Samples of Urban and Rural Methadone Clients: Comparing Health Outcomes, Blood Borne Virus Transmission Risk, and Validity of Hepatitis C Self-report

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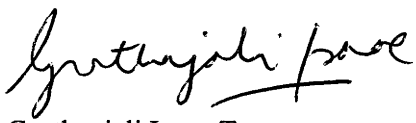
Declaration

This thesis represents my own work except where otherwise acknowledged



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2007

Dedicated to my friend Karen Lees (1957-2006),

who started this journey with me,

but was not able to finish it with me.

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Abstract

Background

Methadone maintenance treatment has been shown to be the most beneficial and cost effective treatment in decreasing heroin dependence and the health and social consequences associated with it. Provision of methadone treatment in Australia varies between jurisdictions due to the federal and state structure of health service delivery.
There has been limited research comparing outcomes for urban and rural methadone clients. Recent research has shown that rural Injecting Drug Users (IDUs) and new entrants to methadone treatment programme have poorer outcomes in relation to availability, access, cost and confidentiality associated with health service provision and delivery.

Hepatitis C Virus (HCV) has emerged as a major health issue amongst IDUs and it is estimated that 60 to 80 per cent are HCV positive. HCV is most effectively transmitted through blood and approximately 90 per cent of infections in Australia are associated with unsafe injecting drug use. It is thus important for IDUs to be aware of their HCV status and to practice behaviours that minimise HCV transmission. Available research suggests that IDUs have inaccurate knowledge of actual status, resulting in poor validity of HCV self-report as an indicator of true status.

Aims

The study had two aims. Firstly, to measure and compare health outcomes and Blood Borne Virus (BBV) transmission risk amongst urban and rural methadone clients, and to identify factors significantly associated with these outcomes within the two groups. BBVs of interest were Human Immune Deficiency Virus (HIV), Hepatitis B Virus (HBV) and HCV. My focus was on BBV risk due to injecting as methadone being orally administered aims to decrease the frequency of injecting. The second aim of the study was to investigate the validity of HCV self-reported status amongst IDUs by comparing it to serological status.

Methods

The Australian Capital Territory (ACT) methadone treatment programme was chosen to represent the urban study group, while the Southern New South Wales (SNSW) programme was chosen to represent the rural study group.

A cross sectional study design and a random sampling strategy were used to minimise selection bias into the study. One hundred clients per study group were needed to elicit a significant difference of 20 per cent in health and BBV risk outcomes between groups ($p \leq 0.05$, power=80%). The Opiate Treatment Index (OTI) and Blood Borne Virus Risk Assessment TraQ (BBV TraQ) were used to measure health and BBV risk outcomes respectively. Sensitivity, specificity, positive and negative predictive values and likelihood ratios were used to measure validity of HCV and HIV self-reported status. Serological status of the participant at the time of the study was used as the gold standard to ascertain HCV status. Validity of HIV self-reported status was measured for comparison.

Results

A total of 118 clients were recruited into the study; 62 in the urban study group (ACT) and 56 in the rural study group (SNSW). The two study groups were not significantly different in relation to most sociodemographic characteristics, previous drug use and risk factors, treatment history and BBV serological status. However, programme policy and delivery characteristics (such as cost of methadone, cost of travel to dose, takeaway dose policy, and access to case managers) significantly differed between the study groups ($p<0.05$). Overall, 51 per cