoring of the pharmacist's service

The paper-based form used to monitor the enquiries was based on those used by Gerret et al (1987) and the UKDIPG guidelines. This was considered appropriate, as all necessary information was recorded quickly and preferable to designing a completely new form that would have required piloting. The electronic database was useful for data manipulation by the researcher, but not used at the agency itself as the necessary software was not available. The use of progressive focusing once the service was over to re-categorise the enquiries and define further the knowledge and skills required, was appropriate to extract the maximum amount of information out of the data. Such examination is recommended in research methods texts (Coolican, 1994, Bailey et al 1995).

It may be argued that use of a panel to identify the themes of the enquiries would have been more objective than the pharmacist doing this. This was not considered at the time of study design. However, the familiarity of the pharmacist with the cases may have enhanced the accuracy of categorisation. Use of a panel would be considered in further work.

10.1.1.7 Knowledge and skills categorisation

The methods used to categorise the knowledge and skills used to undertake the service are given in 8.2.1.2. It can be criticised that knowledge and skills are intrinsically linked and cannot be separated as easily as it appears in this work. Such categorisation was done to enable an outline description of what was required to handle the enquiries to be made for future use, so it should not be interpreted as a definitive, distinct summary. Knowledge and skills are separated in a similar manner by the RPSGB in their competency-based standards defined in the MEP (RPSGB, 2000). As the categorisation was undertaken by the researcher, it must be recognised that the categorisation relates to her own opinions and experiences only. If a peer-group panel had been used to categorise the knowledge and skills, a different set of categories and opinions on sources of such may have resulted. Indeed, if several groups had been used it is possible that each would have come up with different opinions, depending on their experience in the field. For future work that focused more on the knowledge and skills needed for such service provision, the use of several peer groups would be considered to investigate this in more detail.

10.1.2 Methods used to evaluate the pharmacist's service

10.1.2.1 Methods used to establish DA client outcomes

The outcomes experienced by DA clients after contact with the pharmacist were determined through self-reporting by the client to the pharmacist or self-reporting of the client to their worker, who in turn reported the outcome to the pharmacist. On four occasions this reporting was by the client themselves and on five occasions by a worker. Several criticisms of this method can be made. Firstly, if the client wished to please the pharmacist, for example because they were grateful for the help they had received or were reluctant to disclose that they had not followed advice, they may have reported favourable outcomes even if they had not occurred or exaggerated any perceived benefits. Also, outcomes reported through the drugs worker relied on the worker correctly passing the information on to the pharmacist. Nine clients who had contact with the pharmacist were followed up so the group from whom outcomes were gathered did not represent the total group ($n = 25$) who received information and advice from the pharmacist. Since it is not known what outcomes were experienced by the other 16 clients conclusions on outcomes from the service cannot be drawn. It is possible that an unfavourable outcome may have deterred the client from making further contact. There is also difficulty because no controls could be performed. For example, the clients could not

be matched with similar others with the same enquiry who did not receive information and advice. Despite these criticisms of the method, the recommendation of a more appropriate method of follow up is difficult in the context of the situation. The use of a paper-based questionnaire distributed to all client contacts may have reduced bias but this would have limited the extent of the information that could have been collected. Clients may have been discouraged by the request for written information. Also, it was desirable to assess the outcomes at a time remote from the contact. Defining when to return the questionnaire would have been difficult. It is also doubtful whether an adequate response rate would have been achieved using a questionnaire for return at a later date.

10.1.2.2 Use of the discussion group to gather staff opinion on the pharmacist's service.

The discussion group was used after the pharmacist's service had operated to explore the key areas that were identified before the service began. This method was considered to be the most appropriate at the time of this work, despite the limitations outlined below. Semi-structured interviews could have been used but would have to have been conducted by someone other than the pharmacist to avoid bias, which was not possible. However, with hindsight greater attempts should have been made to use a member of staff from the University to moderate the group, rather than the researcher. Also, the one-to-one nature of interviews does not allow for the interaction and exchange of ideas within the group that is possible with focus groups. This was considered important so that statements made could be disputed or endorsed freely. Similarly, a nominal group would have allowed opinions to be identified in the group, but the benefit of this technique is that it allows key points to be ranked in order of importance. This was not desirable in this instance since all opinions were required and no ranking was needed. Moderation of the group by the pharmacist may be criticised as having biased the discussion, as said in 10.1.1.1. The researcher was aware, through her attendance at team meetings, that the culture of the team was to constructively criticise each other's practice and to challenge bad practice. At the time of the work, she considered the team likely to be honest in their assessment of the pharmacist's service and that it might be possible to minimise this bias. Honesty was an agreed ground-rule between the moderator and the group and several facilities for expressing opinion were made available to the workers. It was considered that providing a facility for anonymous comment would allow any opinions to be expressed that individuals felt unable to raise in the group. However, the honesty of the team cannot be demonstrated and it is disputable whether bias was removed. Also, the small number of team members may have led workers to believe that they could be

identified through anonymous typed comment, by the style and nature of their writing. Therefore it must be concluded that there was a lack of objectivity in the method used and in future work of this nature to avoid such problems an independent moderator would be used.

It may be criticised that a liking for the pharmacist could have influenced the responses. If this was the case, it might have happened regardless of whom conducted the discussion group. The researcher considered it not possible in this case to identify responses given because someone is liked from objective evaluation. In future work, guidance would be sought on whether the method could be designed to avoid this.

A criticism of the questions used is that the moderator did not ask at the end for any further comments, allowing areas not explored to be raised. However, the facility to submit written comments may have compensated for this to some extent.

The round table format may be criticised as stifling discussion. However, this was done to allow all participants the chance to express their opinions. Opening the discussion up to the floor afterwards was done to allow more natural conversation to then occur.

The full discussion was transcribed and from this written account, progressive focusing used to identify the key themes. This transcription may be criticised as unnecessary, as progressive focusing can be done directly from the recorded discussion. However, the researcher transcribed the discussion to protect against data loss, in the event of the tape breaking.

10.1.2.3 The measurement of DA workers attitude to the pharmacist's service

The design of the attitude questionnaire

The attitude questionnaire was kept short so it took up no more than 2 sides of an A4 sheet. This was done to prevent the workers tiring, which might encourage less consideration to be given to the questionnaire. A five-point Likert scale was used as it is reported to be not so fine that respondents have difficulty placing their opinion or too coarse so the scale cannot differentiate between opinions (Coolican, 1994). The advantage of this method is it illustrates where on a scale between favourable and unfavourable a person's attitude to the subject lies, giving more insight than simply asking to respondent to chose between 'agree' or 'disagree'. It is also simple to construct. The weaknesses of this method are that the respondents' score can only be interpreted relative to the distribution of scores of other respondents i.e. X has a more favourable

attitude to the subject than Y. No measure can be made of how far apart the differences in attitude lie i.e. we cannot say X's attitude is twice as favourable as that of Y. Also, including the measure '*undecided*' can result in ambiguous results. It cannot be distinguished if selecting this means attitude to the subject is neutral i.e. cannot decide because the respondent has no strong opinion or if they are torn between two feelings in both direction i.e. cannot decide because in one context they may agree but in another context they may disagree. Also, if someone scores a central value on average, this also does not tell us if they have lots of undecided opinions, or if they gave equal numbers of strongly in favour and strongly against responses, thus resulting in a score overall in the middle. In the latter case this may suggest two different attitudes had been measured. This appeared not to be true in this study as no one scored a mid point value on either occasion when the questionnaire was administered.

The wording used in the questionnaire referred to 'a pharmacist' at Drugs Action, but it must be acknowledged that it is likely that the responses were made relating to the service received and hence the responses more correctly probably relate to the pharmacist who conducted the service, not pharmacists in general.

Content validity was used to examine whether the statements covered the attitude being measured sufficiently i.e. the attitude of the workers to the pharmacist's service. The supervisory team were used as the assessing panel. However, it may have been more appropriate to have used an expert panel of drugs workers from other non-statutory agencies, as they may have been in a more suitable position to assess the pertinent issues. This would be considered in further work.

Comparing responses to pairs of favourable and unfavourable statements checked reliability. The criticism of this method of reliability checking is that it uses scores that are from an as yet, unreliable test. However, it is generally accepted as satisfactory (Coolican, 1994).

Piloting

The attitude questionnaire was piloted on two workers. This number may be criticised as being too low. However, the total sample size was small so having a greater number of participants in the pilot work was considered undesirable. The purpose of the pilot was not for validation but to assess readability and relevance. Inclusion of the pilot workers in the final sample was considered appropriate. However, it may be criticised that the pilot workers were asked to complete the pre-service questionnaire again when it was

administered to the team four days later. They may have had time to consider the issues in the interim period, which could have influenced their responses. However, on comparison their pilot responses were similar to their final responses. Further work would use the pilot responses in the data analysis, if appropriate; and not re-administer the questionnaire.

Coding

The questionnaires were coded so the researcher could match the respondents' pre and post service questionnaires. The respondents were not, however, made aware of this coding. This may be criticised as unethical. In defence, it was considered important that the workers were not aware that the researcher would know their responses, as this may have introduced bias. For this reason, this was considered by the researcher and the supervisory team to be an appropriate situation in which to not inform the participants about such codes. However, this may be considered unethical by others. In future work the advice of an ethics advisor would be sought on such matters.

Important factors in attitude measurement

Several factors known to be important in attitude measurement must be discussed in relation to the method used for this study.

I Self completion

The questionnaire was based on self-assessment, which makes it entirely subjective. There is no way of determining if different respondents score attitude in the same way. However, Moser and Kalton (1971) suggest that scoring of attitude by the researcher is not necessarily more objective, so self-completion was chosen in preference to researcher assessment.

II The 'halo' effect

This term is used to describe the situation whereby the respondent has a general liking for a subject, so scores all aspects of the questionnaire positively. To reduce this effect, statements were included that covered issues that team members were known to feel strongly about. For example, statement 6 compared worker's knowledge on drugs of abuse with that of pharmacists, statement 7 related to conflict of interest and statement 20 related to confidentiality. The researcher considered that since the workers had an advocacy role for their service users, it was unlikely that they would favour suggestions about a proposed new service if they had concerns.

III *Familiarity with the researcher*

All of the DA team knew the researcher was a pharmacist. They had had prior exposure to her during the client interviews conducted for part one (chapter 2). Therefore, the baseline measurement of attitude to having a pharmacist attached to the team may be influenced by this familiarity. Attempts were made to minimise the impact of this exposure, as follows:

Introduction prior to questionnaire completion:

The researcher asked staff, during the briefing about the questionnaire, not to consider the statements as relating to her as a pharmacist, but to consider them in the context of their opinions of pharmacists as a whole. They were informed that no names were to be put on the questionnaires, although workers may consider they could be identified from their handwriting when responding to the open questions.

Scaling method:

Boxes were used in place of numbers, which are often used on such scales. This avoided the possibility of making the respondents feel like they were allocating a mark out of five to the researcher

10.1.3 Ethical and indemnity considerations

Ethical approval from the Joint Ethical Committee of Grampian Health Board and the University of Aberdeen was not sought, on the advice of the Robert Gordon University research ethics advisor, who did not consider this necessary. However, in hindsight, the researcher considers that application for approval would have been good practice, although the University is not obliged to do so.

Also, a matter overlooked at the study design stage was that of indemnity cover for the work of the pharmacist. She held her own private policy for indemnity but did not investigate whether the work at Drugs Action was covered in this. Employers have a responsibility for the actions of their employees, however the researcher was not an employee of Drugs Action or the Robert Gordon University, she was a student of the latter. Therefore, it should have been investigated whether the University held indemnity insurance that covered research activity.

not include brief contacts made for information and advice only ($n = 1009$). However, it is notable that self-referral to the agency did occur to a greater extent than self-referral to the pharmacist's session. The small number of self referrals may be because the role of the pharmacist is perceived by many of the general public and other organisations to be one of supply and not necessarily information and advice detached from supply. Matheson (1998) found this perception to be true when they explored this issue in semi-structured interviews with 124 drug users. There may also have been a fear that the pharmacist would make any disclosed drug use known to other health care workers. The workers could reassure confidentiality when they offered referral. The small number of referrals may also have been due to ineffective publicity. However, without further information, these points cannot be confirmed.

Members of the public were asked if they would consider asking a community pharmacist similar enquiries (9.1.5). The responses largely suggested they would not. Although this matter was not explored in detail, it is interesting to note that no comments were made that suggested the community pharmacist was not perceived to have the necessary knowledge. This may however have been because the respondent considered such comments would offend the pharmacist asking the question. The attitude of the community pharmacist towards drug use appeared to be the factor in the group that would influence judgment, with some local pharmacists known to have a good rapport with drug users being identified as being potentially approachable. Matheson (1998) identified the attitude of the pharmacist towards drug users to be an important factor in the perceptions of service users. Two enquiries were presented where members of the public had sought previous advice from community pharmacists and had not been satisfied with the response received. Although two isolated incidents, this illustrates the use of Drugs Action to verify information when doubted.

Had the service been provided for longer, the number of self referrals may have increased, as towards the end of the service some clients who had previously seen the pharmacist were asking to speak with her or for their drugs worker to pass on information, to report on the outcome of their issue. Also, once the service had stopped a small number of clients were reported by workers as having asked to speak with the pharmacist. However, this information only makes the suggestion that self referral may have increased over time, extended service provision would have been necessary to confirm this. Further exploration could also be done to establish the importance of word-of-mouth in promoting use of the service. Worker referral was found to be the main means through which the pharmacist made contact with members of the public and highlights the importance of the drugs worker in identifying issues where the pharmacist

could potentially contribute. Of the seven outside service workers who made contact with the pharmacist, DA workers referred four and the remaining three all came from the specialist prison officer who worked along side the DA prison worker. This again highlights the role of worker referral.

10.2.1.2 Publicity of the pharmacist's service

Although the effectiveness of the publicity used was not directly monitored, the data on the use of the service shows that worker referral was the most effective method of encouraging members of the public and outside organisations to use the service. Had the publicity distributed to outside organisations been more effective, it may have been expected that a greater number of self-referrals would have been seen. Figure 9.2 shows the number of contacts made per week over the 26-week period. Figure 9.3 shows the same data but broken down into enquirer group. Neither the data overall or the data for each group shows any trends in service use. This supports the view of the pharmacist that the service was a response service with a workload dictated by issues as they arose at Drugs Action. If service activity data per week had been available from Drugs Action, this could have been compared with these graphs to look for similarity in the patterns of use. i.e. to see if times of greater pharmacist activity corresponded with greater agency workload. However, data was only presented for the overall financial year 1997/8 (Drugs Action, 1998).

10.2.1.3 The urgency of the enquiries dealt with by the pharmacist

In terms of prioritising workload, the majority of enquiries (n = 49; 64%) were considered by the pharmacist to require a response as soon as possible. All but one of the members of the public required an immediate response, which is not surprising since the majority were seen face-to-face so considered to require a quick response. This illustrates, as with many services which work with the public directly, the need for the pharmacist to be able to respond quickly. It must be remembered that defining the urgency of the enquiries in this way reflects the pharmacist's interpretation of the urgency but may not have represented the enquirers' interpretation or actual urgency. The term is used to illustrate how the pharmacist prioritised the workload, not describe the nature of the enquiries.

Of the contacts requiring a response as soon as possible, 94% (n = 46) received it immediately. This shows that the pharmacist was able to meet the priority in the majority of cases. For the enquiries that required a response as soon as possible but could not be

dealt with immediately, the enquirers were kept informed of the reason why their response was delayed and the anticipated time it would take to formulate a response.

10.2.1.4 The nature of the enquiries

Eleven different categories of enquiry were identified. As the majority of the enquiries received were either from the drugs workers or directed to the pharmacist by the drugs workers, the opinion of the drugs workers on the nature of enquiries appropriate for the pharmacist will have influenced the type of enquiries received. Also, categorisation was based on the pharmacist's interpretation and opinion, so different classification may have been made had this task been undertaken by someone else. However, it was perceived that since the pharmacist had first hand experience of the enquiries, her interpretation was likely to be more accurate than that of someone who was grouping on the basis of having read the recorded information only. Seventy three percent of enquiries were in categories that were concerned with matters that related to medicines or illicit drug substances. These categories were: Drug information (both prescribed and non prescribed), drug testing, drug related health problems, identification and adverse drug reactions (both prescribed and non prescribed). This indicates that the pharmacist was viewed as a source of knowledge on drugs and their effects. A small number of enquiries relating to pharmaceutical services were directed to the pharmacist ($n = 3$), perhaps not surprisingly suggesting that the pharmacist was viewed as a source of advice on this area. Interestingly, six enquiries requested medical information that did not involve a pharmaceutical component. This suggests recognition that pharmacists have a familiarity with the medical profession. These enquiries may have been directed at the pharmacist due to the absence of medical input into the team. Seven enquiries related to requests for information on harm reduction techniques such as safer injecting. The pharmacist was known to the team to have knowledge of this area from the work described in part one. These enquiries may reflect recognition of her specialism and not suggest that drugs workers, who already have training in the area of harm reduction techniques, would regard pharmacists in general as a source of further advice. Overall this data illustrates the areas where the pharmacist was viewed as being an appropriate source of information and advice. It also classifies pharmaceutical and medical issues that related to the agency clients and workers. The absence of drugs workers with a background in medical professions may have meant more health and drug related enquiries were directed to the pharmacist than would have been in an environment staffed, for example, by nurses. This is viewed positively as it might have allowed the identification of a broader range of health and drug related issues where there is a need to provide education and training to pharmacists and appropriate others who work with drug users.

10.2.1.5 Methods of reply

Table 9.4 describes the methods of reply that the pharmacist used to respond to enquiries. Because of the nature of the service being directly accessible, it is not surprising that verbal response was used, at least in part, in the majority of cases. Also, since all the enquiries from members of the public were received face-to-face and all but one of these required a response as soon as possible, the use of verbal communication was to be expected. However, it is notable that half of the responses to workers were supported with additional written information. The request for written information could be made by the workers or the decision to endorse verbal informal with written could be made by the pharmacist. Therefore, this figure must not be interpreted as the number of requests made for written information to the pharmacist. It should be taken as an illustration of the number of responses where written information was considered useful by one of the parties involved and a demonstration of the need for the pharmacist to be able to support the information and advice given with written materials.

The pharmacist produced some written materials in formats considered suitable for the intended recipients. These included a fact sheet on carrying methadone abroad for clients and staff and three evaluations of technical information to give advice on practice, at the request of the staff.

10.2.1.6 Ethical and moral dilemmas.

As anticipated, situations did arise that presented the pharmacist with moral and/or ethical dilemmas. The interpretation of such as dilemmas is subject to some degree of interpretation, as the belief that something presents a dilemma will be influenced by the knowledge, experience, morals, beliefs and to an extent, the characteristics of the pharmacist concerned. Had the service been provided by a different pharmacist, the classification of issues as dilemmas may have varied, as may their handling procedures.

The pharmacist considered four areas presented dilemmas (9.1.8 and described in appendix 28). A total of 24 enquiries, which accounted for 28% of the total number of enquiries, were considered to present some moral or ethical dilemma that required consideration before responding. No estimate could be found in the literature of the overall extent to which either UK drug information or community pharmacists experience ethical and moral dilemmas. After considering each situation, the pharmacist was able to respond to all the dilemma enquiries in a manner she considered upheld her professional

requirements. There were no situations where the pharmacist considered it appropriate to refuse to give any advice or information. The pharmacist's rationale for each dilemma area is given in appendix 28. As said in 8.1.7.5, it was not considered wise to develop protocols for handling dilemmas as the researcher considered this might actually increase risk, if individual situations were not considered in their own context. For example, had the pharmacist decided that she would not handle any tablet identification enquiries on the basis that it may assist someone in participating in illicit drug use, this would have precluded the identification of two cases where the enquirers wrongly assumed the identity of a drug and could have suffered if their assumption continued. It would have also precluded the assistance given to the outreach worker when at a youth project where an unknown tablet was found on the floor.

From her experience of the dilemmas presented, the pharmacist considered that there were benefits to all enquirers from receiving advice. Once this benefit was established, the level of harm from presenting the information had to be considered. Also, professional ethics, even if considered to increase the harm to the patient, had to be upheld. On the basis of these factors, the information given had to be chosen carefully. It had to minimise the patient risks without compromising the competing value unnecessarily or unethically. This conclusion may be applied to other situations, although the level of interpretation and action taken will be individual.

10.2.1.7 The knowledge and skills required to provide the service

The greatest proportion (52%) of the knowledge used to respond to the enquiries was considered by the pharmacist to be core knowledge, meaning common to all pharmacists. A further 25% was considered to be a combination of core knowledge enhanced with specialist information. Specialist knowledge, which was considered had to be acquired through specialisation in drug misuse, was used to respond to 23% of enquiries. It is important to remember that this information cannot be used to generalise about the provision of such a service. It is influenced by the background and experience of the pharmacist concerned and her opinion. However, what it does illustrate is that pharmacists are likely to have acquired knowledge and skills during their training and through working in the community or hospital environments which can be applied in the specialist drugs setting. Most of the enquiries in the category that contained the greatest number of enquiries (drug information (prescribed)) were responded to using core knowledge, with only a few requiring core and specialist knowledge. This general

grounding can be built on to develop specialist skills, as suggested by the ability of the pharmacist to respond to the enquiries she received.

The major topics of the knowledge required to provide the service are defined in 9.1.9. This raises the question of whether these topics can be used to define the training needs of pharmacists when providing information and advice to drug users. Although the pharmacist's service at Drugs Action was defined by the non-health-based nature of the team and the opinions of the workers on what was appropriate to refer, it may be expected that the issues that presented are not likely to be unique to Drugs Action. It is likely, but not confirmed by this study, that similar issues would arise elsewhere. Anecdotal information from others working in the field supported this view. Assuming that such issues presented in other situations/agencies, the training needs of the pharmacists providing the service may differ due to different experiences from the pharmacist who provided this service. Therefore, the list and categorisation cannot be taken definitively, it applies only to this case study. However, the lists may be useful as check lists, acting as a guide to direct a pharmacist establishing such a service, in their professional development. This list could be added to and modified, based on the monitoring of their service.

The information sources that the pharmacist used to acquire knowledge will have been influenced by the nature of the service and all the factors that defined this. Therefore, it is again not a definitive list for future service development. However, it provides a guide to appropriate sources to consider acquiring when developing a similar service. Access to some of the sources such as databases and journals may be considered to be outwith the reach of many community pharmacists at present, hence restricting the possibility of such a service being undertaken by a community pharmacist seconded to a drugs agency for such sessions. However, information technology is rapidly becoming more accessible and important within health care and as the role of the pharmacist becomes more clinical and funding systems change, it is possible that such information will become more to hand. As learning styles vary between individuals, the importance placed on each source will vary with the individual. Again, this list could be added to with the monitoring of further services.

The skills required to provide the service are defined in 9.1.9. Again, they are subject to the variability that applies to the knowledge categorisation. It can be questioned as to how accurately can it be said where a specific skill was applied. For example, listening skills for pharmacists are developed in many of the undergraduate courses, including the course the pharmacist undertook. However, it can be argued that such skills may be

learned at an earlier stage and developed through teaching and practice. Similarly, the categorisation used in this work assumes that the listening skills the pharmacist used to work with drug users and workers were the same as those she learned to apply in other situations. It was the opinion of the pharmacist that the listening skills needed for this service did not differ, others may argue against this, illustrating again the subjectivity of such categorisation. Despite this subjectivity, the list of core skills and one specialist skill identified could be used as a guide for others when developing future services and selecting appropriate pharmacists.

In summary, this work suggests that specialist training in the philosophy of harm reduction and harm reduction techniques, the psychological theories of drug use, drug testing, drug misuse statistics and prevalence, social services and welfare right and the drug-using sub culture, its terminologies and language would be useful in addition to the core knowledge described (9.1.9).

10.2.2 The evaluation of the pharmacist's service

10.2.2.1 Client follow-up

Nine of the 25 members of the public who made contact with the pharmacist were followed up using the methods implemented, which relied upon further contact with the agency. This was considered to be a good proportion of contacts, since some contacts were not of the nature that would require further contact with the agency. However, as discussed in 10.1.2.1, this proportion is small, the numbers involved were not large and it is unknown what was the consequence of intervention in the 16 people not followed up. Therefore, it cannot be assumed that the results of those followed up indicate that interventions made by the pharmacist led to positive outcomes in all cases i.e. the results gathered from those followed up cannot be extrapolated to apply to those lost to follow-up and therefore it cannot be concluded that all clients benefited from the service. What can be said is that of those who were able to be followed up, the majority did appear to have benefited from contact with the pharmacist as most of the outcomes reported showed a positive effect from the pharmacist's intervention. In addition, some follow up led to the provision of further information and advice, which was considered to be a further endorsement of the service. It is notable that the drug users in cases nos. 2 and 8 (appendix 29) only used the agency for needle exchange and did not wish to receive worker input, yet both actively returned to the agency to discuss their outcomes with the pharmacist. It is worthy of further investigation, whether some contacts who may not wish to formally see a drugs worker, would be willing to use a drop in pharmacist's information

and advice service, after initial contact. Such a service may give the opportunity to deliver general health advice as well as drugs information and advice. It would be important to determine whether the formality of the service i.e. drop-in vs. pre-booked one-to-one appointment or the professional's status i.e. drugs worker vs. pharmacist, influenced the use of the service. In one case (no.8), a negative outcome occurred after the pharmacist's intervention, as the client's prescription was stopped. Although an isolated incident, this highlights that although joint working is being encouraged in drugs services (Scottish Office, 1999), problems can occur when this is attempted. In conclusion, the outcomes that could be established mostly showed a positive benefit from contact with the pharmacist, however the lack of follow-up of all contacts means that it cannot be concluded that the pharmacists service was of positive benefit to the members of the public who used it.

10.2.2.2 Drugs worker discussion group

The opinions expressed were generally agreed upon within the team, conflicting opinions did not arise. Others who worked in outreach locations and the base workers agreed with the point made by one outreach worker that the service was of greater benefit when working in the base. Overall, the team considered that the agency had benefited from the service, highlighting that the service had enhanced their knowledge and understanding. They also identified that the function of the pharmacist to resource and interpret information was beneficial. The team expressed confidence in the service that they had received. They did not consider that confidentiality of the service had been a concern of the clients, because the trust they had in the agency was assumed to apply to the pharmacist. They considered the attitude of the pharmacist had been conducive to being part of their team. The team were concerned that the service had created an expectation amongst clients that could not be met. Overall, the feedback suggested that the service had been well received by the team. The potential for bias caused by the pharmacist moderating the discussion group described in 10.1.1.1 and 10.1.2.2 must be considered. It could be said that only positive comments were made because the team wanted to please the pharmacist, as they were familiar with her and may have had a liking for her. The nature of the team is such that criticism of each other's practice is commonly undertaken but the existence of this is difficult to evidence, as extracts from team meetings, which could be used to illustrate this are confidential. However, the report of the discussion group, which is copied as section 9.2.2, was given to the workers for approval and anonymous comment. All workers approved the report to be an accurate representation of their views, suggesting that the report did reflect their opinions. In

addition, the attitude questionnaires, which the team thought to be anonymous, also showed a positive attitude towards the service (9.2.2.3). However, the existence of biased reporting cannot be eliminated.

The exposure of the team to the service highlighted the capabilities of pharmacists to the team, as reported in the discussion group. However, it was the opinion of the team that the service received had not changed their opinions of pharmacists in general, as they viewed attitude to be a personal characteristic and fundamental to the success of such a service. They highlighted the need to judge each individual and how their opinion on a profession could not be informed by their experience of one person. They also distinguished a difference in the level of specialist knowledge they considered the pharmacist to have from that of other pharmacists, specifically referring to community pharmacists. This was reflected in the classification of knowledge the pharmacist made, which indicated that she considered specialist knowledge was necessary to handle some of the enquiries received.

The opinions of the team after exposure to the pharmacist's service were positive, although pre-service discussion with the co-ordinator and advisor identified several areas of concern around having a pharmacist as part of the team. Opinions were not gathered from the whole team before the service started, which can be criticised. By gathering only the opinions of two of the workers, it is assumed that these represented the views of the team, however this is unknown. Had a discussion group been carried out before the service started, it would have given further information against which the post service data could be compared. The co-ordinator and advisor were part of the post service discussion group and responded positively to the areas that they initially raised as concerns. This shows that their pre-service concerns did not develop when the service was provided.

10.2.2.3 The attitude questionnaires

The reliability of the questionnaire was found to be satisfactory (table 9.5). Most respondents gave the same response to both statement pairs and for all but one question, all other responses only differed by one. This was considered to indicate adequate internal reliability. However, statements 4 and 5 were removed by the reliability analysis. It is worthy of discussion that statements 4 and 5 appeared next to each other on the questionnaire. This was because the statements were ordered using random number tables. Randomisation until paired statements did not appear next to each other may have been more appropriate, to reduce the chance of obvious recognition that a

statement has been presented in positive and negative form. The reliability analysis performed in SPSS, removed nine statements from the attitude score calculations (table 9.6), as they did not give adequate item-total correlation. The final value of Cronbach's alpha was considered to indicate high internal reliability.

The use of Cronbach's alpha should be discussed briefly. It may be criticised that this statistic should not have been used in such a small group of respondents since it is based on correlation between the items and the total and correlation co-efficients calculated on small sample sizes have very wide confidence limits. However, the group were not a small sample of a larger population so the results were not used to generalise about a larger group. The measurements represented the attitude of the total population i.e. all the Drugs Action workers who were employed during the study period. Hence the correlation co-efficient calculated is the actual correlation, so confidence intervals are irrelevant. This means that for a study that examines a total population, Cronbach's alpha can be used regardless of the population size (Cronbach, 1951, Bowling, 1997, Simpson, 2000).

Nine statements may be considered to be a high number to remove. This suggests that the statements could have been constructed more carefully, and with hindsight this is believed to be true. There is some difficulty in using attitude scales in a specialist group. Attitude scales should measure a range of attitudes to a subject within the sample population. However, nature of drugs agency teams may mean the attitude of the worker to drug use, drug users and harm reduction is an important factor in selection at recruitment therefore polarisation of attitudes may already exist. Several of the removed statements were considered on reflection to relate to matters that the team are likely to hold similar views on (1 = induction training, 2 & 20 = confidentiality, 4 & 5 = client comfort with the service). Statements 6, 11, 18 and 19 were considered to be vague in their wording and may have caused some confusion. The use of a peer panel to review the statements would be used in further work prior to and after piloting.

A least favourable attitude score would have been 11, a midpoint score 33 and a most favourable attitude score 55. As said, a midpoint score may indicate either an undecided opinion or that two attitudes have been measured, one positive and the other negative. From table 9.7 it can be seen that all workers scored a pre-service attitude which lay between the midpoint and favourable. Overall, the attitude of the team became more favourable after service exposure. The attitude of two workers became slightly less favourable after exposure, whereas the rest became more favourable. There was no information provided in the open questions asked on the post-service questionnaire to say why this was. The difference in one score was only one, which suggests that this is not

significant. However, the other had a difference of eight. It would have been interesting to have explored this further, however this could only have been done by making the respondent aware that their identity was known. This was not considered appropriate. Statistically, it was found that there was a significant difference between the pre and post service attitudes, indicating the attitude of the team overall became more positive after exposure to the service. As said, attributing this change to the service alone is difficult since the workers may have been exposed to other factors during the interim that influenced their attitude. The team had an attitude that tended towards positive before the service was implemented. However, had the experience of the team with the pharmacist's service been a bad one, this would likely have caused the average post service attitude score to be lower than the pre-service score.

The pre-service open questions established what role the team anticipated a pharmacist might have within the team and their concerns. The post service open questions asked them, based on their exposure to the service, if they considered a role for a pharmacist existed within the agency and to define what they thought this to be. All drugs workers said they did think there was a role for a pharmacist. In the pre-service questionnaire, five aspects to the role of a pharmacist at DA were anticipated. In the post service questionnaire, five very similar aspects to the role of a pharmacist at DA were identified. This suggests that the pharmacist's service met the expectations of the team. The fulfilment of the teams expectations by the service could illustrate why a positive attitude towards the service was shown, however the bias discussed in 10.1.1.1 and 10.1.2.2 must also be remembered.

With regard to the point about training, the provision of training by the pharmacist has not been discussed because the training provided was not a planned part of the methods of this study or evaluated as such. However, it should be noted that the pharmacist provided a training session to the team called '*Drug use and concurrent illness*', which focused on the use of illicit drugs by people with medical conditions including epilepsy, asthma and mental illness. She also participated with the needle exchange worker in establishing a support group for the Grampian needle exchange pharmacies, in collaboration with pharmacists from Grampian Health Board. This group were given training by the pharmacist on two occasions. The first event was entitled '*Safer injecting*' and the second '*Medical complications of injecting*'.

10.2.2.4 Cost of service provision

The approximate cost of the service was calculated only to guide potential funders on how much investment such a service may need in monetary terms. It should be noted that this cost does not include photocopying made at academic libraries outwith RGU, internet access, printing costs of letters and prepared materials, start-up costs including pre-service negotiations and the answering machine, publicity for the service including poster production and postage. Therefore, the actual cost would have been higher than the approximate costs that could be established. It is very important to note that this is not a pharmacoeconomic evaluation and therefore, the economic benefits of the service have not been calculated. In such an evaluation, the economic impact of patient care would be considered.

If the service were to be established by contracting a community pharmacist into the agency for one session per week, it may be expected that the costing would need to include locum fees to cover the absence of the pharmacist from their shop. Similarly, if a hospital pharmacist were used, a consultancy fee may be charged by the Trust that is greater than the salary costs considered in this study.

10.2.3 Possible future developments

10.2.3.1 Specialisation and accreditation

It has been suggested recently that the future of community pharmacy is through specialisation (Kayne, 2000). If such a vision became reality, drug misuse could be one area where community pharmacists could establish themselves as experts. Such a model could be compared to that suggested in *Drug Misuse and Dependence - Guidelines on Clinical Management* (Department of Health, 1999), where GPs who work with drug users are categorised depending on their degree of specialisation. In Kayne's model, local community pharmacists would specialise in different areas, working together to meet the needs of their community. In the case of drug users, this differs from the current 'shared-care' structure in place in some regions, as drug users could form the majority of clients presenting at the specialist pharmacies. One of the benefits of shared-care is that it distributes the workload amongst pharmacies, aimed to prevent individual pharmacies experiencing excessive problems related to working with drug users such as difficulties arising from the current controlled drugs laws and shop-lifting (Roberts, and Bryson, 1999). It might be difficult in practice to find pharmacist(s) from one pharmacy willing to

specialise in this area. However, implementation of the changes recommended in the Working Party on Pharmaceutical Services for Drug Misusers report (1998) might prevent the occurrence of some problems in the first place. For example if pharmacists were able to take verbal confirmation of instructions for controlled drug prescriptions from a prescriber, followed later by written confirmation, difficulties due to errors in the Misuse of Drugs Act prescription handwriting requirements may be minimised. It is the researchers personal belief that changes in the framework of community pharmacy from being business-based to being part of the NHS would create an environment in which Kayne's model would be more likely to develop. This could encourage specialisation not only in the provision of services to drug users but to the general public as a whole. It would also remove the belief, reported to be held in the social science field of ethics and professions, that community pharmacy is an incomplete or marginalized profession (Latif, 2000). Given that in this study the drugs workers played a key role in referring clients to the pharmacist and the pharmacist found the majority of enquiries from workers were made on a face-to-face basis, it would be more appropriate for a specialist pharmacist to provide and information and advice service from within a drugs agency rather than a community pharmacy, especially until trust and reputation had developed. It would also be essential to have a private area available for discussion. However, such changes are also recognised as unlikely to happen in the near future.

The results of this study and further multi-centred studies could inform the Schools of Pharmacy of specific areas in which to provide training, building on the recommendations of the Working Party on Pharmaceutical Services for Drug Misusers (1998). At post-graduate level, such courses could form the taught element of the accreditation process used to benchmark the specialists suggested in Kayne's model (Kayne, 2000). It is the author's opinion, based on her experiences reported in this study and of pharmacy practice, that a practical component would also be essential as part of the accreditation process.

10.2.3.2 Links with the statutory sector

Organisations within the voluntary sector vary greatly in size, activity and function. For example the sector encompasses large organisations such as Greenpeace and local self-help groups (NCVO, 2000). Overall, a large number of people are employed in the voluntary sector, accounting for approximately one in 25 full time paid jobs in the UK, with further numbers of volunteers (Taylor, 1998). The author refers to her previous work and that of Leat, which established that voluntary agencies might have many similarities with

public sector agencies, if their area of activity, size and population they serve are similar. However, she also found in her previous work that voluntary agencies are more likely to have a wider spread of activities and a greater advocacy role than statutory sector organisations. It is also noted that whereas public sector agencies will be working to political frameworks, voluntary agencies may be working under their own autonomy. Currently, a government framework to promote partnership between voluntary agencies and the public sector exists (Taylor, *ibid*). The government and bodies representing the voluntary sector have signed the Compact agreement, making a commitment to partnerships and joint working (Taylor, *ibid*, NCVO, 2000). A detailed analysis of this is not within the remit of this work, however in the future it is likely that individuals working in the statutory and voluntary sectors will be working more closely together. This raises the question of whether a specialist information and advice pharmacists at a voluntary agency might be able to operate a similar service from a statutory service drugs agency, possibly in some form of shared contract of employment between both agencies.

As this study was a case study in the voluntary sector, it does not illustrate that such a service could operate. Although issues of the clients may potentially be similar in a statutory agency, government frameworks, the composition of the team and other services provided would likely influence the use of the service by clients and the pharmacist's role within that team. For example, some statutory services have a prescribing arm. If the prescribing protocols were such that identified illicit drug use was punished by removal from the service, it is anticipated that clients would be unwilling to discuss enquiries relating to illicit drug use with the pharmacist. However, if the protocols did not impose such penalties, there may potentially be a role for pharmacists within such teams. In teams with medical and nursing input the nature of the enquiries may differ, for example, questions relating to safer injecting may be directed towards a nurse specialist and medical service questions directed towards a doctor. However, many of the areas addressed in this study related to topics that the researcher considered to require the knowledge and skills of a pharmacist to be addressed, for example drug information, adverse drug reactions and information on pharmaceutical services. Additionally, an important matter if providing a service to more than one agency is that of client confidentiality. Agreement between all parties on the boundaries of confidentiality would have to be agreed before the potential of a shared post could be investigated. If such agreement could be reached, there might be potential for future work investigating the role of a specialist information and advice pharmacist shared between agencies within the voluntary and statutory sectors.

10.3 Conclusions and further work

The first research question set for this study was: Is there a role for a pharmacist in the provision of information and advice within a voluntary sector drugs agency?

The results from this case study suggest that there is a role for a pharmacist at Drugs Action, a voluntary sector drugs agency. The pharmacist contributed to the work of the agency by providing information and advice to a range of clients, workers and outside agency professionals on pharmaceutical and related matters.

The second research question asked: What is the nature of the information and advice sought by people who consulted the pharmacist?

Through categorisation of the enquiries by the pharmacist into eleven separate categories, the nature of the enquiries the pharmacist handled has been defined and further described. Categorisation by the pharmacist was considered the most appropriate method to use compared to using an independent panel, as she had the greatest familiarity with the enquiries. Drug information, on both prescribed and non-prescribed drugs formed the majority of the enquiries.

The third research question asked: What knowledge and skills were required to provide the service?

The knowledge and skills required to handle the enquiries was defined and categorised by the pharmacist. This shows what was perceived to be required for this particular case study, based on the opinion of the pharmacist who provided the service. Categorisation by an expert panel could have been undertaken and might have been more objective. However, this would have excluded the opinions of the pharmacist who provided the service.

Based on these three research questions, it is considered that the first hypothesis of this study, which was: It is possible to implement a pharmacist-led information and advice service within a voluntary sector drugs service, has been proven. This case study showed that a pharmacist-led information and advice service could be implemented at Drugs Action, and further described the use of the service, the nature of the enquiries received and knowledge and skills that the pharmacist considered were required to handle the enquiries.

The fourth research question set for this study was: What were the agency client outcomes from the service?

As discussed, it is not possible to draw conclusions on the overall service based on what was measured, as it is not known what the outcomes were for the agency clients who could not be followed up. Those who were followed up showed largely positive outcomes from their contact with the pharmacist, but there could be bias in the reporting, as outcomes were measured by the pharmacist. In those who could not be followed up it is unknown whether they experienced an unfavourable outcome, which could have contribute to non-presentation at a later date or whether they experienced a favourable outcome and did not present at a later date because of lack of need for further input.

The fifth research question set for this study was: What were the opinions of the other agency staff on the service received?

The agency staff reported favourably on the service they received, considering that the pharmacist had contributed positively to the team. However, as discussed, bias due to using the pharmacist who provided the service to gather this information, cannot be excluded, despite the facility of ways to express opinion anonymously. Hence, although the staff reported favourably on the service and did not raise concerns, it is considered possible that some opinions could have been withheld due to the biased nature of data collection and the possibility of identification from the writing style and nature of typed anonymous reports.

The sixth research question set for this study was: What was the attitude of the other agency staff to the service?

The attitude measurement suggested that exposure to the pharmacists service had caused a positive shift in the attitude of the team towards having a pharmacist as part of the team. However, as attitude was measured using paper-based questionnaires in the presence of the pharmacist and because of the possibility of identification through hand writing style when answering the open questions, the bias in measurement cannot be excluded.

Based on the fourth, fifth and sixth research questions, it is considered that the second hypothesis for this study, which was: The pharmacist-led information and advice service would be of positive benefit to its users, cannot be proven. Although data was gathered that suggested those who used the service gained positive benefit, the bias in the

assessment of the workers and agency clients and lack of follow up of all agency clients who used the pharmacist's service, casts doubt on the strength of the findings. This hypothesis could only be upheld if a further service was implemented by the pharmacist at Drugs Action and the outcomes experienced by service users and their opinions on the service measured by an independent researcher or team of researchers. Similarly, the future work suggested below would have to be researched by different people to those providing the services.

The demonstration from this study that it is possible to implement a pharmacist-led information and advice service within a voluntary sector drugs agency, suggest that the next stage of work would be to conduct a multi-centred study examining the role of several information and advice pharmacists in a variety of agency setting. These setting could include both voluntary and statutory sector agencies. Additionally, the provision of such a service to multiple agencies by one pharmacist could potentially be explored. By using pharmacists from a variety of educational backgrounds, further information could be gathered on knowledge and skill requirements, allowing a greater understanding of educational and training requirements to be established for this role.

In addition, if specialisation were to become the way forward for community pharmacy, a further area for research is specialisation of the community pharmacist in drug misuse. This could enable specialist information and advice services for drugs workers, other agency professionals and members of the public to be delivered from such community pharmacies. However, the reality of the willingness of community pharmacists to specialise in the area of drug misuse can be questioned, given the potential difficulties that might arise and the common prejudices seen against drug users. If specialisation in this area did occur, this would open up many new areas for research, for example education and training needs of pharmacists and staff, service uptake and outcomes, cost effectiveness and the impact on the commercial aspect of community pharmacy practice.

Chapter Eleven

Closing comments

The hypothesis from the first study was upheld by this work and the direction of future work in this new area of exploration has been mapped out. The call for a change in the paraphernalia supply laws made by Runciman (2000) and supported by others in the field, the increasing need for evidence-based practice and the high importance of patient safety within the clinical governance framework makes the question of paraphernalia supply to IDUs very pertinent at this time. Although injecting drug use is an illegal activity, this does not mean that it is acceptable for health care providers to supply injecting paraphernalia that is not fit for purpose or could increase the risks. Harm reduction is a realistic and pragmatic philosophy, which in turn underpins important health care interventions. There is a huge need for further research into injecting paraphernalia to enable harm reduction interventions such as the supply of paraphernalia to be made on the basis of scientific information, clinical evidence and calculated risk: benefits. The work presented in part one of this thesis is the first step towards gathering such evidence.

The first hypothesis from the second study was upheld as it has been shown that a pharmacist-led information and advice service can be implemented within a voluntary sector drugs agency. The second hypothesis in the second study regarding the benefits of the service could not be upheld however as the methods used to evaluate the service were not considered robust enough and recommendations for future improved methods have been made. The work in part two illustrates a case study of multidisciplinary working between a healthcare professional (the pharmacist) and health and social care professionals (the drugs workers) within the voluntary sector rather than the more traditional locations of pharmacists i.e. the statutory sector (NHS) or commercial business. Although the results of one case study cannot be extrapolated to all pharmacists and drugs agencies, this serves as a useful first investigation into such multidisciplinary working. As the role of the pharmacist changes within the new NHS, multidisciplinary and cross-sectorial working is likely to become increasingly important. This study provides evidence of such a case study within the drugs field, from which further investigation can be developed, as described in chapter 10.

Both studies in this thesis provided information and knowledge not previously available, and thus advanced understanding of the chosen areas. A list of conference presentations and reprints of publications from this thesis are given in appendix 30. Initially it was over-estimated what was achievable within the limits of a PhD project. This over-estimate was largely due to the inexperience of the researcher and the fact that this type of study was new and unique, so no previous guidance was available. Both the limits of time and the limits of the inexact and uncontrollable nature of injecting drug use were not fully appreciated when work began. With hindsight this can be said, but at the time the study was planned by the author who had limited previous research experience, it seemed plausible. Similarly, in both discussion chapters (chapters six and ten), the methodology has been criticised retrospectively. The positive aspect of recognising these limits is that the experience and knowledge gained can be used to build on what has been learned and inform the further work.

This work has examined a few small areas. The diverse and complex nature of drug use and harm reduction presents many more challenges for research and practice. The great harm that drug use can cause individuals, communities and society makes its reduction fundamentally important, as the removal of drug use from society is an unattainable goal. Harm reduction must be the underpinning philosophy of drugs and public health policies. Scientific evaluation of many new and existing harm reduction interventions must be done in order to preserve life, promote health and uphold human rights. Pharmacists can make a contribution to this being achieved.

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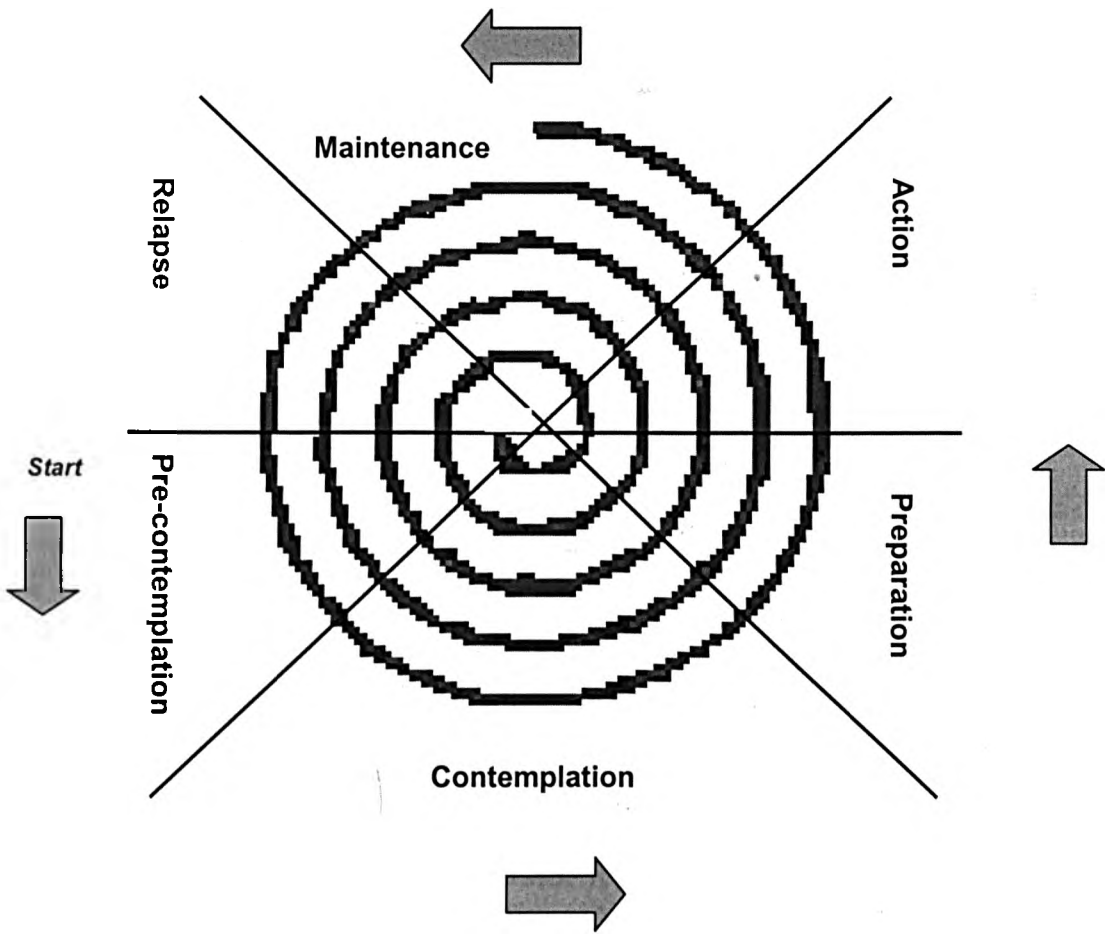
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APPENDICES

Spiral model of the stages of change

Adapted from: Prochaska, J.O., DiClemente, C.C., and Norcross, J.C., 1992. In search of how people change: applications to addictive behaviours. *American Psychologist*. 47(9): 1104, figure 1.

A selection of available safer injecting information leaflets

Clockwise from the top:

What Works? Safer Injecting Guide (Exeter Drugs Project, 1992), *Not Just Syringes* (Viral Protection Campaign, 1998), *A Guide to Safer Injecting* (HIT, 1997) and *The Safer Injecting Handbook*, (Preston and Derricott, 1997).

Centre: *Dig: A Guide for Injecting Drug Users* (Lifeline, 1999).



JOINT ETHICAL COMMITTEE
OF
GRAMPIAN HEALTH BOARD
AND
THE UNIVERSITY OF ABERDEEN

TO BE COMPLETED BY ALL APPLICANTS

Name of Applicant: ...Jennifer Scott.....

Position Held: ...Research pharmacist.....

Address for Correspondence: ...The Robert Gordon University.....
...School of Pharmacy.....
...Schoolhill.....
...Aberdeen,...AB101FR.....

Contact Telephone Number ...01224 262522.....

Title of Research Project: ...Development, Implementation and Evaluation of Harm
Reduction Techniques for Intravenous Drug Misusers.

Funding Sponsor (MRC, Charity etc.): Internal funding from RGU for PhD project.

FOR OFFICIAL USE ONLY

Date of Meeting:

Action to be taken:

.....

.....

.....

Additional Comments:

.....

.....

Reference Number:

JOINT ETHICAL COMMITTEE
OF
GRAMPIAN HEALTH BOARD
AND
THE UNIVERSITY OF ABERDEEN

Staff undertaking medical research work involving human subjects are invited to provide the following details of the project for consideration by the Joint Ethical Committee of the Grampian Health Board and the University of Aberdeen.

The Joint Ethical Committee consists of members nominated by the Grampian Health Board and the University of Aberdeen and its function is to examine and give an opinion on the ethical aspects of all clinical research investigations referred to it, including therapeutic innovation, or any experimentation involving human subjects.

The Joint Ethical Committee meets on the last Thursday of each of the following months: January, March, May, July, September and November.

Projects must be in typescript and submitted by 12 noon two weeks in advance of meetings. This deadline will be strictly adhered to. 18 copies of the application must be submitted. The proforma is held on disc by the Secretary.

Investigators are asked to provide information in the form of answers to the following questions. Where questions are not relevant or not applicable please indicate. Please use extra sheets if necessary and insert these in the appropriate places. If the Model Consent form and the APB1 terms for compensation are being used, these forms should NOT be included.

The Consultant in charge/Head of Department is particularly requested to check the technical aspects of the project and to make sure that the Patient Information sheet is readily understood with the signature confirming that this responsibility has been accepted.

1. (a) **Names of investigators responsible for the project**

Project team consists of:

Research project student: Jennifer Scott

Director of studies: Dr Arthur Winfield (Senior lecturer, RGU)

Project Supervisors: Dr Emily Kennedy (Boots teacher practitioner, RGU)

Dr Christine Bond (Dept. General Practice, University of Aberdeen)

Advisors to project: Dr Jennifer Hall (Drug Development Officer, GHB)

Miss Luan Bruce (Needle Exchange Worker, Drugs Action)

(b) **Names and background of individuals directly involved in carrying out the project**

Jennifer Scott. Pharmacist. This project is expansion of Honours project carried out in 1994. Previously worked in Pharmacy R&D at Roche Products (UK) Ltd and Pharmacy Department, Queen Elizabeth II Hospital, Welwyn Garden City, Hertfordshire.

2. (a) Name of Consultant or GP in charge of patients:

Not Applicable

(b) Names of other consultants/departments/laboratories/records department who are involved in a significant amount of extra work.
Has permission/agreement been obtained? YES / NO

Not Applicable

(c) Name of any other individual (and their department) involved:

Not Applicable

3. State the title of the proposed project (and project number of previous application, u where relevant)

Development, Implementation and Evaluation of Harm Reduction Techniques for Intravenous Drug Misusers.

4(i) Give an outline of the project and indicate its intended value:

To assess in the laboratory current and new methods used to remove particles from solutions of drugs of abuse prepared for intravenous injection, using a technique which mimics that used by intravenous drug misusers. From the results information on harm reduction techniques will be prepared for drug users, drugs workers, GPs, pharmacists, hospital staff and others who work in the harm reduction field. To establish the techniques used by intravenous drug misusers, semi-structured interviews will be carried out with twenty five drug users.

Laboratory based information about the process of preparation of solutions will allow evidence based information to be available to support various harm reduction techniques. Safer injection advice will lead to less injuries and medical complications of intravenous drug misuse, thus reducing the workload of those who deal with these problems such as GPs and A&E staff.

Many needle exchanges nationally are staffed by trained nurses and offer wound assessment facilities. It is proposed as a small part of this project, to write protocols that could be used for the establishment of such a clinic at Drugs Action should funding become available to employ a nurse on a part time basis.

A copy of the research proposal has previously been sent to Ms Conway. This gives more detailed information about the nature of the study.

4(ii) Give a brief description of the protocol of this investigation

Not Applicable

4(iii) Has statistical advice been sought?

YES / NO / NOT RELEVANT

Yes, have SPSS and Epi Info on RGU network and am attending Research Methods Course run in-house which includes advice on stats. Studied statistics and biometrics as part of pharmacy degree course, and can also consult university statistics lecturers.

4(iv) Specify whether it is part of a larger (e.g. multi-centre/international) study

Please give details and numbers of patients for Grampian

Not Applicable

5. (a) **Specify the procedures involved and indicate those which are likely to cause distress or discomfort:** Not Applicable

(If venepuncture is one of the procedures involved, please indicate the quantity of blood to be taken per sample and whether part of routine sampling).

- (b) **Indicate those which are not standard/routine practice.** Not Applicable
- (c) **If a questionnaire is to be used, please enclose a copy. If the questionnaire is a standard one, it will be sufficient to give its title.**

Copy of semi-structured interview schedule enclosed. Used as a guide.

6. (a) **Specify the number and type of patients/volunteers likely to be involved or excluded from the project:**

approximately twenty five

- (b) **How will the patients/volunteers be identified/recruited?**

Recruited through Drugs Action and community pharmacies

7. (a) **Where will project be undertaken.**

School of Pharmacy at RGU.

Client interviews to be carried out at Drugs Action, 48a Union Street, Aberdeen and community pharmacies that have facilities available for private discussion.

- (b) **What is the likely duration of the study:**

PhD is to be three years. Client interviews will be approx twenty minutes in length, conducted when possible over the period of a few weeks.

8. **State the potential hazards, if any, and the precautions to be taken to meet them:**

Not applicable

- 9 (a) **Does the project involve exposure to X-Rays or radioactive substances?** NO

If YES, has the Radiation Protection Advisor (Dr B Heaton, Department of Bio-Medical Physics and Bio-Chemical Engineering) given approval of the dosage involved? YES/NO

- (b) **Does the project involve the use of isotopic tracers?** NO

If YES, have you contacted Dr F W Smith, Consultant in Nuclear Medicine, ARI or Dr B Heaton (as above) for advice.

YES/NO

10. **In the case of a project involving the administration of a drug, the following questions must be answered:** Not Applicable

(i) **Specify the Drug:**

(ii) **Is this drug available:**

(a) on prescription YES/NO

(b) by issue of a trial certificate YES/NO

(c) or has it been exempted YES/NO

(iii) **To what extent and to which categories of patients/volunteers has the drug been administered prior to this project?**

(iv) **Will the use of this drug involve suspension of standard or alternative treatment during the project? What will be the implications, if any, for the patient?**

(v) **Involvement of Drug Companies** (Where relevant) Not Applicable

(a) **Please give precise details of any financial arrangements which exist with a drug company including name of funding account or use to which monies will be put. The project will not be approved until this information is provided.**

11. **For all other projects, state what arrangements are in place for compensation in the event of injury or death.** Not applicable.

(b) **Does the company accept the Association of the British Pharmaceutical Industry's guidelines:**

Clinical trials compensation for medicine-induced injury?

(See Appendix I) If yes, Appendix I sheet should not be included.

YES/NO

12. **Patient/Volunteer Information and Consent**

(a) **Patients' right to withdraw**

Do you undertake to inform the patients/volunteers that they are free both to refuse to participate and to withdraw at any stage and that this will not alter their medical care in any way?

Clients will participate in interview only if they wish to do so, confidentiality and reason for research will be fully explained to them prior to commencing interview.

(b) **Patient/Volunteer Information**

The Committee expects to receive a Patient Information Sheet which explains in clear concise lay-man's terms how the patient/volunteer will be involved in the research project, including, in particular, details of any risks or likely side-effects and freedom not to participate or to withdraw affecting their medical care.

A COPY SHOULD BE GIVEN TO THE PATIENT TO KEEP.

Please enclose a copy of your Patient Information Sheet Not Applicable

(c) **Consent**

(i) **Consent, which should be as fully informed as possible, should be obtained in all circumstances from the patients/volunteers. The model consent form should normally be used (when it need not be included). Do you propose to use it? YES / NO**

If not, please enclose a copy and state the reason for its use.

Not applicable. Interviewees will be completely anonymous and verbal agreement to participate is all that will be required.

(ii) Where informed consent cannot be obtained, that of a responsible relative should be obtained BUT it must be realised that this has no legal force.

(iii) Children. The consent of a child should be obtained, regardless of age provided he/she can understand what is being asked of him/her. Parental consent must also be obtained.

(iv) Only in exceptional circumstances will the Committee accept a verbal explanation on its own. In that event the Committee will require a detailed written statement of the investigator's verbal explanation.

(d) (i) **Communication with other professionals involved in the care of the patients e.g. nursing staff, general practitioners etc.**

Drugs Action Staff are fully aware of the project and what it involves. They have agreed to allow me access to their clients. I have signed the Drugs Action Confidentiality Agreement and am also bound by the Code of Ethics of the Royal Pharmaceutical Society. Project will be fully explained to community pharmacists who agree to allowing access to their clients.

Researchers are reminded of their responsibilities to inform appropriate nursing staff and GPs of their patients' involvement in the research project.

(ii) **Please indicate enclosures:**

Patient Information Sheet: Not Applicable

Patient Consent Form: Not Applicable

Written account of verbal explanation. YES

Letter to G.P. NOT APPLICABLE

Questionnaire YES

NB The Committee strongly discourages the exclusive recruitment of persons in any dependent relationship with the investigator, (e.g. students, nurses, laboratory technicians etc.) as subjects in research projects unless there are special reasons for so doing.

13. **Good Clinical Research Practice : Please state to which UK Guidelines/standardse.g.. the investigation will adhere.**

Not Applicable

14. **Any additional relevant information:**

Name of Applicant (in block capitals)

JENNIFER SCOTT BSc (Hon) MRPharmS.....Nonmedically Qualified

Signature of Applicant

.....

Appointment held ..Research Pharmacist studying for a PhD.....

.....

Department ..The Robert Gordon University, School of Pharmacy.....

Date9 January 1997.....

NAME OF CONSULTANT/HEAD OF DEPARTMENT IF OTHER THAN APPLICANT who has approved this project and checked the patients information sheet.
(in block capitals)

..Dr ARTHUR WINFIELD.....

.....

Signature

School/Hospital/College ..Head of Department of Pharmacy Practice, School of Pharmacy,
The Robert Gordon University.....

Please Note:

1. The Committee expect to receive notification of any adverse or unforeseen circumstances arising out of this study.
2. In all projects, signature by the Consultant in Charge/Head of Department is essential.
3. Please notify the Committee on completion/abandonment of the project.
4. Please send a copy of any publication which results. *
5. The Committee may audit a project at any time. *

This form should be completed and returned to Ms L Conway, Clerk to the Joint Ethical Committee, Grampian Health Board, Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE.

Any enquiries can be directed to either Ms L Conway, (01224) 663456 Ext 75225 or

Professor E Russell, Consultant in Public Health Medicine, Medical School, Foresterhill, Aberdeen, AB9 2ZD or to the Chairman or Vice-Chairman.

*** Please note: Publication rights and right to audit must remain with my employers, The Robert Gordon University.**

**GRAMPIAN HEALTH BOARD
AND
UNIVERSITY OF ABERDEEN
JOINT ETHICAL COMMITTEE**

Chairman:

**Prof C Kidd
Institute of Medical Sciences
Dept of Bio-Medical Sciences
North Hut
Foresterhill
ABERDEEN**

**Tel: (01224) 273005
Fax: (01224) 273006**

Our Ref: LCNAA

Clerk to the Committee

**Ms Lynn Conway
Dept of Public Health Medicine
Grampian Health Board
Summerfield House
2 Eday Road
ABERDEEN, AB15 6RE**

**Tel: (01224) 663456 Ext. 75225
Fax: (01224) 404014**

Project No: 97N012

31 January 1996

**Ms Jennifer Scott
The Robert Gordon University
School of Pharmacy
Schoolhill
Aberdeen
AB10 1FR**

Dear Ms Scott

Development, Implementation and Evaluation of Harm Reduction Techniques for Intravenous Drug Misusers

The above project was considered at the Joint Ethical Committee meeting of 30th January 1997, and I am pleased to confirm that ethical approval for this project has now been granted.

With regards to medical indemnity, I enclose a form which should be completed and returned to either; (i) Dr J Hern, Clinical Director, Aberdeen Royal Hospitals NHS Trust, Foresterhill House, Ashgrove Road West, Aberdeen, (ii) Dr R Scorgie, Medical Director, Grampian Healthcare NHS Trust, Westholme, Woodend Hospital, Aberdeen, or (iii) Clinical Director, Moray Health Services NHS Trust, 317 High Street, Elgin, as appropriate, if you wish one of the above Trusts to accept liability for medical indemnity for this project. Where drugs are received from a drug company for use in a trial, these must be stored in the Pharmacy Department for reasons of good practice.

We would be very glad to receive, in due course, copies of any publications arising from this research. Thank you for bringing this study to the Committee's attention.

Yours sincerely

**Lynn Conway
Clerk to the Committee**

Please quote project number in all correspondence

Tables 4 and 5a, reproduced from the Scottish Drug Misuse Statistics, 1995, with permission from the Information and Statistics Division, Scotland (October, 1999).

**4 Main drug of misuse; by health board in which agency is located:
year ending 31 March 1995**

MEDICAL AND NON-MEDICAL
NEW INDIVIDUAL PATIENTS/CLIENTS

Scotland	Penal establishment inmates		Health Boards (excluding Penal establishment inmates)																											
	Total	Injec ¹	Argyll & Clyde		Ayrshire & Arran		Borders		Dumries & Galloway		Fife		Forth Valley		Grampian		Greater Glasgow		Highland		Lanarkshire		Lothian		Tayside		Shetland			
New Individual patients/clients	8 359	2 878	773	255	478	78	263	74	60	17	84	67	159	62	149	23	405	145	2 358	1 242	20	3	204	89	1 050	49	137	14	17	1
Heroin	2 327	1 886	235	185	131	89	88	57	14	11	63	47	33	25	15	11	195	127	1 462	1 078	3	3	72	56	33	16	2	1	-	-
Morphine	51	40	7	7	2	1	-	1	1	-	-	22	18	-	-	3	2	13	10	-	-	1	-	1	1	1	-	-	-	-
Mefenadione	816	24	74	3	15	1	47	4	3	-	5	-	9	-	22	6	89	1	328	6	8	-	3	-	194	1	39	2	-	-
- prescribed only	450	15	49	-	8	-	89	2	-	-	2	-	7	-	15	5	47	1	57	1	-	-	5	1	136	2	57	3	-	-
Dihydrocodeine	268	3	20	1	10	-	2	-	2	-	-	-	5	-	14	1	54	-	2	-	1	-	1	-	152	1	5	-	1	-
- prescribed only	448	8	24	-	22	-	1	4	-	-	-	7	1	5	-	6	1	140	3	2	-	5	-	211	1	12	-	-	-	-
Diphenone	25	21	4	4	1	1	4	2	-	-	2	2	-	-	-	3	1	6	6	-	-	1	1	2	2	2	2	-	-	-
Buprenorphine	245	175	36	23	6	5	5	3	3	9	6	11	7	-	-	1	1	123	105	-	-	3	-	16	15	5	5	-	-	-
Other Opiates	32	3	1	-	3	-	3	-	1	-	1	4	-	3	-	-	-	9	1	1	1	2	-	4	1	-	-	-	-	-
Diazepam	118	-	18	-	8	-	4	-	6	-	-	5	-	13	-	3	-	12	-	2	-	1	-	43	-	3	-	1	-	-
- prescribed only	185	2	24	-	9	-	1	-	5	-	1	4	-	18	-	3	-	11	-	-	-	5	-	100	1	3	1	1	-	-
Temazepam	46	-	7	-	7	-	2	-	-	-	-	2	-	3	-	5	-	7	-	1	-	4	-	7	-	1	-	-	-	-
- prescribed only	585	50	154	24	128	2	16	2	2	1	2	24	-	8	-	3	-	156	21	-	-	46	-	26	-	2	-	-	-	-
Other Benzodiazepines	21	-	1	-	5	-	-	-	-	-	-	4	-	-	-	1	-	7	-	-	-	2	-	1	-	-	-	-	-	-
Other Sedatives	7	-	-	-	2	-	-	-	-	-	1	-	1	-	1	-	-	-	-	-	-	1	-	3	-	-	-	-	-	-
Amphetamine	180	41	17	6	28	-	14	2	7	1	2	1	5	1	7	1	22	10	32	9	-	-	12	1	27	8	-	7	1	-
Cocaine	23	3	8	2	4	-	1	-	1	-	-	-	1	-	1	-	1	8	1	-	-	-	-	-	-	-	-	-	-	-
Ecstasy	74	-	18	-	8	-	4	-	1	-	1	2	-	-	-	5	6	14	-	-	-	-	5	-	12	-	-	-	-	-
Hallucinogens	31	-	11	-	2	-	2	-	2	-	-	3	-	1	-	1	3	-	-	-	-	-	2	-	4	-	-	-	-	-
Cannabis	266	-	34	-	41	-	18	-	7	-	-	6	-	10	-	17	46	-	-	-	-	26	-	48	-	5	-	8	-	-
Solvents	33	-	2	-	4	-	-	-	1	-	-	4	-	3	-	2	6	-	-	-	-	4	-	6	-	-	-	1	-	-
Other Drugs	25	1	2	-	3	-	-	-	-	-	-	1	-	2	-	-	-	7	1	-	-	-	-	10	-	-	-	-	-	-
No Drug Coded	121	-	17	-	8	-	1	-	1	-	-	3	-	12	-	3	-	56	-	1	-	3	-	16	-	-	-	-	-	-

- 1 Total number of individuals misusing the drug listed as the main drug.
- 2 Number (out of the total) who are injecting.
- 3 Includes cases where some or all of the drug mentioned was obtained licitly or where the source is unknown.

Source: Scottish Drug Misuse Database

**5a All drugs of misuse; by health board in which agency is located:
year ending 31 March 1995**

MEDICAL AND NON-MEDICAL
NEW INDIVIDUAL PATIENTS/CLIENTS

Scotland	Penal establishment inmates		Health Boards (excluding Penal establishment inmates)																											
	Total	Injec ¹	Argyll & Clyde		Ayrshire & Arran		Borders		Dumries & Galloway		Fife		Forth Valley		Grampian		Greater Glasgow		Highland		Lanarkshire		Lothian		Tayside		Shetland			
New Individual patients/clients	8 359		773		478		263		60		84		158		149		405		2 358		28		204		1 050		137		17	
Heroin	2 842	2 048	268	228	158	76	102	84	16	13	72	54	54	36	24	19	258	170	1 724	1 261	5	4	83	62	54	31	6	5	-	-
Morphine	124	78	18	13	4	1	4	2	1	1	1	44	28	1	1	4	3	39	24	-	-	1	-	5	3	2	1	-	-	-
Mefenadione	1 059	26	117	4	22	1	54	4	8	-	8	-	20	-	25	6	83	1	453	7	9	-	16	-	204	1	40	2	-	-
- prescribed only	769	31	82	5	20	-	104	2	3	-	9	-	16	1	29	11	103	4	128	1	-	-	8	1	200	3	86	3	-	-
Dihydrocodeine	497	7	43	2	27	-	10	2	4	-	3	-	3	-	9	-	15	1	188	1	2	-	4	-	181	1	7	-	1	-
- prescribed only	1 005	23	67	3	67	-	31	2	9	-	11	1	18	2	16	-	24	2	370	11	5	-	17	1	307	1	43	-	-	-
Diphenone	118	86	16	16	1	1	13	7	1	1	8	7	6	4	-	-	18	11	26	18	1	-	4	1	8	8	16	14	-	-
Buprenorphine	571	351	80	41	55	8	28	19	6	8	14	7	30	17	4	2	9	6	278	208	2	1	11	2	41	32	15	14	-	-
Other Opiates	108	24	10	8	11	1	8	4	3	-	4	2	16	4	8	-	8	1	22	2	2	-	8	1	10	2	1	1	1	-
Diazepam	684	2	86	2	41	-	24	-	12	-	-	15	-	30	-	34	-	148	-	3	-	12	-	258	-	17	-	3	-	-
- prescribed only	962	16	124	7	75	-	26	-	17	-	3	-	22	1	43	-	40	-	178	3	-	-	9	-	385	2	41	3	1	-
Temazepam	365	8	51	2	16	-	14	2	-	-	2	5	-	17	-	26	-	52	4	1	-	8	-	151	-	22	1	-	-	-
- prescribed only	2 318	497	354	75	231	13	102	48	16	10	22	7	42	3	44	7	84	7	1 024	303	2	-	107	9	270	5	41	7	-	-
Other Benzodiazepines	211	2	18	1	33	-	7	-	-	-	1	-	8	-	7	-	18	-	97	1	-	-	5	-	22	-	-	-	-	-
Other Sedatives	85	5	9	-	7	-	4	-	1	-	1	-	1	-	9	-	11	-	34	-	-	-	1	-	18	4	1	1	1	-
Amphetamine	645	143	57	17	67	1	44	21	23	8	7	2	19	4	24	4	42	16	185	38	2	1	32	1	98	24	13	7	12	1
Cocaine	80	17	14	4	10	1	4	-	-	-	-	1	-	8	-	6	-	29	9	-	-	5	1	8	1	1	1	-	-	-
Ecstasy	328	14	68	3	38	1	13	-	10	-	3	-	13	-	13	1	31	1	83	-	2	-	20	-	62	8	-	-	-	3
Hallucinogens	196	1	41	-	18	-	11	-	12	-	-	-	12	-	8	-	13	-	26	1	-	-	21	-	30	-	-	-	-	6
Cannabis	1 385	-	83	-	158	-	87	-	22	-	24	-	47	-	28	-	142	-	381	-	1	-	57	-	297	-	38	-	12	-
Solvents	48	-	3	-	9	-	-	-	1	-	-	-	4	-	3	-	2	-	8	-	-	-	5	-	8	-	2	-	-	2
Alcohol	482	-	30	-	54	-	17	-	17	-	3	-	19	-	15	-	31	-	134	-	-	-	43	-	98	-	8	-	13	-
Other Drugs	158	8	7	-	12	-	5	1	5	-	-	5	-	8	1	11	-	70	5	-	-	2	-	32	1	1	-	-	-	-
No Drug Coded	121	-	17	-	8	-	1	-	1	-	-	3	-	12	-	3	-	56	-	1	-	3	-	16	-	-	-	-	-	-

Needle exchange agencies visited as part of baseline data collection process.

Drugs Action
48a Union Street
Aberdeen
AB10 1BB

tel: 01224 624555

The Harm Reduction Team
25-29 Spittal Street
Edinburgh
EH3 9DU

tel: 0131 229 5995

The Harm Reduction Centre
Constitution House
55 Constitution Road
Dundee
DD1 1LB

tel: 01382 201919

The Exchange
16a Cleveland Street
London

tel: 0171 530 4580

Interview Schedule for Filter Study ..CONFIDENTIAL

The project:

I am testing filters in the lab and need information about drugs and filters used. Hopefully I shall then be able to produce some safer injection advice about using filters and will be able to provide scientific data that could potentially be used to support funding for filter distribution. I will also be looking at injection site injuries, so I will ask about this too.

The questionnaire is designed to find out information I need to know to support my lab work. I want to know about the stages involved in preparation of the hit so I can copy them. I also want to know about the process of injecting and injection site injuries. Any information provided will be useful. Not all questions may be applicable to you or you may feel you do not wish to answer certain questions, this is fine you have the option to decline to comment.

Confidentiality:

I am looking to talk to about 25 people and need to make sure that I interview a broad range. Therefore before I begin the questions I need to ask a few details about yourself.

This interview is **completely confidential**. Do you object to the interview being taped, to avoid time being spent writing down answers? The interview will be identified only with the number of the interview (i.e.: first, second etc.) and time started and time stopped. Otherwise, answers will be written down, which is fine but will take longer. Taped interviews will last approximately 20 minutes, written ones probably an hour.

Honesty:

It is easy when being asked about something such as drug use to tell people what you think they want to hear which is not always the same as what is the case. It is really important to be honest if I am to get some accurate results from my work, and therefore to produce the best information for users. It's not a test to see who has the safest injection technique, the interviews will not be heard by Drugs Action staff or anyone else except myself. Everything is completely confidential.

General Information:

- Sex of client: M F
- Age of client:
- Age when first injected:
- Are you still injecting?

If yes, how often do you inject? If no, why did you stop?

If no, how long ago did you stop injecting?

CONFIDENTIAL**Interview Questions:*****Preparation of Hit:***

- Who prepares your hits? (self/ partner/ friend?)
- (If self) How did you learn how to prepare hits? (friend?)
- Have you ever taught someone else how to inject?
- What needles and barrels do you use? (orange, green needles, 1ml, 5ml barrels etc.)
- Have you ever had any safer injection advice? (if yes where from? Needle X centres, pharmacies doing needle X, other medical people, friends. Leaflets or verbal?)

*****¹

Drugs:

- What drugs do you use or have you used by injection? (timescale?)
- Have you ever injected tablets or capsules?
- If yes: what have you used? (examples?)
- Do different types of tablets get mixed together in a hit?
- How many go into each hit? (what factors influence this? e.g. not used before, mixing with other drugs)
- Do you test the strength of the hit first? (toot helps steady hand)

Crushing:

- What drugs do you crush? (e.g. heroin, speed, tablets-which ones?)
- How do you crush? (e.g.: between two spoons, with a book)

Acids:

- What acids do you use? (e.g. citric, ascorbic (vit C) vinegar, lemon Juice)
- What drugs would you add acid to? (just skag or speed or to tablets too?-which ones?)
- How much do you add? (e.g.: pinch, like salt on chips, few drops of lemon juice?)

¹ The line of asterisk indicate the point at which in the post-piloting interviews the question 'Please tell me how you prepare your hits' or 'Please tell me how your hits are prepared' was asked.

CONFIDENTIAL**Water:**

- What kind of water gets used? (from boiled kettle, from tap, from cup that gets shared?)
- How much water would get added? (indicate in teaspoons, e.g.: half a tsp., one tsp. etc. or volume in mls such as half a 2ml barrel)

Heating:

- What drugs would you heat? (skag, speed, tablets, capsules?)
- What is used as the heat source? (lighter, candle, match, cooker?)
- How long do you heat for? (till it dissolves, till it boils?)

Filtering:

- Do you worry about particles in the hit? (understand the risks?)
- Do you worry about bacteria in the hit? (understand the risks?)
- How do you get rid of the stuff that doesn't dissolve? (if at all) (tip spoon more common or filter?)
- Does filtering take away some of the hit?
- What drugs would you filter? (skag, speed, tabs, caps?)
- What would you use as a filter? (cigarette end, cotton wool ball or bud, toilet tissue?)
- Do filters get reused?
- Do you keep old filters to use them to make another hit? (if so, how?)
- Should filters be available from places that exchange needles? If so what type?

*****²

² The line of asterisk indicate the point at which in the post-piloting interviews the question 'Please tell me how you inject' or 'Please tell me how you are injected' was asked

CONFIDENTIAL***Injecting process:***

- Do you alternate injecting sites? (if yes how often?)
- Do you swab site before injecting?
- What are the stages of injecting?
 - Tourniquet?: Where? When is it released?
 - Flush back to check got vein?
 - Do you do anything to avoid bruising?
 - Inject slowly?
 - Do you press on site after?
- Have you ever had any injection site injuries?
 - If yes: What? (e.g.: track marks, collapsed vein, abscess, clot)
 - What did you do?
 - What do you think would be the best way for people to get injection site injuries treated?
 - Why?
- What do you think would be the best way to get new advice across to people? (leaflets designed by DA users, Leaflets designed by others, video made by DA staff,)
- What factors do you think make people not practice safer injecting ? (desperate for hit, injecting with people who don't do it, already being stoned)

Thank you once again for your time and input. Just to reinforce this interview is in the strictest confidence. The tapes/ transcripts will be kept in a locked office and only used by researcher.

Information Sheet for Drug Action/Pharmacy Clients asked to participate in Interviews.

You have been asked if you are willing to be interviewed as part of a research project. The information on this sheet is designed to tell you what the project is about:

What is the project about?

I am testing filters in the lab and need information about drugs and filters used. Hopefully I shall then be able to produce some safer injection advice about using filters and will be able to provide scientific data that could potentially be used to support funding for filter distribution. I will also be looking at injection site injuries, so I will ask about this too.

The interview is designed to find out information I need to know to support my lab work. I want to know about the drugs you have used and how you prepare hits, so I can copy this in the lab, as closely as possible. I also want to know about any injuries you have had due to injecting. Any information provided will be useful. Not all questions may be applicable to you or you may feel you do not wish to answer certain questions, this is fine you have the option not to comment. If you feel at any stage in the interview you don't want to carry on with it, you can leave without question. The decision to take part and continue is entirely up to you.

Confidentiality:

I am looking to talk to about 25 people and need to make sure that I interview a broad range. Therefore before I begin the questions I need to ask a few details about yourself to make sure I am speaking both men and women with a range of ages.

This interview is **completely confidential**. You will be asked if you mind the interview being taped, to avoid time being spent writing down answers. The interview will be identified only with the number of the interview (i.e.: first, second etc.). Otherwise, answers will be written down, which is fine but will take longer. Taped interviews will last approximately 20 minutes, written ones probably an hour. The choice to have your interview written or taped is yours.

Honesty:

It is easy when being asked about something such as drug use to tell people what you think they want to hear which is not always the same as what is the case. It is really important to be honest if I am to get some accurate results from my work, and therefore to produce the best information for users. It's not a test to see who has the safest injection technique, the interviews will not be heard by Drugs Action/pharmacy staff or anyone except myself. I am not a DA employee nor do I work for any other drug treatment agency. The only contact I have with pharmacies is occasional work filling in when pharmacists are off (this is called locum work). Everything is completely confidential.

Consent forms:

If you agree to take part, you will be asked to sign a consent form to say you are willing to be interviewed. Just like the tapes and written interviews, these will be kept in a locked office and will only be seen by the researcher. They will be destroyed after the research is over. You can sign a false name or just your initials, you do not have to give your own name. Consent forms are something that is a standard part of any research project and the reason for having them is so I have something in writing that said you agree to the interview taking place.

I am very grateful to those who agree to being interviewed, for giving up their time and contributing information to my research.

*Thank you
Jenny Scott
Robert Gordon University*

Interview with Drugs Action/Pharmacy Clients.**Consent form**

I have read the information sheet about the interviews and agree to take part.
I understand that I can withdraw from the interview at any time and this will not affect my treatment from Drugs Action or the pharmacy. I understand that the interview is completely confidential.

signed

_____ date _____.

Scottish Drug Misuse Statistics 1995-6

Summary of Information established from the Statistics

Data is collected from the SMR form which is completed by agencies at initial contact with drug users. These agencies are defined as: Penal Establishments, General Practice, Police surgeon, Specialist Drug Services, Out patient services, Inpatient services and Residential rehabilitation. Initial contact is defined as: person attending the agency for the first time or previous attendance more than six months ago.

By means of matching certain criteria (initials, D.O.B and sex) and an adjustment is made for double counting of individuals who may have been to more than one agency (e.g. GP and needle exchange). However, true matches cannot be guaranteed and it is likely some will have been wrongly matched and some missed.

Clients are asked to report their **main** drug of misuse. This is defined as the drug to which they are most addicted or they are using most often. Table 4, page 26 of the bulletin details the main drug of misuse indicated and the number of clients who reported injecting their main drug. This is given as a total for Scotland and by healthboard in which the agency is located. Below, this information is shown for each drug mentioned as the percentage of the total number of injectors (n) who reported it as their main drug.

Clients report drugs used in the past month. This cannot be taken as representing the drugs likely to be used by all the drug using population, since many who have established connections with services or who have no need for services, will have more stable drug using careers. What this does indicate is the drugs being used at the time over the past 12 months when users access services (NB: this access can be voluntary as in needle exchange or compulsory as in penial establishments).

Table 1: Percentage (%) of clients who reported drug as main drug of misuse by injection.

Drug	Scotland (n=2070)	Grampian (n= 145)
heroin	81.4	87.6
morphine	1.9	1.4
methadone *	1.9	1.4
dihydrocodeine*	0.4	1.4
dipipanone	1.0	0.7
buprenorphine	8.5	0.7
other opiates	0.1	0.7
diazepam*	0.1	0.0
temazepam*	2.4	0.0
amphetamines	2.0	7.0
cocaine	0.1	0.0
other drugs	0.1	0.0

Table 2a: Decending order of percentage (%) of clients who reported drug as main drug of misuse by injection. Shown for Scotland.

Drug	Scotland (n=2070)
heroin	81.4
buprenorphine	8.5
temazepam*	2.4
amphetamines	2.0
morphine	1.9
methadone *	1.9
dipipanone	1.0
dihydrocodeine*	0.4
other opiates	0.1
diazepam*	0.1
cocaine	0.1
other drugs	0.1

Table 2b: Decending order of percentage (%) of clients who reported drug as main drug of misuse by injection. Shown for Grampian.

Drug	Grampian (n= 145)
heroin	87.6
amphetamines	7.0
morphine	1.4
methadone *	1.4
dihydrocodeine*	1.4
dipipanone	0.7
buprenorphine	0.7
other opiates	0.7
diazepam*	0.0
temazepam*	0.0
cocaine	0.0
other drugs	0.0

Table 5a, page 27 of the bulletin details all drugs reported to have been used in the past month. The number of clients who indicated having used each drug by injection is also given. Table 3 below, shows this as percentage of clients who reported having used a drug, who used it by injection.

Table 3: Percentage (%) of clients who indicated drug had been used in past month by injection.

Drug	Scotland	Grampian
heroin	72.0	65.9
morphine	62.9	75.0
methadone*	6.5	5.1
dihydrocodeine*	3.7	15.0
dipipanone	74.6	61.1
buprenorphine	63.2	66.7
other opiates	22.0	12.5
diazepam*	2.0	0.0
temazepam*	23.9	10.9
other benzodiazepines	0.9	0.0
other sedatives	5.2	0.0
amphetamines	26.2	38.1
cocaine	21.3	0.0
ecstasy	4.3	3.2
hallucinogens	0.5	0.0
other drugs	5.1	0.0

Table 4a: Decending order of percentage (%) of clients who indicated drug had been used in past month by injection. Shown for Scotland.

Drug	Scotland
dipipanone	74.6
heroin	72.0
buprenorphine	63.2
morphine	62.9
amphetamines	26.2
temazepam*	23.9
other opiates	22.0
cocaine	21.3
methadone*	6.5
other sedatives	5.2
other drugs	5.1
ecstasy	4.3
dihydrocodeine*	3.7
diazepam*	2.0
other benzodiazepines	0.9
hallucinogens	0.5

Table 4b: Decending order of percentage (%) of clients who indicated drug had been used in past month by injection. Shown for Grampian.

Drug	Grampian
morphine	75.0
buprenorphine	66.7
heroin	65.9
dipipanone	61.1
amphetamines	38.1
dihydrocodeine*	15.0
other opiates	12.5
temazepam*	10.9
methadone*	5.1
ecstasy	3.2
diazepam*	0.0
other benzodiazepines	0.0
other sedatives	0.0
cocaine	0.0
hallucinogens	0.0
other drugs	0.0

Note: SMR form asks for route(s) of administration so it is understood from this that all routes used for a particular drug should be recorded.

* note: Separate statistics for these drugs are recorded on the SMR distinguishing whether they have been prescribed or obtained from other/not stated source. The figures indicated here are a sum of both prescribed and non prescribed use.



GRAEME NAPIER

REGIONAL PROCURATOR FISCAL FOR
GRAMPIAN, HIGHLAND AND ISLANDS

Atholl House
84-88 Guild Street
ABERDEEN AB11 6QA

DX AB67

Tel: 01224 585111

Fax: 01224 585550

Ms Jennifer Scott MR PharmS
The Robert Gordon University
School of Pharmacy
Schoolhill
ABERDEEN
AB10 1FR

Your Ref:

Our Ref: R/E/1/GN/LR

1 May 1997

Dear Ms Scott

RESEARCH PROJECT - ROBERT GORDON UNIVERSITY

I refer to this matter. I have now heard from Crown Office who indicate that so long as you may lawfully be in possession of the drug samples there would be no objection to this research. The only condition which we would insist upon is that the samples could only come from seizures in cases which have been concluded. These samples could only be taken therefore from drugs which are destined for destruction.

I suggest therefore that you confirm that the School of Pharmacy will have a licence from the Home Office to allow you to have access to these drugs for research purposes, agree arrangements via Grampian Police regarding your obtaining possession of these drugs and agree with them, with the assistance and advice from their Forensic Science Laboratory, methods of ultimate destruction including the certificate procedure if destruction is carried out at the University.

I would be pleased to hear from you whether you are in fact able to proceed with your research and would also be interested in knowing the ultimate results of this research.

Yours sincerely

G NAPIER

Acting Regional Procurator Fiscal



GRAEME NAPIER

REGIONAL PROCURATOR FISCAL FOR
GRAMPIAN, HIGHLAND AND ISLANDS

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I would be pleased to hear from you whether you are in fact able to proceed with your research and would also be interested in knowing the ultimate results of this research.

Yours sincerely

G NAPIER
Acting Regional Procurator Fiscal



HOME OFFICE

Action Against Drugs Unit
50 Queen Anne's Gate, London, SW1H 9AT
Direct Line 0171 273 3806 Fax 0171 273 2157

12 AUG 1997

Prof. R Richards
Head Of School Of Pharmacy
The Robert Gordon University
Schoolhill
Aberdeen
AB10 1FR

Your reference:

Our reference: DDA/1621/1/1

Date: 11 August 1997

Dear Prof. Richards

**MISUSE OF DRUGS ACT 1971
MISUSE OF DRUGS REGULATIONS 1985 (AS AMENDED)**

I refer to your application of 20.05.97 to have "street" heroin added to your licence, to possess, no 97/MM/4546 to enable one of your PhD students, Ms Jennifer Scott to conduct a research project.

Following referral to our inspectorate, I am now in a position to advise you that, under Regulations 8(2)(f) and 10(1)(a) of the Misuse Of Drugs Regulations, you are exempt from requiring a licence to possess heroin.

I should, however, take the opportunity to remind you that the samples, used in the research project must **only** be obtained from Grampian Police in accordance with the directions of the Acting Regional Procurator Fiscal, outlined in his letter to Ms Scott of 01.05.97.

I hope that this satisfactory, but if you have any further questions, please do not hesitate to contact me on the above numbers.

Yours sincerely

Mr S A Winch

JOINT ETHICAL COMMITTEE
OF
GRAMPIAN HEALTH BOARD
AND
THE UNIVERSITY OF ABERDEEN

Staff undertaking medical research work involving human subjects are invited to provide the following details of the project for consideration by the Joint Ethical Committee of the Grampian Health Board and the University of Aberdeen.

The Joint Ethical Committee consists of members nominated by the Grampian Health Board and the University of Aberdeen and its function is to examine and give an opinion on the ethical aspects of all clinical research investigations referred to it, including therapeutic innovation, or any experimentation involving human subjects.

The Joint Ethical Committee meets on the last Thursday of each of the following months: January, March, May, July, September and November.

Projects must be in typescript and submitted by 12 noon two weeks in advance of meetings. This deadline will be strictly adhered to. 18 copies of the application must be submitted. The proforma is held on disc by the Secretary.

Investigators are asked to provide information in the form of answers to the following questions. Where questions are not relevant or not applicable please indicate. Please use extra sheets if necessary and insert these in the appropriate places. If the Model Consent form and the APB1 terms for compensation are being used, these forms should NOT be included.

The Consultant in charge/Head of Department is particularly requested to check the technical aspects of the project and to make sure that the Patient Information sheet is readily understood with the signature confirming that this responsibility has been accepted.

1. (a) **Names of investigators responsible for the project**
Project team consists of:
Research project student: Jennifer Scott
Director of studies: Dr Arthur Winfield (Senior lecturer, RGU)
Project Supervisors: Dr Emily Kennedy (Teacher practitioner, Boots the Chemists & RGU)
Dr Christine Bond (Dept. General Practice, Univ.of Aberdeen)
Advisors to project: Dr Jennifer Hall (Drug Development Officer, GHB)
Miss Luan Bruce (Needle Exchange Worker, Drugs Action)
- (b) **Names and background of individuals directly involved in carrying out the project**
Jennifer Scott. Pharmacist. This project is expansion of Honours project carried out in 1994. Previously worked in

Pharmacy R&D at Roche Products (UK) Ltd as pre-registration pharmacist and Pharmacy Department, Queen Elizabeth II Hospital, Welwyn Garden City, Hertfordshire, as Clinical Services Pharmacist. Currently research pharmacist, RGU and part time locum pharmacist and drugs worker.

2. (a) Name of Consultant or GP in charge of patients:

Not Applicable

(b) Names of other consultants/departments/laboratories/records department who are involved in a significant amount of extra work.
Has permission/agreement been obtained?

YES / NO

Not Applicable

(c) Name of any other Individual (and their department) involved:

Not Applicable

3. State the title of the proposed project (and project number of previous application, where relevant)

Development, Implementation and Evaluation of Harm Reduction Techniques for Intravenous Drug Misusers.

4(i) Give an outline of the project and indicate its intended value:

In January 1997 the Ethics Committee approved a research proposal for this study. This application, is to extend one aspect of the work.

This is the extract that was given in the Jan 1997 approved proposal:

'To assess in the laboratory current and new methods used to remove particles from solutions of drugs of abuse prepared for intravenous injection, using a technique which mimics that used by intravenous drug misusers. From the results information on harm reduction techniques will be prepared for drug users, drugs workers, GPs, pharmacists, hospital staff and others who work in the harm reduction field. To establish the techniques used intravenous drug misusers, semi-structured interviews will be carried out with twenty five drug users.'

Laboratory based information about the process of preparation of solutions will allow evidence based information to be available to support various harm reduction techniques. Safer injection advice will lead to less injuries and medical complications of intravenous drug misuse, thus reducing the workload of those who deal with these problems such as GPs and A&E staff.'

This is the details of the extended part of the study, for which I seek approval:

Data is being collected in the laboratory on the effectiveness of filters on removing particles from injections, and predicted benefits to health of injecting drug users (IDUs) made. This study has created much interest both nationally and internationally. Once this work is complete, it is proposed that the most effective filter, the pre-syringe filter, be assessed for user acceptability. To do this, it is proposed to distribute a small number of pre-syringe filters to IDUs for use and collect their views and opinions on the suitability for purpose of the filters, using a questionnaire. It is currently forbidden to distribute any injecting paraphernalia according to the Drug Trafficking Act, Section 9a (except needles and syringes which are exempt). The Police Federation are currently reviewing this act. If a change in the law does happen, this work will provide valuable evidence for

purchasers and providers when deciding which filters to supply to IDUs, to reduce harm and thus save costs in healthcare. I have contacted The Crown Office and Regional Procurator Fiscal, to seek exemption from prosecution under the current legislation to allow this study to be done. They are considering this matter. Obviously, this part of the study can only be done with their approval. Therefore, approval from the Ethics Committee is being sought for this part of the study, but it will only go ahead if also approved by the Crown Office. The Ethics Committee obviously have the ethical side of this application to consider and the Crown Office the legal issues. The contact person at the Crown Office is Mrs Angiolini. The information which follows is for this proposed work:

4(ii) Give a brief description of the protocol of this investigation

See attached protocol

4(iii) Has statistical advice been sought?

YES/NO/NOT RELEVANT

(Previously sought: refer to earlier application).

4(iv) Specify whether it is part of a larger (e.g. multi-centre/international) study

Please give details and numbers of patients for Grampian

Not Applicable

5. (a) Specify the procedures involved and indicate those which are likely to cause distress or discomfort

Not Applicable

(If venepuncture is one of the procedures involved, please indicate the quantity of blood to be taken per sample and whether part of routine sampling).

(b) Indicate those which are not standard/routine practice. Not Applicable

(c) If a questionnaire is to be used, please enclose a copy. If the questionnaire is a standard one, it will be sufficient to give its title.

See enclosed.

6. (a) Specify the number and type of patients/volunteers likely to be involved or excluded from the project

Numbers will depend on recruitment. This is a very small project to gather users opinions. It is hoped that at least 5 people could be recruited, maximum will be 20. These are the figures given to the Crown Office. All volunteers be current injectors of street heroin who use the Drugs Action needle exchange. See protocol for specific inclusion criteria.

(b) How will the patients/volunteers be identified/recruited?

They will be a non-randomised quota sample recruited from the Needle Exchange at Drugs Action. They must be frequent users of the needle exchange (i.e. at least one visit every 2 weeks). They will be identified by the drugs workers to the researcher, who will then explain the study and ask details to see if they fit the selection protocol (see details). The researcher will then give them the volunteer information sheet, and ask them to decide if they would like to be included. They will then sign a form to say they understand the study and have had it fully explained to them. This will say they can pull out at any time and that the forms are confidential, no names are to be used in the study report or disclosed to third parties. They

will be required to give a contact number and agree to being telephoned, to arrange follow up and check on safety issues, if they do not return to DA within 14 days.

7. (a) Where will project be undertaken

School of Pharmacy at RGU for preparation and data analysis.
Drugs Action, 48a Union Street, Aberdeen for subject recruitment and questionnaire distribution.

(b) What is the likely duration of the study:

Short time period, of approx two to four weeks.

8. State the potential hazards, if any, and the precautions to be taken to meet them:

Clients will be assessed for suitability before being included in this study. The selection protocol has been designed to minimise this risk (see above).

The effect of the filter on drug concentration and particle load will be explained. The data on drug concentration has yet been completed. If the pre-syringe filter shows significantly less drug retention than the makeshift filters, there is obviously a risk to health, so clients will only be recruited who do not normally use a makeshift filter. If the difference in drug concentration is not significant, clients who use makeshift filters can be included. The use of the presyringe filters will need to be explained to the clients to ensure they are using them correctly. Injecting technique will be assessed and harm reduction information given at time of recruitment. This project focuses on reducing the risks associated with injecting heroin, which in itself carries large risks. This risk will NOT be increased by this study.

9 (a) Does the project involve exposure to x-rays or radioactive substances? NO

If YES, has the Radiation Protection Advisor (Dr B Heaton, Department of Bio-Medical Physics and Bio-Chemical Engineering) given approval of the dosage involved? YES/NO

(b) Does the project involve the use of isotopic tracers? NO

If YES, have you contacted Dr F W Smith, Consultant in Nuclear Medicine, ARI or Dr B Heaton (as above) for advice.

YES/NO

10. In the case of a project involving the administration of a drug, the following questions must be answered: Not Applicable

(i) Specify the Drug:

(ii) Is this drug available:

(a) on prescription YES/NO

(b) by issue of a trial certificate YES/NO

(c) or has it been exempted YES/NO

- (iii) To what extent and to which categories of patients/volunteers has the drug been administered prior to this project?
- (iv) Will the use of this drug involve suspension of standard or alternative treatment during the project? What will be the implications, if any, for the patient?
- (v) Involvement of Drug Companies (Where relevant) Not Applicable
- (a) Please give precise details of any financial arrangements which exist with a drug company including name of funding account or use to which moneys will be put. The project will not be approved until this information is provided.

11. For all other projects, state what arrangements are in place for compensation in the event of injury or death. Not applicable.

(b) Does the company accept the Association of the British Pharmaceutical Industry's guidelines:

Clinical trials compensation for medicine-induced injury?

(See Appendix I) If yes, Appendix I sheet should not be included.

YES/NO

12. Patient/Volunteer Information and Consent

- (a) Patients' right to withdraw

Do you undertake to inform the patients/volunteers that they are free both to refuse to participate and to withdraw at any stage and that this will not alter their medical care in any way?

Yes, they will be informed that refusal to participate or desire to withdraw, will not alter the treatment they receive from Drugs Action.

- (b) Patient/Volunteer Information

The Committee expects to receive a Patient Information Sheet which explains in clear concise lay-man's terms how the patient/volunteer will be involved in the research project, including, in particular, details of any risks or likely side-effects and freedom not to participate or to withdraw affecting their medical care.

A COPY SHOULD BE GIVEN TO THE PATIENT TO KEEP.

Please enclose a copy of your Patient Information Sheet. See enclosed

- (c) Consent

- (i) Consent, which should be as fully informed as possible, should be obtained in all circumstances from the patients/volunteers. The model consent form should normally be used (when it need not be included). Do you propose to use it? YES/NO

If not, please enclose a copy and state the reason for its use.

I have modified the Model Consent form to suit the purpose of needle exchange clients, not GP or hospital doctor patients. The basic structure has been retained. See enclosed.

- (ii) Where informed consent cannot be obtained, that of a responsible relative should be obtained BUT it must be realised that this has no legal force.
- (iii) Children. The consent of a child should be obtained, regardless of age provided he/she can understand what is being asked of him/her. Parental consent must also be obtained.
- (iv) Only in exceptional circumstances will the Committee accept a verbal explanation on its own. In that event the Committee will require a detailed written statement of the investigator's verbal explanation.

- (d) (i) Communication with other professionals involved in the care of the patients e.g. nursing staff, general practitioners etc.

Drugs Action Staff will be made fully aware of the project and what it involves. They have agreed to allow me access to their clients. I have signed the Drugs Action Confidentiality Agreement and am also bound by the Code of Ethics of the Royal Pharmaceutical Society.

Researchers are reminded of their responsibilities to inform appropriate nursing staff and GPs of their patients' involvement in the research project.

- (ii) Please indicate enclosures:

Patient Information Sheet	YES
Patient Consent Form:	YES
Written account of verbal explanation.	YES
Letter to G.P.	NOT APPLICABLE
Protocol for volunteer inclusion.....Yes	
Questionnaire	YES
Instruction Sheet for Volunteers	YES

NB The Committee strongly discourages the exclusive recruitment of persons in any dependent relationship with the investigator, (e.g. students, nurses, laboratory technicians etc.) as subjects in research projects unless there are special reasons for so doing.

13. Good Clinical Research Practice : Please state to which UK Guidelines/standardse.g.. the investigation will adhere.

Not Applicable

*** Please note: Publication rights and right to audit must remain with my employers, The Robert Gordon University:**

A list of publications from this study and copies where available have been enclosed.

14. Any additional relevant information:

Name of Applicant (in block capitals)

JENNIFER SCOTT BSc (Hon) MRPharmS.....Not medically Qualified

Signature of Applicant .

6/10/98

Appointment held

..Research Pharmacist studying for a PhD.....

Department

..The Robert Gordon University, School of Pharmacy.....

Date

...22 Septmeber 1998.....

NAME OF CONSULTANT/HEAD OF DEPARTMENT IF OTHER THAN APPLICANT who has approved this project and checked the patients information sheet.
(in block capitals)

..Dr ARTHUR WINFIELD.....

Signature

.....

.....

School/Hospital/College..Head of Department of Pharmacy Practice, School of Pharmacy, The Robert Gordon University.....

Please Note:

1. The Committee expect to receive notification of any adverse or unforeseen circumstances arising out of this study.
2. In all projects, signature by the Consultant in Charge/Head of Department is essential.
3. Please notify the Committee on completion/abandonment of the project.
4. Please send a copy of any publication which results. *
5. The Committee may audit a project at any time. *

This form should be completed and returned to Ms L Conway, Clerk to the Joint Ethical Committee, Grampian Health Board, Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE.

Any enquiries can be directed to either Ms L Conway, (01224) 663456 Ext 75225 or Professor E Russell, Consultant in Public Health Medicine, Medical School, Foresterhill, Aberdeen, AB9 2ZD or to the Chairman or Vice-Chairman.

* Please note: Publication rights and right to audit must remain with my employers, The Robert Gordon University.

A list of publications from this study and copies where available have been enclosed.

APPENDIX (II)

CONSENT FORM**CONSENT BY PATIENT/VOLUNTEER TO PARTICIPATE IN:**

Collection of drugs users opinions on the suitability for use of pre-syringe filters when preparing injections of street heroin.

Name of Patient/Volunteer: (Initials, DOB and Drugs Action client reference number)

Name of Study: Development, Implementation and Evaluation of Harm Reduction Techniques for Intravenous Drug Misusers.

Principal Investigator: Jennifer Scott

I have read the patient/volunteer information sheet on the above study and have had the opportunity to discuss the details with Jennifer Scott and ask questions. Jennifer has explained to me the nature and purpose of the study to be undertaken. I understand fully what is proposed to be done.

I have agreed to take part in the study as it has been outlined to me, but I understand that I am completely free to withdraw from the study or any part of the study at any time I wish and that this will not affect the service I get from Drugs Action in any way.

I understand that this investigation is part of a research project designed to promote harm reduction knowledge, which has been approved by the Joint Ethical Committee and the Crown Office.

I hereby fully and freely consent to participate in the study which has been fully explained to me. I agree to follow the instruction sheet and information supplied.

Signature of Volunteer:

Date:

I confirm that I have explained to the volunteer named above, the nature and purpose of the trial to be undertaken.

Signature of Investigator:

Date:

Please note: This form will be kept in confidential in a locked cabinet until the study is finished. No names are disclosed to anyone else. These forms will be destroyed after the study is finished.

*GRAMPIAN HEALTH BOARD
AND
UNIVERSITY OF ABERDEEN*

GRAMPIAN RESEARCH ETHICS COMMITTEE

Chairman

Mrs M Ross
Senior Lecturer
Dept of Law
University of Aberdeen
Regent Walk
ABERDEEN, AB24 3FX

Tel: (01224) 272421
Fax: (01224) 272442

Clerk to the Committee

Mrs Diane Murray
Dept of Public Health
Grampian Health Board
Summerfield House
2 Eday Road
ABERDEEN, AB15 6RE

Tel: (01224) 663456 Ext 75225
Fax: (01224) 404014

Project No: 98/00263

5th November 1998

Ms J Scott
Research Pharmacist
Robert Gordon University
School of Pharmacy
Schoolhill
Aberdeen, AB10 1FR

Dear Ms Scott

Development, implementation and evaluation of harm reduction techniques for intravenous drug misusers

The above project was considered at the Grampian Research Ethics Committee meeting of 29th October 1998, and I am pleased to confirm that ethical approval for this project has now been granted subject to the following amendments:

1. The Committee had concerns about the disposal of the filters. Can you please clarify to the Committee what will happen to the used filters.
2. The Committee were concerned that you stated in your application that the right to audit remains with your employers. The Ethics Committee may wish to audit this project at a later date as part of the post approval monitoring process. I would be grateful if you could clarify the Robert Gordon University's position.
3. In the Patient Information Sheet, please add a sentence that if the patient refuses to take part, there will no detriment to their future care.

With regards to medical indemnity, I enclose a form which should be completed and returned to either; (i) Dr J Broom, Research & Development Director, Research & Development Offices, Aberdeen Royal Hospitals NHS Trust, Aberdeen Royal Infirmary, Foresterhill, Aberdeen, (ii) Medical Director, Grampian Healthcare NHS Trust, Westholme, Woodend Hospital, Aberdeen, or (iii) Medical Director, Moray Health Services NHS Trust, 317 High Street, Elgin, as appropriate, if you wish one of the above Trusts to accept liability for medical indemnity for this project.

We would be very glad to receive, in due course, copies of any publications arising from this research. Thank you for bringing this study to the Committee's attention.

Yours sincerely
Mrs Diane Murray
Clerk to the Grampian Research Ethics Committee

M.D. Murray

Please quote project number in all correspondence

Information Sheet for Volunteers

'Gathering users opinions on the use of filters'

Injections made from street heroin contain solid particles which don't dissolve. Some of these particles are too small to see but can still cause problems if they get into your blood stream (such as hard lumps). I have been testing filters in a lab to find out which ones work best at removing solid particles from injections made with street drugs. I spoke to some users at Drugs Action before I did the experiments to find out how they prepared their injections. I then copied their techniques as best I could, so the tests were as realistic as possible.

The filters which worked best are called 'syringe filters' and my tests showed they take out 99% of all particles, and the amount of drug in the hit is similar to that in hits filtered with cigarette filters. Now I have found these filters work best, I am looking for volunteers to test them. I want to give a few filters to some people who regularly inject heroin and then find out what they thought about using them (by asking them to fill out a questionnaire). All information about the people involved will be treated confidentially.

Legally, needle exchanges are not allowed to give out filters, but I have been given special permission to give out filters for this study from the Procurator Fiscal. This law is being reviewed, so if it changes in the future, this study will provide information on which kind of filters to distribute.

For safety, volunteers must not be on a script for any substitute drugs (e.g meth, vallyies, Dfs etc)

If you are **not** on a script and can answer yes to the following questions, you are suitable to volunteer:

- Do you inject street heroin on a regular basis (at least twice a day, every day)?
- Have you been using for at least 3 months?
- Do you usually visit the Drugs Action needle exchange at least once a fortnight?

People who agree to volunteer will be asked some questions about their drug use. This is for safety, to make sure they are suitable volunteers. They will then be told if they can be included. People who volunteer will be asked to sign a consent form, this is to prove they willingly agreed to take part. Grampian Health Board Ethics Committee have approved this study and may ask to look at the results once the study is finished. **No names** will be given to them, just information on results.

Please note, volunteers can pull out at any time and don't need to give a reason.

Volunteers who agree to take part will be asked to give their first name or nick name, initials and date of birth. They will also be required to give a contact address and telephone number, so they can be followed up if they have not been back to the Drugs Action needle exchange in the next 2 weeks. This is purely a safety measure. All information will be kept confidential and destroyed once volunteers have returned to the agency. **No one will be told that you are a volunteer for this study.**

The volunteer will be given a few filters and then it will be explained how to use them by the researcher or drugs worker. A new safer injecting booklet will also be given.

A questionnaire asking what the volunteer's thought about using the filters will then be attached to the volunteer's needle exchange card. Next time the volunteer is in the needle exchange, they will be asked to fill out the questionnaire. It will take about five minutes to complete. The questionnaire must be filled out in the exchange, it cannot be taken away.

The researcher will check the cards 2 weeks after the filters have been given out. If any volunteers have not yet returned to Drugs Action, they will then be contacted by telephone. If this is done, the researcher will ask for the volunteer by first name but not disclose that she is calling from Drugs Action.

Volunteers can pull out of the study at any time. Even if they have taken filters away, they can decide later not to use them. All that is asked is that they write on the top of the questionnaire when they return that they didn't use the filters. Unused filters must be handed back to the researcher, by giving them to a Drugs Action worker at next visit. Used filters must be disposed of in your cin bin.

The researcher will have checked that volunteers are suitable to be in the study, by asking questions. Therefore, it is important that volunteers do not distribute filters to anyone else for use when injecting. **They must only be used by the volunteer.**

If you have any questions about this study please ask the person who gave you this sheet.

Refusing to take part in this study will not have any adverse affect on the service you receive from Drugs Action. It is your choice to participate.

All information is treated confidentially.
Thank you very much,

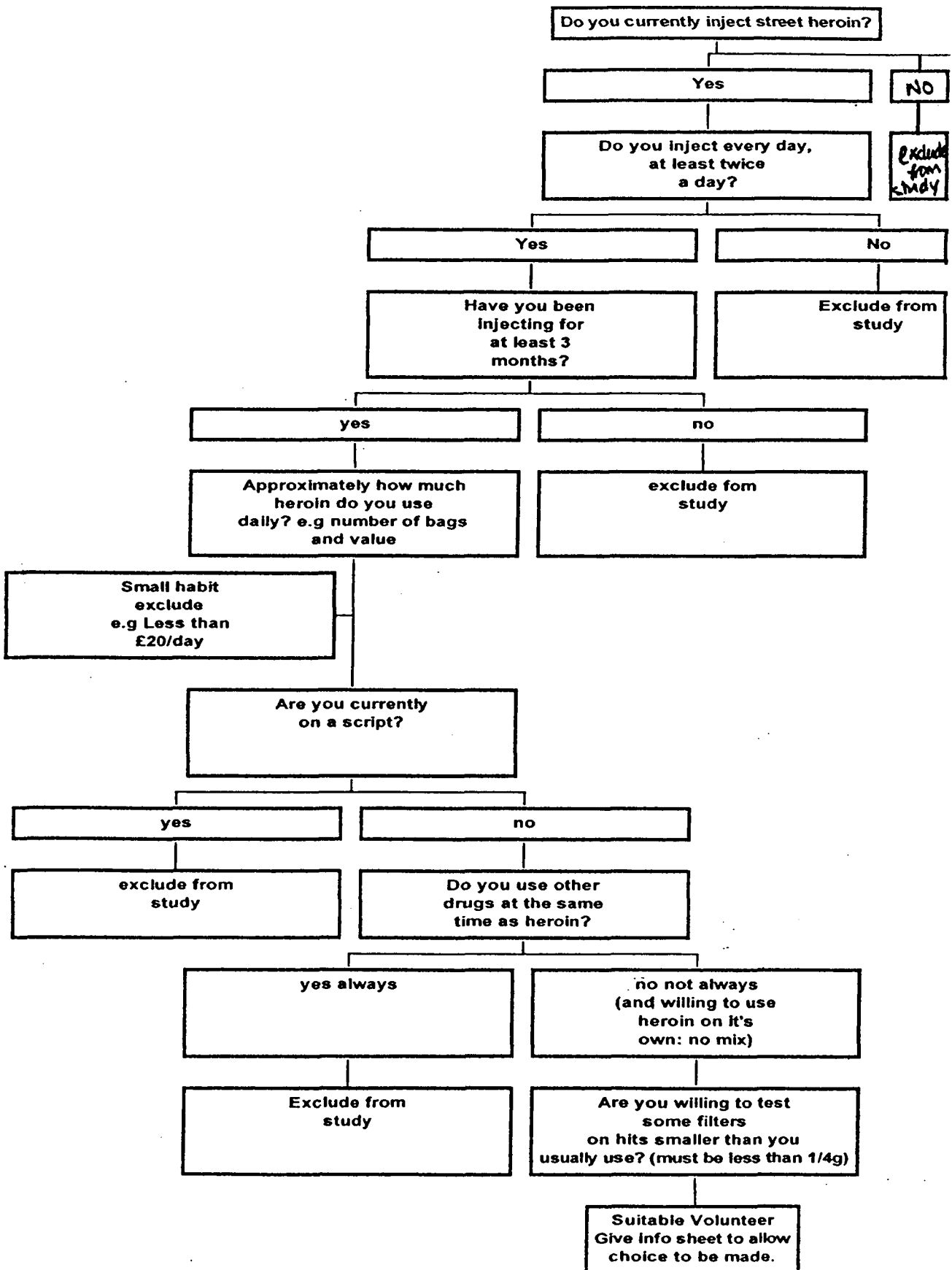
Researcher, RGU.

'Gathering users opinions on the use of filters'

Protocol for Study

- a) The researcher will be present at Drugs Action needle exchange to recruit volunteers personally, on the basis of a non random quota sample.
- b) Potential volunteers will be given the information sheet to read and the questions on it asked.
- c) The researcher will then ask the potential volunteer: Do you usually visit the Drugs Action needle exchange at least once a fortnight?
- d) If the answer to this question is yes, the person's needle exchange card will be retrieved from the filing cabinet and the details of initials, dob and frequency of visits verified. Any mismatch, will exclude the volunteer.
- e) Then the flow diagram shown overleaf will be used to identify potential volunteers:

Inclusion criteria for volunteers



f) The person will then be asked if they wish to volunteer and told they can pull out at any time.

g) If the person wishes to volunteer, they will then be asked if they understand the information sheet and have any questions. It will be drawn to their attention, as detailed on the information sheet, that they must agree to supply a contact telephone number and agree they can be contacted if they haven't returned to the Drugs Action needle exchange within two weeks and filled out a questionnaire.

h) If the person agrees to go ahead with participation, they will then be asked to briefly describe the process they use to prepare and administer their injections. The researcher will interject appropriate harm reduction information on the basis of the techniques used. (e.g using clean, sterile needle each time to avoid transmission of hepatitis C and HIV, ways to reduce the risks of overdose, ways reduce injuries etc). They will be advised that injecting drugs is dangerous and should not be done alone.

i) The researcher will then show the volunteer a filter of the type for this study and explain how it is used and the rules of the study (see Instruction sheet). The user must agree to only use it with a small bag of heroin (£10 bag) and not to use filters more closely together than every fourth hit (e.g one hit with filter, three without etc).

j) The volunteer will again be asked if s/he wishes to participate.

k) If yes, the volunteer will be told not to give the filters to anyone else to use, as they personally have been assessed for the study. They will be reminded that injecting street drugs is dangerous, and offered harm reduction literature to take away, if required. They will be given an instruction sheet for using the filters and advised that they must follow the instructions on this sheet.

l) The volunteer will then be invited to ask questions and then asked to sign the consent form.

m) The volunteer will then be given 4 filters to test according to the instructions supplied and thanked for their participation in the study.

n) The person's first name, initials, DOB and contact details will be recorded on confidential participants list. A questionnaire will be attached to their NX card. If they have not returned to DA within 2 weeks, they will be contacted.

Instruction Sheet for Using the Syringe Filters

Please follow these steps when testing the filters. Not only does this tell you how to use the filters, it includes advice to help reduce the harm from injecting.

Remember: Only use the filter for a ¼ gram hit or less, do not use it for bigger hits as it has not been tested with bigger amounts. Only use with heroin, no other drugs. Also, don't use all four filters for four consecutive hits, filter one in every four hits maximum.

1. To stop bugs, viruses and dirt getting into your hits wash your hands before you prepare anything.



2. Use your own kit, including spoons, water, citric and cook up in your own space (e.g on a newspaper). Other people's kit should be in their own space, not yours. This is to stop viruses like hep C or HIV passing between people.



3. Take a new detachable syringe (1ml) and spike (usually orange for arm veins). If you usually use the end of the works to stir when you are cooking up, take the spike and syringe out of their packets before you cook up and fit them together.



4. Cook up, stirring with the covered spike.



5. Once you've cooked up, take the spike off the end of the syringe (do not remove the cover yet).



6. Take the filter out of the packet and fit it onto the nozzle of the syringe. (Only one end fits) as shown in the drawing below:



7. Put the tip of the filter into the clear liquid in the hit and draw back the plunger of the syringe slowly. The filtered liquid will fill the syringe, but it is quite slow.



8. When all the liquid has drawn through remove the filter and put on the covered spike firmly.



9. The hit is now prepared. Follow the safer injecting advice in the leaflet provided.



10. The filter will look stained from the hit. This is the particles and dirt that doesn't dissolve, the heroin drug will be dissolved in the hit. **DO NOT** reuse the filters, as bugs can grow in wet filters. **DO NOT** break open the filter to try to cook up the bit inside. Trying to cook it up may damage you. Put used filters into your cin bin and return to Drugs Action. Unused syringe filters must be returned to Drugs Action too.

Remember: Don't inject alone, if you OD there will be no one around to help. If you are worried that someone has OD'd phone 999 for an ambulance immediately. Ask the Drugs Action staff if you want more leaflets, advice or info. on drugs.

Client initial, DOB & DA ref. No. _____

Questionnaire for syringe filter testers.

Thank you for testing the filters for this study. Please tell me what you honestly thought of your experiences of using them. I need to know about good and bad experiences to get a true picture.

**1. What filters do you usually use when preparing your hits?
e.g cigarette end, Rizla filter, cotton bud, don't usually filter?**

2. You were given 4 syringe filters. How many of these did you use? (please circle):

none

one

two

three

four

If you didn't use all the syringe filters, what was your reason for this?

**3. What Injecting site(s) did you use when you tested the filters? e.g: arms, hands, feet, groin?
(Please write them below):**

4. Do you usually use insulin syringes for your hits?

Yes

No

5. If Yes to Q4, is it a problem to use detachable syringes and spikes instead of the insulin ones?

Yes (please write the problems below)

No

6. Did you have any problems using the syringe filters?

Yes (please write the problems below)

No

7. Do you think the hit was any different when you used the syringe filters?

Yes (please explain below)

No

Please turn over the page → → →

8. Compared to your usual filters, how easy do you think the syringe filters were to use? (please tick)

Much easier

A bit easier

No difference

A bit more difficult

Much more difficult

9. Overall, what do you think of the syringe filter compare to your usual filters? (please circle and write any further comments):

The syringe filter
is better

My usual filter.
is better

There is no difference.

Please comment why you think this?:

10. Do you think users would need a bit of practice with the syringe filters to get the hang of using them?

Yes

No

11. If the law changed and it became legal to give out filters from needle exchanges, what kind would you prefer to be given out?

Syringe filters

Cigarette filters

Other (please state)

Please write any further comments you have on the filters you tested below:

Thank you for your help with this study, it is greatly appreciated. If you want to speak directly to Jenny, the researcher about your experiences with the filters please ask the needle exchange workers to ask her to come and speak to you.

Pharmacist Session Enquiry Form

Enquiry No. _____ Date _____ Enquirer ref. _____ C W

Last date of use (if applicable): _____ ASAP _____

Details of Enquiry:

Clients, if applicable :

Would you consider asking a chemist in a shop about a query such as this?
(note response and why)

Response:

Response details					
Time	Immediate	Non Immediate (state)			
Method	Verbal	Written	Photocopy (state)	Leaflet (state)	Other (state)
Source	Knowledge base	Further Knowledge	Literature (state)	Other (state)	
Category					

Pharmacist Enquiry Form

Date: _____ Name of worker making enquiry: _____

Last date of use of reply (if applicable): _____ ASAP (please tick)

Method of reply required (please tick):

Verbal Written Published Info. Requested

Please note Jenny will be at Drugs Action every Tuesday afternoon.

If you need a reply before her next session please phone her office on 01224 262522. An answer phone will take your message if she is not available.

Details of Enquiry:

For reference use:

Response details					
Time	Immediate	Non Immediate (state)			
Method	Verbal	Written	Photocopy (state)	Leaflet (state)	Other (state)
Source	Knowledge base	Further Knowledge	Literature (state)	Other (state)	
Category					

What if I can't make it on Tuesday afternoons?

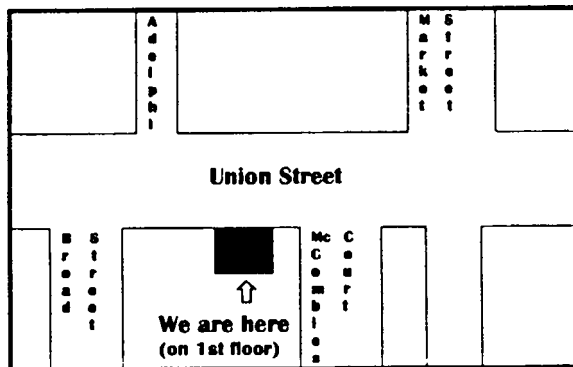
☎ Phone anytime during opening hours and leave your query with a Drugs Action worker

You can leave a number for reply or phone back the following Tuesday afternoon.

✉ Ask in writing: the staff can give you a pharmacist enquiry form. Fill out your enquiry and state your preferred method of reply. e.g. written reply (to collect at Drugs Action or have posted) or telephone reply.

This is a Free and Confidential Service

How to find us:



Other Services at Drugs Action include:

**Helpline
Needle exchange
Free Condoms
Counselling
Women Only Sessions
Joint work with maternity services
Outreach Services
Recreational Drugs Team
Family Support Group
HIV worker
Prison work**



Drugs Action
48A Union Street
Aberdeen
01224 624555

PHARMACIST'S ADVICE SESSION

**Tuesday Afternoons
2-5pm**

**No appointment
needed**

**Free and
Confidential**



Pharmacist's Advice Session

From September 1997 a pharmacist will be available at Drugs Action every Tuesday afternoon from 2-5pm for a six month trial period to provide information and advice.

This service is available to drug users, family members, friends and people who work with drug users.

What kind of information and advice?

Any aspect of drug use or health problems which you would like to discuss with a qualified pharmacist

e.g:

- ◆ How drugs affect the body**
- ◆ Drug interactions**
- ◆ Drug related injuries and illnesses e.g. abscesses, hep C**
- ◆ Non drug related health problems e.g. colds, 'flu**
- ◆ Sexual health and contraception**
- ◆ Children's Health**

Confidentiality

As with all Drugs Action services, this is a confidential and free service.

Making Contact

**You don't need an appointment, just drop in.
Tuesday 2-5pm.**

**Drugs Action are at
48a Union Street
see map overleaf →**

**or phone 624555 and ask to
speak to the pharmacist.**

DA



Pharmacist's Session

From September a Pharmacist will be available at Drugs Action every Tuesday afternoon from 2-5pm to provide Information and advice on a range of subjects.

e.g.

- ◆ **How drugs affect the body**
- ◆ **Drug interactions**
- ◆ **Drug related injuries and illnesses e.g. abscesses, hep C**
- ◆ **Non drug related health problems e.g. colds, 'flu**
- ◆ **Sexual health and contraception.**
- ◆ **Children's health**

This is open to anyone and as with all Drugs Action services it is completely anonymous and confidential.

Please drop in Tuesdays between 2-5pm or ask the staff for a confidential Pharmacist Enquiry form  or phone on 01224 624555 

Grampian Lesbian, Gay and Bisexual
Switchboard
PO Box 174
Aberdeen

Grampian Racial Equality Council
9a Little Belmont Street
Aberdeen

Home Start Mastrick
Mastrick Parish Church
Greenfern Road
Aberdeen

SACRO
18 Little Belmont Street
Aberdeen

Substance Misuse Service
(formerly Drug Problem Service)
Old Irvine Ward
Royal Cornhill Hospital
Westburn Road
Aberdeen

Torry Advice Centre
26 Menzies Road
Aberdeen

Victim Support
Aberdeen Branch
4 Albyn Place
Aberdeen

Victoria House
West North Street
Aberdeen

Women's Centre
Shoe Lane
Aberdeen

Grampian Welfare Rights
47 Belmont Street
Aberdeen

Grampian Women's Aid
10-16 Exchequer Row
Aberdeen

Incest Survivors Group
PO Box 91
Aberdeen

Social Work Department
Quarry Centre
Cummings Park Crescent
Aberdeen

The Samaritans
60 Dee Street
Aberdeen

Victim Support
Regional Office
47 Belmont Street
Aberdeen

Victim Support
Buchan: 01771 623741
Deveron & District (Banff): 01261 842735
Gordon, Wyness Hall, Jackson Street,
Inverurie.

Voluntary Service Aberdeen
38 Castle Street
Aberdeen
AB1 1AB

Services that received Pharmacists Session publicity
(taken from the DA service publicity distribution list)

Aberdeen Alcohol Counselling Service 62 Dee Street Aberdeen	Aberdeen Counselling and Information Service 44 Castle Street Aberdeen
Aberdeen Friendship Group 14 Dee Court Dee Street Aberdeen	Aberdeen Rape Crisis Centre 54 Frederick Street Aberdeen
Aberdeen Women's Aid 66 The Green Aberdeen AB11 6PE	Aberlour Childcare Trust 31 Auchinyell Road Aberdeen
Aberlour Childcare Trust 8 Sunnybank Road Aberdeen	Alford Centre 8 Alford Place Aberdeen
Benefits Agency Greyfriars House Gallowgate Aberdeen AB10 1ZU	Children's Family Trust 16 Nothrburn Avenue Aberdeen
Citizen's Advice Bureau 47 Market Street Aberdeen	Craiginchies Prison Drug Team Grampian Place Torry Aberdeen
Cruse Bereavement Care 19 Fonthill Road Aberdeen	Cyrenians Day Centre 62 Summer Street Aberdeen
Cyrenians: Women's Hostel c/o Caroline	Cyrenians: Stopover 61 Langstane Place Aberdeen 01224 210194
Cyrenians: Stopover 252 Union Street Aberdeen	Cyrenians: Cygnet Project Union Street Aberdeen
Deeside Family Centre Gidleness Road Torry Aberdeen	Family Planning Centre 13 Golden Square Aberdeen
Fersands Family Centre 19b Sandilands Drive Aberdeen	G.U.M Clinic Woolmanhill Hospital Woolmanhill Aberdeen

Outcome Results from Pharmacist's Session Interventions

Enquiry No. _____ Drugs worker: _____ Date of follow up: _____

Key issues at query:

Key interventions:

Outcome (including time indicators):

DRUGS ACTION STAFF QUESTIONNAIRE

Section 1.

Please read the statement on the left and tick the box which best fits your response to it on the right.

	Strongly Agree	Agree	Undecided	Disagree	Strongly disagree	Not Applicable
1. I think it is vital that a pharmacist attached to the team receive induction training from DA.						
2. I think the clients would feel confident that a pharmacist working at DA was providing a confidential service.						
3. I think a pharmacist could contribute to staff training.						
4. I think the clients would feel comfortable talking to a pharmacist at DA.						
5. I think the clients would not feel comfortable talking to a pharmacist						
6. I think drugs workers know more about 'drugs of abuse' than pharmacists.						
7. I think a pharmacist may have a conflict of interest when working with DA clients						
8. I think the information a pharmacist could contribute is already available to the team i.e. in text books, leaflets, from outside organisations.						
9. I think the clients would benefit from having a pharmacist at DA.						
10. I think a pharmacist would not be able to contribute positively to the team.						
11. I think I would feel happier a pharmacist gave out medical advice than a drugs worker.						
12. I think attitude is a personal thing and not moulded by profession.						
13. I think a pharmacist would not be much use to DA clients.						

Continued over ⇨

	Strongly Agree	Agree	Undecided	Disagree	Strongly disagree	Not Applicable
14. I think a pharmacist could contribute to training for outside organisations.						
15. I think communications with medical-based services would be improved if done by a pharmacist.						
16. I think a pharmacist could contribute positively to the work of the team.						
17. I think a pharmacist would have problems communicating with clients.						
18. I think it unlikely that a pharmacist will be able to have a non judgmental attitude to clients because of their profession.						
19. I think a pharmacist would not understand the nature of drug use.						
20. I think clients on a script may worry about confidentiality when talking to a pharmacist at Drugs Action.						

1. Please briefly describe what you see, if any, the main role of a pharmacist at Drugs Action to be:

2. Please briefly describe reservations, if any, you have about a pharmacist coming to work at Drugs Action:

Thank you for completing this questionnaire

Jenny Scott
 The Robert Gordon University
 tel: 01224 262522

DRUGS ACTION STAFF QUESTIONNAIRE [post service]

Section 1.

Please read the statement on the left and tick the box which best fits your response to it on the right.

	Strongly Agree	Agree	Undecided	Disagree	Strongly disagree	Not Applicable
1. I think it is vital that a pharmacist attached to the team receive induction training from DA.						
2. I think the clients would feel confident that a pharmacist working at DA was providing a confidential service.						
3. I think a pharmacist could contribute to staff training.						
4. I think the clients would feel comfortable talking to a pharmacist at DA.						
5. I think the clients would not feel comfortable talking to a pharmacist						
6. I think drugs workers know more about 'drugs of abuse' than pharmacists.						
7. I think a pharmacist may have a conflict of interest when working with DA clients						
8. I think the information a pharmacist could contribute is already available to the team i.e. in text books, leaflets, from outside organisations.						
9. I think the clients would benefit from having a pharmacist at DA.						
10. I think a pharmacist would not be able to contribute positively to the team.						
11. I think I would feel happier a pharmacist gave out medical advice than a drugs worker.						
12. I think attitude is a personal thing and not moulded by profession.						
13. I think a pharmacist would not be much use to DA clients.						

Continued over ⇨

	Strongly Agree	Agree	Undecided	Disagree	Strongly disagree	Not Applicable
14. I think a pharmacist could contribute to training for outside organisations.						
15. I think communications with medical-based services would be improved if done by a pharmacist.						
16. I think a pharmacist could contribute positively to the work of the team.						
17. I think a pharmacist would have problems communicating with clients.						
18. I think it unlikely that a pharmacist will be able to have a non judgmental attitude to clients because of their profession.						
19. I think a pharmacist would not understand the nature of drug use.						
20. I think clients on a script may worry about confidentiality when talking to a pharmacist at Drugs Action.						

1. Based on your knowledge, experience and opinion of the pharmacy sessions which were provided at Drugs Action, do you think there is a role for a pharmacist as part of the team?

Yes No

If you answered yes to the above question, please expand by stating what you see the main role to be:

If you answered no, please expand by explaining why you think no role exists:

Thank you for completing this questionnaire
Jenny Scott
The Robert Gordon University
tel: 01224 262522

Examples of enquiries received by the pharmacist at Drugs Action.

Category: Adverse Drug Reaction (Prescribed)

Example 1: a male amphetamine user presented to the duty worker shortly after his release from prison and was referred to the pharmacist. He was concerned that while he was in prison and drug-free his asthma had become much worse. He wanted to know if his symptoms could be a withdrawal effect due to stopping his amphetamine use? He described his asthma as mild before his imprisonment. On questioning, he reported he had been experiencing chest pain and tightening infrequently for several months, which was not accompanied by wheezing. He had received ibuprofen 400 mg tds for these symptoms while in prison and had been given further supply for the same on release. He had no knowledge of having taken ibuprofen previously and was unsure if he had ever taken aspirin. The ibuprofen had been given regularly in prison, however he was taking it less frequently since his release. The pharmacist considered the worsening of the clients' asthma to possibly be an adverse reaction to the ibuprofen. She advised the client of this and suggested he discontinue the ibuprofen and consult his doctor about the chest pain and tightening. [She considered the chest pain and tightening could be attributable to his heavy and prolonged amphetamine use, so this was categorised a drug-related health problem (see below)]. The client reported not being registered with a GP, so the pharmacist informed him of the procedure to obtain one. An appointment was also made for him with a drugs worker to look at issues identified around his drug use.

Example 2: the duty worker referred a male ex-heroin user to the pharmacist. He had received naltrexone from his GP, who was in another city. He had returned to Aberdeen the previous day for the festive period and commenced his therapy that same day, previously having received lofexidine. He reported shakiness and 'feeling nervous' since waking on that day. Since he was unable to see his GP for two weeks he came to Drugs Action for advice. He wanted to know if the naltrexone could be responsible for his symptoms. The pharmacist questioned him on his therapy, and on his feelings around returning to Aberdeen. She informed him that naltrexone can cause anxiety and nervousness, so may be responsible for his symptoms. She also identified he was worried about returning to the city. There were pressures from being with his family and temptation from being in the near vicinity of people who he had known when he was using heroin. She offered further support from a drugs worker during his period in Aberdeen.

Category: Adverse Drug Reaction (Not Prescribed)

Example 1: A young woman telephoned the help-line. She told the duty worker that she had taken a 'half gram wrap of speed' the previous evening and now could not see very well. She also reported being epileptic. The worker encouraged her to go to her GP but she insisted she was unwilling to do so and she would not speak directly with the pharmacist. The duty worker contacted the pharmacist for assistance in formulating a response. He wanted to know if amphetamine could affect vision and what information the pharmacist could supply on the use of amphetamine in epileptic people. He did not know what treatment she received for her epilepsy. The pharmacist informed the duty worker that, although not a common side effect, amphetamine might cause visual impairment. She also acknowledged that the problem could be attributed to an unknown adulterant in the drug. The pharmacist also told the worker that stimulant use, such as amphetamine and ecstasy, was particularly inadvisable in epileptics as the stimulant effect can induce seizures. She advised the worker that the client should be strongly persuaded to consult her GP and the confidentiality of GPs explained. The duty worker relayed this information to the client, explaining that although there was harm reduction advice given for stimulant use, in her case, it was considered that any use would result in a high level of risk.

Example 2: A drugs worker consulted the pharmacist after a regular appointment with a male client, who was a poly-drug user. The client used stimulants and sedatives on a frequent basis. The client reported recent memory loss and feeling 'vague'. He had recently started using ketamine. The drugs worker was working with the client to try to reduce the number of different drugs he consumed and place boundaries on those he did use. The drugs worker wanted to know if the memory loss and vagueness could be a reaction to the ketamine, so he could prioritise the use of this drug in context with the others. The pharmacist confirmed that memory impairment had been attributed to heavy ketamine use. The impairment has in some cases been long term. However, it was possible that other drug use may be contributing to the problem, particularly the use of benzodiazepines. The pharmacist provided the drugs worker with written information on ketamine and supported discouraging the client from using it.

Category: Drug Information (Prescribed)

Example 1: The duty worker referred a male heroin user to the pharmacist for information. Previously, the client had been on a methadone reduction programme, but had relapsed and his prescription had been stopped. Although he now wished to stop using heroin, he

was reluctant to begin another methadone programme as he reported feeling very lethargic when receiving methadone and having experienced severe withdrawal on dose reduction. He was keen to undertake a detoxification programme using lofedixine and had been referred to the specialist prescribing service. On assessment, he was informed that he was not suitable for such a programme as his blood pressure (B.P) was too low. The client wanted to know 'if this was true'? He had been asked to return in one week for further assessment. The pharmacist explained that lofedixine has to be used with caution in people with low blood pressure and the information from the specialist service was true and they were safeguarding his welfare. Since he had only had his B.P taken on one occasion, she also advised the client to request his blood pressure to be monitored again on his next appointment, to check if it remained low. The pharmacist also explained that heroin can reduce blood pressure in large doses, so advised the enquirer not to use any before his appointment.

Example 2: A drugs worker asked the pharmacist for information to give a client in her next appointment. The woman was taking paroxetine, prescribed by her GP, for depression. She did not usually drink alcohol, but with the forthcoming festive season, wanted to know if it was safe to do so, along with her medication. She was a relative of a drug user and took no other drugs herself. The pharmacist informed the drugs worker that paroxetine does not commonly interact with alcohol so the majority of people experience no problems. However, as a precaution, she suggested only consuming a moderate amount of alcohol and experimenting first with half a glass of wine, to investigate for increased sedation.

Category: Drug Information (Not Prescribed)

Example 1: An outreach worker requested more information from the pharmacist in relation to a contact she had made at a youth project. A young female had recently found out she was four months pregnant and had been smoking cannabis on a frequent basis. She would not discuss this with her doctor or midwife and asked the drugs worker what the effects of cannabis would be on the foetus. The drugs worker asked the pharmacist for information on the effects of cannabis at all stages of pregnancy and breast-feeding. The pharmacist undertook a literature review and provided the outreach worker with a summary of the information she had gathered and copies where appropriate. In relation to the contact, the pharmacist advised the drugs worker that although some evidence had suggested a risk of low birth weights, this had not been proven. Overall there was considered to be no risk of an increase in foetal abnormalities or developmental

retardation. However, the evidence on risks of childhood cancers was inconclusive. It is certain there would be risks from the tobacco smoke. The pharmacist advised the worker to encourage the contact to stop smoking cannabis and, if applicable, cigarettes.

Example 2:

The agency received a report from the police forensic laboratory on the analysis of recently seized Ecstasy tablets in the Aberdeen area. All analysed tablets contained more than one active compound and none contained MDMA. The Incite workers asked the pharmacist to review the report, provide further information on some of the compounds and to suggest harm reduction advice that could be given to Ecstasy users on these particular tablets, acknowledging that guarantee of contents cannot be given on appearance alone. The pharmacist prepared a report summarising the risks from each identified compound and combination of compounds, making recommendations on advice for users. She also provided published information to the workers, where appropriate.

Category: Drug Testing

Example 1: A female was referred to the pharmacist after contacting the duty worker for information. Until one week previously, she had been using cannabis on a daily basis. She had also received paroxetine from her GP for depression, which she had stopped taking 10 days previously. Her reason for discontinuing both drugs was that she had a pre-employment medical for an administration job with an oil company. She wanted to know if either drugs would be detectable if she was given a urine test. The pharmacist informed the woman that cannabis use with a frequency such as hers could be detectable for at least 30 days. She gave the woman an information leaflet on cannabis. The pharmacist established that the woman had not received advice from her GP on stopping paroxetine. She reported feeling *'better without it'* although asked if recent dizziness could be due to stopping treatment. The pharmacist explained that since she was receiving the paroxetine from her GP she should not be penalised by the company if it was screened for and detected. The woman indicated she felt embarrassed at having to take an antidepressant, so had not declared this on her application. The pharmacist also informed the woman that some people do experience withdrawal symptoms if they suddenly stop taking medicines such as paroxetine, but her dizziness should be investigated. She suggested the woman explain her reasons for stopping her treatment to her GP, just as she had to the pharmacist. She identified several personal pressures that the woman reported being under, so gave her information on a generic counselling agency where she could get support.

Example 2: A drugs worker referred a male client, with a history of poly-drug use, including heroin, cocaine and amphetamine, to the pharmacist. He was under the care of a specialist prescribing service and no longer using street drugs. He had been prescribed thioridazine for periods of irritability and violent outbursts and had hoped they would '*calm him down*'. On taking one dose he slept for 18 hours and felt '*knocked out*' on waking. He did not intend continuing this prescription and wanted to know if the specialist prescribers would be able to tell by his urine test if he substituted his prescribed medication with diazepam bought on the streets. The pharmacist informed the client that the two drugs were not similar and they could be differentiated in urine screening. She discussed the different effects of diazepam and thioridazine and the potential risks from self-medicating with diazepam. These included the risk of dependence, increased involvement with dealers that could promote relapse onto other drugs, and the dangers of mixing diazepam with other drugs if he did relapse. She also discussed the dangers of mixing either drug with alcohol. The pharmacist also discussed the reasons why the client received the prescription and what he had hoped the thioridazine might do. The clients' next appointment with the specialist service was in two weeks. He was reluctant to take further thioridazine, so the pharmacist discussed the possibility of the client splitting the tablets and taking half his prescribed dose. He said he might be willing to try this to see if there was less sedation. The pharmacist encouraged the client to tell the specialist service about his experience with the thioridazine and if he continued it, to tell them what dose he was taking.

Category: Health Problem (Drug related)

Example 1: A woman presented at the needle exchange for advice from the duty worker, who sought the pharmacist's advice. The client had had an abscess on her arm some weeks previously and had at the time taken antibiotics from her GP. She was no longer injecting and had switched to inhaling vaporised heroin as an alternative method of administration. Although no longer painful or red, the abscess had not healed completely and the centre was described by the worker as '*black and hard*'. The woman wanted to know whether this was normal and would heal in its' own time or should she go back to her GP? The pharmacist inspected the site and observed the centre of the abscess to be filled with a necrotic plug. She advised the woman that this was unlikely to clear without further medical attention and suggested she go back to her GP or practice nurse for wound care.

Example 2: A drugs worker asked the pharmacist for advice that he could give to a client in his next one-to-one appointment. The client was taking 70 ml of methadone 1mg/ml daily, diazepam and temazepam, all of which were being prescribed. The doses of the benzodiazepines were unknown by the worker. The client was severely constipated and experiencing bleeding on defecation. The client had informed his GP, who had explained that methadone causes constipation. However, the client reported that he had not received further advice or treatment and was reluctant to discuss the matter with his GP again. He was embarrassed to talk to his community pharmacist. He asked his worker if he knew what he should buy to relieve his constipation. The worker had discussed eating habits with the client and established that he had a very poor diet. The pharmacist discussed the treatment of constipation with the worker. She informed the worker that for immediate relief, glycerine suppositories may be suitable, however she was concerned about the reported bleeding. For continued relief lactulose may be of benefit. She suggested the worker establish what fruit juices, fruit and vegetables the client liked and suggested trying to incorporate some into his diet. She also told the worker to encourage the client to drink plenty of liquids. The pharmacist suggested that at the next appointment the worker tried again to encourage the client to speak with his GP for advice on the bleeding and report any over-the-counter medicines used.

Category: Harm Reduction Technique

Example 1: A drugs worker asked the pharmacist to give advice to one of her clients. The client had begun injecting cyclizine tablets. The drugs worker was aware of general information on the injecting of tablets and had discouraged the client from doing so. However, she wanted to know if there was any information that particularly applied to this formulation. The pharmacist informed the worker that cyclizine causes some other drugs to precipitate if they are mixed together in solution. Therefore, in theory, mixing it with other drugs, which was a known practice of some local IDUs, would be especially risky. Potentially, the precipitate could block veins. The worker informed the client that injecting tablets was especially dangerous and best avoided. If she insisted on injecting cyclizine tablets, she should not mix them with other drugs and she should filter them.

Example 2: The DA co-ordinator had received information on research into the use of the rectal route as a safer alternative to injecting. He asked the pharmacist to review this information and give comments, based on her knowledge of this route for drug delivery and street drugs. The pharmacist assessed the information and prepared a report for the co-ordinator.

Category: Identification

Example 1: A client presented at the needle exchange with a tablet and asked the duty worker if he could confirm its' identity. The worker asked the pharmacist for advice. On questioning the client, the pharmacist established that he owned the tablet, having purchased several from someone else. He had bought them under the premise that they were temazepam tablets, strength unknown. He was concerned because the lettering on the tablets was different from temazepam tablets he had bought previously. He intended to prepare and administer several by injection. The pharmacist used the Tic-Tac service to identify the tablets, which were found to be carbamazepine 100 mg. She told the client what they were and discussed the potential risks of taking them. She advised strongly against consuming them in any way. She provided a leaflet on the general risks from injecting tablets.

Example 2: An outreach worker contacted the pharmacist after a tablet was found on the floor of a community centre where she was working. The community education staff asked the worker to identify it and for advice on the action to be taken. The worker asked the pharmacist for help. The pharmacist took a description of the tablet from the worker and used the Mims identification directory to identify it. She told the worker that from the description, the tablet appeared to be the antihistamine preparation 'Clarityn[®]' (loratidine). She discussed its' uses with the worker who also wanted to know if there was potential for misuse and overdose risks.

Category: Medical Information

Enquiries in this category were requests for the provision of information on medical as opposed to pharmacological matters.

Example 1: The women's worker contacted the pharmacist for information. The request stemmed from a discussion she had had with the medical staff at the recently established 'Golden Square Clinic' (9.1.1). The worker asked the pharmacist if she could provide any information on whether people who were hepatitis C positive should breast-feed.

The pharmacist supplied the worker with papers that reported studies investigating vertical transmission of hepatitis C and included breast-feeding, for review by the clinic team

Example 2: An outreach worker contacted the pharmacist regarding a male client, who was a heroin user. The client had had a seizure two years ago and earlier in the week of contact he had experienced another. The client saw his GP who made a referral to the hospital neurology department. In his appointment with his worker, the client told her he was worried he would be treated badly if the hospital found out he was a drug user and he did not know what the appointment would entail. He had not felt able to discuss the matter with his GP, so asked the outreach worker if she knew what the neurology dept. visit would involve. The worker asked the pharmacist. The pharmacist told the worker that she could only advise from her general knowledge of epilepsy and suggested the client asked for the planned investigations to be explained when he attended or reconsidered asking his GP for further advice. The pharmacist told the worker that the activity of his brain waves would probably be monitored using attached electrodes. She reassured the worker that this was not painful and no anaesthetic was required. She also told the worker to encourage the client to be honest about his drug use with the hospital, as it may be a factor relating to the seizures. She also pointed out that the clients GP and the hospital would communicate on his referral.

Category: Pharmaceutical Services

Example 1: One of the workers told the pharmacist that they were receiving an increased number of help-line calls from people who were unable to find a pharmacy willing to dispense their methadone or supervise its consumption. The worker asked the pharmacist what could be done to help people find a place to get their prescription dispensed. The pharmacist contacted the department of primary care at Grampian Health Board and spoke with one of their pharmacists. They discussed work in place to implement a shared-care scheme, which aimed to spread the workload amongst pharmacies in providing services to methadone patients. In the interim period before the scheme was launched, the pharmacist was told that people having problems finding a pharmacy should be referred back to their prescriber or the dept. of primary care for assistance.

Example 2: A mother whose daughter was an ex-heroin user and receiving a regular prescription of diazepam and zimovane contacted the help-line. She wished to make a complaint to the Pharmaceutical Society regarding service she had received in a pharmacy, whilst collecting her daughters' prescription. She contacted the help-line to ask for the RPSGB phone number. The duty worker asked the pharmacist to speak with the mother. The pharmacist established the details of the situation. She suggested the

mother wrote a letter rather than making a telephone call, as this would allow her to reported all the facts clearly and calmly. The pharmacist considered the issue to be more appropriate to be referred to the Health Board in the first instance, so gave the caller the name and address of the person that complaints should be directed to.

Category: Other

Example 1: A drugs worker asked the pharmacist to explain the legal situation around 'poppers'. This was shortly after the reclassification of amyl nitrate to POM. The pharmacist explained the legal reclassification and copied two news items from journals for the worker.

Example 2: A male ex-heroin user contacted the agency to ask how long names were kept on the addicts index and if employers could access it. The pharmacist explained the recent end to the keeping of the index. She explained it was now archived and could be accessed for research purposes but employers would not use it for checking up. His name would still be on record, but any use of the index for research reporting would be anonymous.

Ethical dilemmas faced by the pharmacist and the handling procedures used.

Provision of information to third parties

The request for information from people secondary to the person about whom an enquiry related was considered to present an ethical dilemma. The competing values were the wishes and needs of the enquirer versus the wishes and needs of the person about whom the enquiry related. Two enquiries arose where the pharmacist was asked to provide information by a person secondary to a drug user. One was from a mother who had found a tablet in her child's bedroom and wanted to know what it was. The other was from a care worker in a children's home who had found a cellophane wrapping of a powder in a dormitory and again, wanted to know its identity. In both cases the children were under 16.

Before giving a response, the pharmacist considered relevant ethical and legal guidance from professional bodies and the literature. The RPSGB (1997) gave no guidance on requests for information from third parties, except in the case of requests from coroners, judges or court officers, where information must be supplied¹. The Code of Practice for Drug Information Services (UKDIPG, 1997a and b) infers the enquirer is the one to whom the pharmacist has a responsibility to provide information, but does not categorically state this. This code also discusses necessity to supply non-patient information when requested to do so by a legal body. Kelly et al (1990) discuss the provision of information to a third party, where both parties are adults. The pharmacist is not considered to have a duty of confidentiality to the person about whom the enquiry is made, since the breach of privacy is on the part of the caller not the pharmacist. The authors suggest establishing whether the caller has a right to the information requested, then making a decision on whether the information should be given. Daly and Bower (1997) again set a case study and asked selected pharmacists to indicate how they would respond. In this case the caller was the parent of a minor. One respondent suggests the pharmacist must establish to whom the duty of confidentiality belongs, the enquirer or the child. It is considered that when the pharmacist has no prior knowledge of the child, the enquirer should be provided with the information. Another states the mother has '*a right to know*', but reports to be responding as a mother and not in her professional capacity. In Scotland, the provision of confidential medical care and legal services is governed by the Age of Legal Capacity (Scotland) Act 1991 (The Law Society of Scotland, 1991). This act dictates that if a medical practitioner believes a child (under 16) is able to understand the nature and possible consequences of a treatment/procedure they can consent to their own treatment.

¹ Since this work was undertaken, the RPSGB have expanded their guidance in this area. See RPSGB, 2000.

Doctors should encourage children to allow their guardians to be informed, except in circumstance where it is clearly in their best interest not to do so. However, if the child is capable of understanding the nature and consequences of the treatment and refuses to allow their guardians to be informed, the doctor should respect their confidentiality. If the child is believed incapable of understanding, parental consent is necessary, except in emergencies. The existence of this act means that it cannot be assumed that a parent or guardian has knowledge of their child's medical care. Therefore, requests for information on such should be handled carefully. Identification of the provision of medical care without the guardians knowledge, informs the pharmacist that a doctor has made the decision that the child is capable of consent and is up-holding their right to confidentiality. The pharmacist is ethically required not to compromise the wishes of the patients' doctor, as stated by the RPSGB (1997 and 1999) and UKDIPG (1997b). Providing information to the parent or guardian that suggests why medication was being prescribed could be seen as compromising the wishes of the doctor. When illicit drug use is suspected, there are further implications from revealing the identity of the substance. If the substance is controlled by the Misuse of Drugs act, there are implications for the person responsible for the house (Tyler, 1995). Knowledge of the presence of a controlled drug without reporting of the drug to the authorities could be interpreted as conspiring in illicit drug use.

In both cases that presented dilemmas, the pharmacist established: (i) who the enquirer was and their perceived right to the information. (ii) if the person the enquirer is calling about was under medical care (or anything from the enquiry indicated this to be the case), (iii) the background to the enquiry being made, such as how the enquirer came to be in possession of the tablet/powder. The pharmacist then arranged for contact to be made with the enquirer later in the afternoon. First it was noted that although the identity of the drugs was suspected, they could not be confirmed without analysis. The tablet found fitted the description of recently reported Ecstasy tablets. This was confirmed by Tic-Tac. The pharmacists suspected the powder to be heroin. The potential consequences of information provision, including benefits and harms to both the enquirer and the owner of the drugs were considered. The legal status of the drugs was also considered. Divulging the identity of prescribed drugs may interfere with the patient-prescriber relationship, or the patient may have a specific reason for not informing the enquirer of their treatment. In such cases, the pharmacist considered it would have been appropriate to declare the prescription status but not the identity. This would allay fears of illegal drug use and encourage discussion between the enquirer and the patient. However, in both cases the drugs were suspected to be illegal. The pharmacist considered it appropriate to inform the enquirer that knowledge or suspicion of the identity of the drug, carried legal implications and they would have to make a decision on what course of action to take if they were given a suspected identity. They were also asked to consider what they would do with

information on possible identity of the drug. Giving a suspected identity of the drugs carried potential consequences for the drug owner, but the pharmacist considered in the given situations that the rights of the enquirer were her priority. The enquirers were informed of the suspected identity of the drugs. The reasons surrounding discovery of the drugs by the enquirers were also explored, which lead to further discussion on prior suspicion of drug use, possible action and privacy. Knowledge of the enquirers on the drugs concerned was discussed and information leaflets sent. Discussion with the drug owner was encouraged, with the importance of maintaining communication highlighted.

Verification of information from another professional source

Nine enquirers [seven members of the public and two DA workers] asked the pharmacist for verification of information received from another health professional. In seven cases this was a GP, in one case a specialist nurse and in one case a pharmacist. In three cases the reported information was considered by the pharmacist to present an ethical dilemma when formulating an honest response. Pharmacists are encouraged to respond to information enquiries from members of the public, but must not undermine any established relationship with their doctor (RPSGB, 1997). The competing areas of the dilemmas were upholding trust of the practitioner versus allowing patients to believe information that was incorrect or had been interpreted as such. The recommendations made by UKDIPG (1997b) again endorse the need for care not to undermine any established relationship with a doctor or pharmacist. However, pharmacists are advised to correct any inaccurate knowledge and inform the relevant practitioner, where appropriate. The three dilemmas that presented were as follows:

(i) See appendix 27, Adverse Drug Reaction (prescribed), example 1. This presented the dilemma that the enquirer had been given ibuprofen by a doctor and monitored by the nursing staff. The pharmacist identified an adverse reaction that had not been identified by the doctor or nurses and advised the enquirer to discontinue treatment. Although this advice did not support the medical advice, it was considered in the enquirers' best interest. The prison doctor was not informed since he was no longer responsible for the enquirers' medical care. The enquirer was urged to register with a GP and obtain further advice.

(ii) A drugs worker asked the pharmacist for information regarding one of her clients, who had been prescribed fluoxetine. The drugs worker knew the medication was prescribed for depression and eating disorders, but was concerned because the client had reported being told by her GP that the drug was a substitute for heroin. The client had not been

told that she suffered from depression and was aware that fluoxetine was an antidepressant. The drugs worker asked if the pharmacist knew if fluoxetine had been used in opiate dependency and for advice on how to deal with the situation as the client wanted to know if what the GP had said '*was true*'. After obtaining information on trials on the use of fluoxetine in dependence, the pharmacist considered that the benefits demonstrated had been restricted to relieving depression co-existing with opiate or cocaine dependence. Although the drugs worker reported the client had no knowledge of suffering from depression, the pharmacist told the drugs worker care was needed, as a diagnosis may have been made but the doctor believed it was in the patient's best interest not to be informed. The drugs worker was advised to suggest the client returned to her GP to ask for further information on her treatment. The pharmacist also suggested the drugs worker discuss the matter with the clients GP if the client was willing to consent to this.

(iii) A male telephoned the help-line and was referred to the pharmacist. He wanted to query information he had received from his community pharmacist. He was on a maintenance dose of methadone and planned to go abroad on holiday. He knew there were regulations that applied to carrying methadone abroad, so asked his community pharmacist for advice. He reported the pharmacist had informed him that if he transferred from methadone mixture 1 mg/ml to methadone tablets 5 mg, he could carry the necessary quantity of tablets abroad, without a licence. The pharmacist established where the enquirer intended travelling to and for how long. She confirmed the information she believed to be true with the Home Office. The client was informed of the correct procedures that applied to his situation and in doing so the pharmacist confirmed that the information received from the community pharmacist was wrong. An information sheet was produced that summarised the guidelines and procedures for taking controlled drugs abroad. A copy was sent to the enquirer to use in discussion with his GP. Further copies were kept in the agency for future use.

Provision of information on drug testing

In Grampian, two main groups undertake drug testing. These are specialist prescribing services and oil companies who screen employees. Thirteen enquiries related to drug testing of body fluids. Nine of these were from drugs workers and four were from members of the public. The pharmacist considered that such enquiries presented moral and in some cases ethical dilemmas. The moral dilemma was whether providing information on drug testing was colluding in illicit drug use. The ethical dilemma was

whether providing information could compromise the intentions of a practitioner by assisting their client in avoiding an undesirable test result.

The dilemmas that arose for the pharmacist were not around the provision of information per se. The DA workers reported their difficulty was not accessing information but interpreting the diversity of published information available. Information sheets for clients on testing produced by the Institute for the Study of Drug Dependence were available. The pharmacist found information on drug testing already in the public domain such as in music magazines and on the world-wide-web. At www.homedrug-test.com/ testing kits could be purchased for use at home and www.drugtest.com/ offered a lab based testing service. Details of drug detection times were on the web pages. Three enquiries from drugs workers were requests for assistance in interpreting published information. The pharmacist considered it appropriate to assist drugs workers in interpreting information generally, as it would assist them in their jobs.

Ten enquiries related to specific client issues. Four of these did not create any dilemmas. The six that created dilemmas will be discussed. Three related to employment. One was from a person who had an interview for a job at an oil company and had used cannabis one week previously (appendix 27, Drug testing, example 1). They wanted to know whether this would show up if a urine test was done. The second was from a person who was employed by an oil company who had been informed he had a urine test in one week and had used cannabis two weeks previously. The third was through a drugs worker regarding a help line call. This was from a person who had a past history of heroin dependency and had successfully detoxified using methadone prescribed by his GP. He had set up his own business some years previously and was in the process of changing his insurance provider for his company. His GP had noted on in the medical report for the insurance company that the person had a past history of heroin use. The company requested a urine test. The person had used cannabis a few days ago and wanted to know if there was a home testing kit they could buy to ensure that the urine test was not done until they had cleared all the cannabis from their system.

Kelly et al (1990) considered the responses of drug information pharmacists to a request for information on the detection time of marijuana in urine in relation to an employment screening; 59% said they would provide all relevant information. The authors state the caller must demonstrate a legitimate and non-harmful intention with the information. It is argued that undertaking employment such that of a bus driver or nuclear power plant technician would endanger the public, therefore there is harmful intention and the pharmacist has a social responsibility not to provide information. However, a positive urine test result indicates recent drug use, the pharmacist considered further evidence was

necessary to establish the person has or intends to work while experiencing pharmacological effects that impair functioning. It cannot be assumed that the person's drug use poses a threat to public safety, without establishing the nature and frequency of use or the job involved. The pharmacist therefore established whether the drug use of the clients would affect public safety. She considered identification of risk to others, would make her responsible for its prevention. Prevention could only be undertaken through discussion of the issues with the person responsible. Denying information alone would not remove the risk. Both the enquiries that related to oil companies were in relation to clerical jobs, considered unlikely to pose any risk to public safety. However, the conflict of undermining the employer was still pertinent. Both enquirers had however, already consumed the drugs concerned. The pharmacist considered it acceptable to inform them of the average time to clear cannabis from the system based on their patterns of use, but she did not advise the callers on ways to change the drug detection time after consumption. She took the opportunity of discussing responsibilities for public safety and offering information on the health and legal risks from using cannabis. The enquiry regarding testing kits presented the dilemma that the pharmacist considered it more harmful to the individual and society if the person lost his business than the risks to the individual and society from his occasional cannabis use. However, this presented the dilemma that cannabis use is illegal and the pharmacist should not impede the activity of the insurance company. The worker had informed the enquirer of the clearance times of cannabis. Aware of the availability of testing kits on the world-wide-web, the pharmacist suggested the worker ask if the enquirer had considered looking on the Internet. She was careful not to collude by divulging any web addresses or recommending any specific service.

Three enquiries related to drug testing by the specialist prescribing service. All three were from people who were using on top of their prescribed medication because they were not coping with the rapid reduction of their prescription. They all wanted assistance in interpreting the ISDD information regarding time to clear specific drugs and advice on when it was 'safe' to use. The dilemma for the pharmacist was that the protocol used by the local specialist prescribing service dictated that patients on substitute therapy who provided two contaminated urine tests during the course of their treatment, should be removed from the treatment list. There was a one-year waiting list for this service, so anyone removed from care would have to wait at least one year for further care if his or her GP was unwilling to provide substitute therapy. This conflicted with the pharmacist's understanding of substitute therapy. She acknowledged that some degree of illicit drug use may continue and that the benefits of receiving substitute therapy experienced by her clients and their communities would be removed if treatment was withdrawn. The pharmacist believed urine testing could be a useful adjunct in patient management only if

honesty with treatment providers was possible. She was also aware that testing laboratories are familiar with avoidance techniques and employ methods to avoid or detect their use (Simpson et al, 1993). The pharmacist considered she should not collude in assisting clients to avoid being removed from the specialist service list, even though she believed it to be wrong, as was a professional responsibility not to undermine the work of other professionals. Therefore, she confirmed that the ISDD information was correct and offered to negotiate with the specialist prescribers on behalf of the clients to discuss changing their care plans. She also used the opportunity to discuss the overdose risks of using on top of methadone.

Identification of unknown tablets/capsules

Seven enquiries fell into this category, three from drugs workers, three from members of the public and one from an outside service worker. One did not present a dilemma. Four have already been described, two under the identification category in appendix 27 and two under provision of information to third parties above. A further two related to clients who had bought tablets on the street and wanted to confirm their identity. The drugs workers informed the pharmacist that when they are asked to identify unknown pharmaceuticals, they use a published identification guide. However, they reported sometimes having difficulty finding information because generics are not included. All the enquiries presented to the pharmacist in this category were ones that the drugs workers were unable to answer themselves. The pharmacist considered an ethical dilemma could potentially arise from such enquiries as the pharmacist may be seen to be assisting in an illegal or immoral activity. However, she also considered refusing to answer the enquiries could cause harm, for example if the drug user mistook one drug for another and took it at a harmful dose or in a dangerous combination.

The pharmacist consulted the literature for guidance. No specific advice was given by the RPSGB (1997) or UKDIPG (1997a, b). Kelly et al (1990) investigated and critically evaluated the responses of pharmacists from DI centres across the USA to six ethical dilemmas. Although the responses were from pharmacists working to the American Pharmaceutical Association code of ethics, the ethical requirements described were sufficiently similar to those outlined by the RPSGB (1997), thus the guidance given was considered relevant to practice in the UK. When discussing the identification of pharmaceuticals, the authors support establishing the rights of the individual to the information. If the individual was not the owner of the pharmaceutical, this brings in the issues relating to the provision of information to third parties. In general, the authors advocate the provision of such information and conclude *'the good of offering such a*

service generally outweighs the possibility of the misuse of the information provided'. In the paper by Daly and Bower (1997), the authors present a case study where a mother asks a pharmacist to identify a tablet she found in her daughter's room. The identification of the tablet is not viewed as the debate, it is around the provision of information to someone other than the tablet owner. In a paper of a similar style, where an ethical dilemma is debated by several pharmacists, Uretsky (Veatch, Uretsky and Kelly, 1992) describes the purpose of drug information as being to provide information not withhold it and points out that in most cases the information can be established from other more inconvenient sources. This in itself, was not considered enough to justify the provision of information if there is concern that the information may be used to cause harm to oneself or others, or to bring about deceit. The pharmacist decided that if the purpose of the request was required to bring about deceit or harm others, she was under no professional requirement to supply the information. This is also the view of Kelly in the above paper. However, this did not apply to the cases encountered. The drug users who wished to verify identification did so because they intended to consume the drugs themselves. The pharmacist considered this an appropriate harm reduction opportunity as in two cases she could prevent mistaken identity. She could also use the opportunity to discuss relevant health and legal issues and the risks from tablet injection, if applicable. It could be argued that withholding information would have been morally wrong, as mistaken consumption could have lead to serious harm. In one case carbamazepine was thought to be temazepam and in the other temazepam was thought to be dihydrocodeine. Another drug user knew the correct identification of his tablets, but the tablets [nitrazepam] were stained with what looked like methadone. This provided an opportunity to discuss the interaction and risks of combined use. Enquiries that related to provision of information to third parties raised the further issues previously described.

Pharmacist's service client follow-up: description of cases

Case study 1.

Background:

A couple came into DA to ask the drugs workers for advice. The man, who had previously been a client of the agency, specified that he trusted the workers so wanted to ask their advice. The woman was not known to the agency. The duty worker asked the pharmacist to join the drop-in appointment to provide advice. The woman received a methadone maintenance prescription, the man reported being drug free for several years. The couple had recently had a baby who was in the Special Care baby unit, being treated for opiate withdrawal. The pharmacist dealt with three of the issues that presented:

Issue (1): The baby was receiving morphine. The couple were worried about dosage information they had read on the baby's drug chart, as they perceived it to be very high. They were also concerned that the dose had not yet been reduced. They came to DA to ask if the dose they reported the baby to be receiving was 'safe'.

Response: From the reported dosage, the pharmacist suspected that the units of dosage had been misunderstood (milligrams instead of micrograms) and she informed the couple of this. She identified the woman felt an incredible amount of guilt about the situation their baby was in, and was being blamed by her partner. The woman had not discussed her baby's care with hospital staff because she feared judgement and her baby being removed by social work. Instead, the couple had been reading the care notes by the crib unguided. The pharmacist explained to the couple what a care plan was. She suggested the couple ask to meet with a doctor and nurse looking after their baby and ask for the care plan to be explained. The drugs worker discussed issues around guilt, self-esteem and child protection.

Issue (2): The woman had an older child who had a form of autism. She wanted to know if taking methadone during her pregnancy would increase the chances of the baby being autistic.

Response: The pharmacist informed the woman that there was no evidence that use of methadone in pregnancy caused autism in children. The pharmacist suggested the woman discuss the issue of autism with the paediatrician.

Issue (3): When the woman began her methadone prescription, her GP had told her she must not drive. Although not usually a problem, she was finding this increasingly difficult as she lived 15 miles from the hospital. She feared the staff would judge her as uncaring as the times of the rural bus service she used and other child-care responsibilities meant she did not arrive at the hospital until half way through the visiting time. The pharmacist also felt her partner was pressurising her into driving and the woman sought support in her belief that she shouldn't.

Response: The pharmacist asked the woman to consider the issues around driving when taking sedative medicines and the risks to others. She also asked the woman to consider the potential consequences for her, her family and other people, if she ignored the advice. She explained the doctor was safeguarding her welfare and that of others. She suggested the woman discuss the issue with her GP at her next appointment. She suggested the woman ask the social worker on the ward if she was entitled to financial assistance with travel. The pharmacist also suggested the woman explain to the staff why she arrived later on.

Was the information used or advice followed?

The woman telephoned the pharmacist one week after contact. She reported that they had met with a doctor and nurse and the baby's treatment had been explained. The couple had misinterpreted information from the notes and were happy with the information they had received. The doctor had also reassured them around the issues of autism. The woman had not approached the social worker about travel expenses, but she had explained to the nurses why she would be late. She had not yet seen her GP, but was happier to travel by bus having been reassured by the ward staff that she was not expected to attend every visiting session for the whole duration.

Further input?

The pharmacist did not make further input to this case. The woman's worker continued to provide support.

Case study 2.

Background:

The duty worker asked the pharmacist to see a needle exchange client who came to DA for advice. The 17-year-old male heroin user presented with swelling in the left testicle and pain down the left leg, causing extreme difficulty in walking. Due to vascular collapse of peripheral veins he was injecting into his left femoral vein. One week previously he had

presented at A&E, where he received antibiotics and non-steroidal anti-inflammatories. The client did not want to return to A&E because he was still injecting. Also, he considered that he would be hospitalised and feared experiencing opiate withdrawal during this period.

Issue (1): The client's presenting symptoms.

Response: From the presenting symptoms and examination the pharmacist suspected the client could be suffering from a deep vein thrombosis (DVT). She explained her suspicion to the client and advised that he must return to A&E urgently.

Issue (2): The client's reluctance to return to A&E or be an inpatient.

Response: The pharmacist asked the client if he would be willing to go to A&E if she made contact with a staff nurse known to her and discussed his case. The client agreed. The pharmacist liaised with an A&E nurse whom she knew, she gave his name to the client and explained that the nurse was waiting for him. She also passed on information from the nurse that admission couldn't be enforced, only advised strongly if it was considered in his best interest.

Was information used or advice followed? The pharmacist saw the client two weeks later. He had acted upon the pharmacist's referral to A&E, and spent 7 days in hospital. He received substitute prescribing during this time and surgical and medical treatment for a DVT. The clients' stepmother also reported this information to the pharmacist at a later date.

Further input?

The client informed the pharmacist on follow-up that he had been prescribed warfarin. The pharmacist established what the client knew about warfarin. She advised him to go back to A&E if his symptoms returned or he experienced any uncontrolled bleeding and stressed the importance of monitoring. The client reported he was no longer reluctant to use A&E services if needed. The pharmacist explained that he was at greater risk from continued heroin injection and discussed the possibility of substitute therapy.

Case study 3.

Background: A client asked her drugs worker for information about injecting cyclizine tablets. The contact is summarised in 9.1.6 under the Harm Reduction Techniques category, example 1.

Issue (1): The client was injecting cyclizine tablets and wanted harm reduction advice.

Response: The pharmacist considered the risks from this practice to be large and the safest option was not to inject the tablets at all. However, the pharmacist and drugs worker both considered it likely the client would continue this practice and advised on the use of a filter and not to mix the tablets with other drugs.

Was information used or advice followed? At next contact with her drugs worker, the client reported continued use. However, she did report not mixing the tablets with other drugs and having used a filter.

Further input? Further input from the pharmacist was not considered necessary.

Case study 4.

Background: The pharmacist was asked by a worker to speak to a mother and her son, who was a heroin user, during a joint one-to-one appointment. The son had a past history of a severe head injury as a child. His GP was willing to prescribe methadone. However, the mother was concerned, as she had read that methadone shouldn't be given to people who have experienced head injuries.

Issue (1): The concern over the safety of methadone in this case.

Response: The pharmacist explained to the mother that in people who have just had a head injury, drugs like methadone have to be monitored carefully. However, a history of a head injury did not carry the risks that an active head injury did and the pharmacist considered methadone could be used, if the GP felt it appropriate. The pharmacist suggested the mother and son discuss the issue with the GP. The pharmacist also discussed safety issues around methadone use. The drugs worker considered the mother had several concerns about methadone and provided information on the benefits and risks to both her and her son.

Was information used or advice followed? On follow-up, ten days later, the drugs worker considered the mothers fears to be reduced. The son had seen the GP regarding a methadone prescription and was in contact with a worker for support.

Further input? Further input was not considered necessary.

Case study 5

Background: The pharmacist was asked by a drugs worker to speak to a client in a one-to-one appointment. The client was a poly-drug user, using diazepam, temazepam, methadone and dihydrocodeine, all orally. Only the latter was received on prescription. The client had no history of heroin use. The client was on a waiting list to see the specialist service. He was not willing to inform his GP of his current illicit drug use in case his prescription was stopped. He asked his drugs worker for advice on reducing his illicit consumption. The drugs worker asked the pharmacist to input.

Issue (1): Advice on reducing the clients' poly drug use.

Response: The pharmacist confirmed that the client was not willing to seek the advice of his GP. She suggested beginning with the benzodiazepines and discussed the issues around benzodiazepine withdrawal. The client considered he was able to stop using temazepam as it was used occasionally. She advised consumption of a steady amount of drugs was preferable to binges and to avoid alcohol, although the client did not drink so this was not relevant. She devised a reduction plan for the client, on the basis of gradual reduction only when able to cope, avoiding rapid removal. She advised this to be followed until his referral came through, at which point he was advised to declare his level of use with the specialist service.

Was information used or advice followed? The client began the reduction plan and reported to his worker that he felt more 'control' over his drug use. After a short period of time he began care from the specialist service.

Further input? Input on this issue was not necessary due to the specialist service referral. The client did however bring his wife, who was not a drug user, to see the worker and pharmacist, for support.

Case study 6.

Background: A client was referred to the pharmacist by the duty worker for information on naltrexone. The contact is summarised in 9.1.6 under discussion of the category Adverse Drug Reaction (Prescribed), example 2.

Issue (1): The client wanted to know if naltrexone could be responsible for the symptoms he was experiencing.

Response: The pharmacist considered naltrexone could be responsible for the symptoms and also identified other issues the client had around his return to Aberdeen.

Was information used or advice followed? The pharmacist arranged an appointment for the client with a drugs worker in one week. He had continued taking the naltrexone although the symptoms had not reduced. He reported feeling reassured by talking with the pharmacist.

Further input? This was not considered necessary.

Case study 7

Background: An outreach worker asked the pharmacist to see one of her clients in a one-to-one appointment. The client had previously been receiving 80 ml methadone daily, but reported feeling exhaustion and heaviness. His GP changed his prescription to dihydrocodeine at the clients' request, prescribing ten 90 mg slow release tablets per day. The client asked the drugs worker for advice on swapping from methadone to dihydrocodeine. He was scared of withdrawal effects and doubted the GPs advice to take the dihydrocodeine in two divided doses.

Issue (1): Client unsure how to swap from one prescribed medicine to another.

Response: The pharmacist explained that the dose of dihydrocodeine was slightly higher than the equivalent dose of methadone, so the client should not experience any physical withdrawal effects. There may be some psychological effects experienced in the first few days until the client feels reassured with the change. The pharmacist confirmed the GP's suggestion of taking the tablets in two doses of 5. She suggested the client try to take the tablets twelve hours apart and explained what the slow release formulation meant.

Was information used or advice followed? The drugs worker saw the client one week later. He made the transition smoothly without any withdrawal effects.

Further input? Further input was not necessary on this matter, but the drugs worker later asked the pharmacist for further advice for this client. The client had received confirmation of a place in a residential rehabilitation unit and needed to reduce the level of his prescribed drug to an amount acceptable for entry. The drugs worker had attended a joint appointment with the client's GP and it had been agreed that the drugs worker and client would devise a reduction plan for discussion with the GP. The worker told the GP she could consult the pharmacist, and the GP supported this. The pharmacist, worker and client negotiated a plan that they all considered realistic. The GP approved the plan and it was followed. The client reached the acceptable level in time to enter the unit.

Case study 8.

Background: The pharmacist was asked to advise on an injection site abscess that a NX client showed to the duty worker. During the examination, the pharmacist established the client was receiving 4 ml methadone daily and not coping on this low dose. She was regularly injecting heroin again. She had not told her specialist prescriber for fear of her prescription being stopped. She reported selling sex to obtain money for heroin. The only contact she had with DA was through her use of the NX and would not approach her GP as he was a family friend and she feared 'letting him down'.

Issue (1): The client had an abscess that looked infected and would not consult her GP.

Response: The pharmacist referred the client to A&E, reassuring her that they were willing to treat such injuries.

Issue (2): The client reported not coping with her prescribed amount of methadone.

Response: The pharmacist discussed issues around the clients drug use, including her goals and psychological difficulties. She also discussed prostitution health and safety issues. She suggested the client see a drugs worker, but she was unwilling. The pharmacist offered to discuss the issues with the prescriber, the client agreed and consented to all information discussed being divulged. The pharmacist did this and the prescriber agreed to review the prescription in light of the information received.

Was information used or advice followed? The client came to the agency to see the pharmacist one week later. She had attended A&E for treatment and the abscess appeared to be healing. The prescriber had discharged her from treatment for non-compliance.

Further input? The pharmacist contacted the prescriber who explained she had acted according to the protocols of her service. The client returned to the agency to see the pharmacist, but at times outwith the session, so no further contact occurred during the period of the service.

Case study 9.

Background: A drugs worker asked the pharmacist for advice he could pass on to a client regarding constipation. The contact is summarised in 9.1.6 under discussion of the category Health Problem (Drug Related), example 2.

Issue (1): The client reported severe constipation and wanted advice from his worker.

Response: The pharmacist made an OTC recommendation and suggested dietary advice. She also suggested further discussion by the client with his GP.

Was information used or advice followed? The client was reluctant to return to his GP, so the drugs worker went with him to discuss the issue, as he considered the client may be experiencing difficulties making himself understood. The GP prescribed lactulose. The drugs worker was did not know if the dietary advice had been followed.

Further input? This was not required.

Presentations and publications relating to this work

1. **'Investigation into the Effectiveness of Filters for use by Intravenous Drug Users.'** Jennifer Scott, Emily J Kennedy, Arthur J Winfield and Christine Bond. Presented at the 8th International Conference on the Reduction of Drug Related Harm, March 1997, Paris, France.
2. **Investigation into the Effectiveness of Filters for use by Intravenous Drug Users: Results from work with heroin.'** Jennifer Scott, Emily J Kennedy, Arthur J Winfield and Christine Bond. Presented at the 9th International Conference on the Reduction of Drug Related Harm, 17 March 1998, Sao Paulo, Brazil.
3. **'Role of the Pharmacist at a Drug Counselling and Needle Exchange Service.'** Jennifer Scott, Emily J Kennedy, Arthur J Winfield and Christine Bond. Presented at the 9th International Conference on the Reduction of Drug Related Harm, 17 March 1998, Sao Paulo, Brazil.
4. **'Investigation into the Effectiveness of Filters for use by Intravenous Drug Users.'** Jennifer Scott, Emily J Kennedy, Arthur J Winfield and Christine Bond. *International Journal of Drug Policy*, 3(2): 181-186.
5. **'Investigation into the Training Need of an Information Pharmacist at a Drug Counselling and Needle Exchange Agency'** Jennifer Scott, Emily J Kennedy, Arthur J Winfield and Christine Bond. Poster presented at the British Pharmaceutical Conference, September 1998, Eastbourne, UK.
6. **'The Effects of filters and added acids on heroin concentration in prepared injections.'** Jennifer Scott, Emily J Kennedy, Arthur J Winfield and Christine Bond. Presented at the 10th International Conference on the Reduction of Drug Related Harm, 23 March 1999, Geneva, Switzerland.
7. **'Examining professional compatibility within the multidisciplinary team'** Jennifer Scott, Emily J Kennedy, Arthur J Winfield and Christine Bond. Presented at the 11th International Conference on the Reduction of Drug Related Harm, 10 April 2000, Jersey, Channel Islands.
8. ***In press: Laboratory study of the effects of citric and ascorbic acids on injections prepared with brown heroin.*** Jennifer Scott, Emily J Kennedy, Arthur J Winfield and Christine Bond. *International Journal of Drug Policy*.

Investigation into the effectiveness of filters for use by intravenous drug users

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Abstract

Injecting drug users are at risk of and can suffer from serious health problems due to intravenous administration of insoluble particles from street drugs and tablets. Makeshift filters are used to try to remove particles from the injections. The decision to distribute filters from Harm Reduction Centres cannot be based on evidence of efficacy and safety as no such published data exists. The work presented here is part of a larger study which anticipates to provide such evidence. Laboratory methods were developed based on information gathered from drug users. Injections were prepared using drugs of abuse and filtered either through makeshift or commercially available filters. The resulting solutions were assayed for particle size and number (using Coulter Counter[®]). Comparisons were made with unfiltered injections. The results presented here are from the first part of this study, which investigated the effectiveness of various filters on reducing particulate count and size range of injections made from tablets. The commercially produced filter (Acrodisk[®]) showed a much greater reduction in particle number and size. This strongly suggests the risks to health could be reduced by the use of such filters. Of the makeshift filters, the Rizla[®] acetate filter showed the most satisfactory reduction in the number of particles, suggesting their use may be preferable to the currently popular cigarette filter. The ongoing work is looking at the effect of the filtration methods on amount of drug in injections made from tablets and repeating the work using street heroin. © 1998 Elsevier Science B.V. All rights reserved.

Keywords: Filters; Intravenous; Drug users

1. Introduction

Public health and health care policies increasingly have to be evidence based. Harm reduction is one area where there is difficulty in making

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some practice evidence based, purely because the only evidence available is anecdotal and not research based (Paxton, 1998). One such example is the provision of injecting paraphernalia. In the UK it is an offence under section 9A of the Misuse of drugs Act (1971) to supply any article believing it to be used or adapted for use to administer a controlled drug except clean needles and syringes. This applies to swabs, citric acid, filters etc. At the 1997 UK Association of Chief Police Officers conference this matter was debated and a firm recommendation made that the law be changed to permit supply of such paraphernalia from recognised agencies including pharmacies (Wray, 1997). The high prevalence of hepatitis C and the link of transmission through sharing filters, water, swabs etc. makes such a change in the law not only very welcome but vital for harm reduction. If such a change in the law does occur, we will then be faced with the decision of what kinds of equipment to supply. Even with no change in the law, evidence of effectiveness is necessary to provide drug users with accurate information. One such example is the use of filters to remove insoluble materials from injections. Intravenous (IV) drug use carries many risks of harm and associated medical complications. Direct access to the vascular system and administration of drugs which are not prepared to pharmaceutical standards for injection (such as street drugs and tablets) are related to some medical problems. Insoluble particles are often present in amounts far higher than those that are considered to be safe in pharmaceutically manufactured injections. Both the size of the particles and the number present in injections are important. In the microcirculation of the body the smallest vessels are the capillaries, which are $\approx 8 \mu\text{m}$ in diameter. Next are the terminal arterioles which are between 20 and 50 μm . The more particles there are and the bigger they are, the greater the risk to health. Consequently, there are limits placed on the particulate content of commercially made injectables. The British Pharmacopoeia (B.P) stipulates that for large volume parenterals (fluids for IV administration, $> 100 \text{ ml}$), there should be no more than

1000 particles per ml over 2 μm and of these no more than 100 per ml should be over 5 μm (British Pharmacopoeia, 1993). There is no limit given in the B.P for small volume parenterals. Obviously, the injections prepared by IDUs will contain greater numbers of particles than those made commercially because of the presence of insoluble adulterants in street drugs and diluents in tablets that are crushed up to make injections. Also the IDU is not preparing injections in an aseptic environment, unlike pharmaceutical industry formulated injections.

Examples of the problems caused by insoluble particles include: phlebitis, abscesses, blocked blood vessels (which can lead to deep vein thrombosis, varicose ulcers and gangrene) and endocarditis. (The latter is more commonly due to bacterial seeding from infected wounds but can be caused by the build up of insoluble adulterants and diluents behind the valves in the heart leading to irritation). (Posner and Guill, 1985, Haverkos and Lange, 1990, Stein, 1990, ANSWER, 1996, Scott and Bruce, 1997). There is a belief amongst some drug users that certain materials are better to be used as filters than others. It is also believed that filtering certain drugs reduces the concentration of drug in the injection, resulting in the loss of the hit.

The definition of an effective filter, devised for the purpose of this study, is as follows: For an IDU's filter to be effective it must reduce the particulate content of the injection to a level that presents a lower risk of harm. It must be acceptable to the user, so must not remove the drug and has to be quick and easy to use. It is the first part of this statement which is being investigated in the work presented here. The overall aim of this study is to provide evidence from the laboratory and liaison with drug users to investigate the effectiveness and predicted safety of filters. If such evidence can be produced its use will be two-fold: to support bids for funding from needle exchanges to enable the distribution of suitable filters and the creation of harm reduction information for IDUs to advise on effective filtering methods.

2. Method

Semi structured interviews were carried out with twenty current or ex-IDUs to explore the drugs that are used by injection and the methods used to prepare injections. From this, the most commonly used drugs by the IV route were established. For financial reasons and constraints on time, it was decided to investigate three pharmaceuticals and one street drug, the most popular drugs being selected for investigation. From the interview data, it was established that heroin was the most commonly used 'street drug' by the IV route. Several pharmaceuticals were also stated as being injected. Data on the use if these were compared with national statistics (Drug Misuse Statistics Scotland, 1996). From this the three pharmaceuticals chosen for investigation; these were Physeptone tablets, Temgesic tablets and Diconal tablets. Use of the latter appears to vary greatly between region, but because of the continuing popularity in some Scottish areas and many beliefs amongst IDUs which warn against filtering of Diconal, it was decided to select this drug for investigation.

It became clear that the method of preparation used by each IDU for heroin was similar, but the preparation method used for tablets varied. Safer Injecting Guidelines published for IDUs were therefore also consulted to assist in establishing the preparation method (Exeter Drugs Project, HIT, 1995).

The type and quantity of tablets used were as follows: Physeptone[®] (methadone 5 mg, Glaxo Wellcome) nine tablets in 5 ml of water; Diconal[®] (dipipanone 10 mg and cyclizine 30 mg, Glaxo Wellcome) two tablets in 2 ml of water; Temgesic[®] (buprenorphine 0.2 mg, Reckitt and Coleman) five tablets in 2 ml of water. The injections were prepared by crushing the tablets between paper with a spoon and mixing the resulting powder on the spoon with water from the kettle which had been boiled and cooled. The methods of filtration investigated were as follows: a piece of a cigarette filter (Lambert and Butler[®]) prepared by removing the surrounding paper and tearing it in two down the middle

then halving one piece with a scissors and smoothing any stray fibres with the fingers before placing it in the edge of the solution. A hand rolling filter (Rizla Extras[®] 7 mm acetate filter tips), used whole, placed in the solution. A cotton bud tip (Unichem 100% cotton), removed from the plastic stalk by pulling and the end twisted to smooth the stray fibres and then placed in the edge of the solution. In all of these cases the needle was attached to the syringe and the solution drawn up through the filter. A commercially available syringe filter was also tested (5 μm Acrodisk[®], Gelman Sciences). This was placed on the end of the syringe and the solution drawn through, then removed and the needle attached. Also investigated were unfiltered solutions prepared in this way and unfiltered solutions prepared by breaking the tablets in half and shaking them with water in the syringe barrel. Controls were tested using boiled and cooled water and Water For Injections BP (Antigen Pharmaceuticals[®]) to investigate the contribution of the filtration and preparation methods on particulate content.

Particle count and size range were measured using the Coulter Multisizer[®], using 0.5 ml samples withdrawn from the injections immediately after preparation. Each test was repeated three times and the average result taken. It was decided to do this instead of taking three consecutive readings from each sample, as there could be a reduction in the particle count as the sample is stirred. The Multisizer operates on the electrical zone sensing principle: there are two electrodes in a conducting fluid (saline which has been filtered twice using a 0.2 μm filter) separated by an orifice of known diameter. A stirrer keeps any particles suspended in the saline. When a particle passes through the orifice there is a change in resistance (measured as a voltage pulse at a fixed current), the magnitude of this relates to particle size. Total number of particles that are drawn through the orifice in a given time (12 s) and number of particles within a size channel can be measured. In this case the 100 μm orifice was used, which measures particles in the size range 2–60 μm .

Table 1
Percentage reduction in total number of particles

Drug	Crush and mix (%)	Shake in barrel	Cigarette filter	Rizla filter	Cotton bud	Acrodisk
Physeptone	100	36	—	—	—	—
Diconal	100	15	29	39	36	99.0
Temgesic	100	24	24	42	56	99.9

3. Results

Changes in trends seen in particle size and number before and after filtration were looked for. The total number of particles present in the injections can be estimated by extrapolating the count from the 0.5 ml sample, but is of little value because there will be a large variation in numbers depending on the volume of water the IDU uses to make injections, how finely the drug is crushed, etc. Therefore, the number of particles in the unfiltered sample was taken to be 100% and the effects of filtration shown as the percentage reduction in the total number of particles. This is shown in Table 1.

The Physeptone solutions were thick and did not pass through the filters quickly or easily. Several filters had to be used as they clogged and it took longer than was deemed acceptable by the IDU. Since this does not fit with the definition of an effective filter given earlier, it was decided not to continue with the Physeptone filtration investigations at this stage. From Table 1 it can be seen that all methods of filtration cause a reduction in the total number of particles in the prepared injections. Preparation by splitting the tablets in two and shaking them in the syringe barrel also reduces the number of particles. However, in preliminary work on the effect of filtration on drug concentration, the amount of methadone was found to be only 90% of the drug contained in the nine Physeptone tablets when they were split and shaken, compared with 100% when they were crushed. A slurry was seen to collect at the bottom of the syringe indicating clumping of excipients and drug, explaining why not all the drug dissolved. This material could block the needle or break down enough to pass down the needle and enter the veins as a solid mass. As expected the

commercial Acrodisk gave the greatest reduction in the total number of particles. Of the makeshift filters, the Rizla gives the best overall performance for both drugs. The cotton bud showed a good reduction in particle count with Temgesic injections, but was not as effective with Diconal. The cotton bud also has loose fibres which could enter the injections after filtering. Because the Multisizer sizes particles as spheres, a long thin fibre passing through the orifice may be counted as several smaller spheres. The cigarette filter was identified in the interviews as being the most commonly used filter, but this preliminary work suggests the Rizla filter to be more effective.

The total number of particles in the sample was taken to be 100% and the distribution of these according to size range is given for each drug in the Table 2.

As said, the particle size analyser gives the total number of particles in the sample and the number of particles in each of the channels within the size range 2–60 μm . Since some of the particles may be <2 μm or >60 μm , the percentage distribution within the size range 2–60 μm does not necessarily add up to 100%. Obviously these particles will still, however pose a risk to health. Table 2 show that all filters cause a shift in size range to the smaller end of the scale for the drugs tested. Again, the Acrodisk shows the greatest reduction in size range with the majority of particles in the filtered solution being smaller than the capillaries in the body. Of the makeshift filters, the reduction in size range appears to be greatest with the cotton bud filter. Splitting and shaking the tablets in the syringe also gives more particles in the smaller size ranges. Thus if no filter was used, this would be preferable to crushing the tablets to a fine powder first.

Table 2
Percentage of particles detected shown by size range for (a) Physeptone, (b) Diconal, and (c) Temgesic injections

Size range (μm)	Crush and mix	Shake in barrel	Cigarette filter	Rizla filter	Cotton bud	Acrodisk
(a) Physeptone						
2-5	24	43	—	—	—	—
5-10	18	15	—	—	—	—
10-20	33	23	—	—	—	—
20-50	3	3	—	—	—	—
(b) Diconal						
2-5	23	32	45	40	39	99
5-10	23	22	25	26	27	1
10-20	37	29	19	26	27	0
20-50	1	1	0	0	0	0
(c) Temgesic						
2-5	9	10	13	12	23	76
5-10	27	30	37	32	33	18
10-20	45	46	38	37	35	6
20-50	1	3	0	1	1	0

Table 3 shows the total number of particles that were counted without the drug present in the injections as a percentage of the total number detected when the drug is present.

This indicates the contribution to the total number of particles that is made by factors such as the kettle, cup, water, spoon, filters, injecting equipment and the non-aseptic environment, including the person preparing the injections (e.g. skin shedding). The contribution to particle count not from the drug is low except in the case of kettle water and the Acrodisk. This is because the total number of particles present is low, so the contribution from the equipment and the environment become significant. It is also shown that in terms of particle count, there is no benefit from

using Water For Injections. However, there are obvious microbiological advantages.

4. Discussion

It has been shown that makeshift and commercial filters reduce the particle count and particle size in injections of Diconal and Temgesic. This suggests that the health risks attributed to the injection of insoluble materials could be reduced by filtering the injections prior to administration. The commercially produced syringe filter would be the most appropriate choice, the cost implications of supplying such filters needs to be considered. Clients who inject these drugs should be

Table 3
Percentage of total particle count that can be attributed to sources other than drug (i.e. controls)

		Mix on spoon	Shake in barrel	Cigarette filter	Rizla filter	Cotton bud	Acrodisk
Physeptone	Kettle	0.1	0.1	—	—	—	—
	WFI	0.1	0.3	—	—	—	—
Diconal	Kettle	0.2	0.2	0.2	0.4	0.3	31.5
	WFI	0.1	0.6	0.2	0.1	0.8	0
Temgesic	Kettle	0.2	0.2	0.2	0.5	0.3	230.0
	WFI	0.1	0.6	0.1	0.1	1.1	0

encouraged to filter. The Rizla acetate filter appears to be more effective than the popular cigarette filter. The filters should be handled to a minimum to reduce contamination risks from the hands, and re-use of filters discouraged. However, many users do not use filters because they claim to lose the 'hit'. Therefore the next stage in this work will develop methods to measure the effects of filtering on the concentration of the drug. Also, since many more people use heroin than tablets by injection, it is important to carry out this work using samples of street heroin. Work is ongoing to fulfil these objectives. When the final results are collated, work will be done with IDU's to test the most effective makeshift and commercially produced filters for user acceptability.

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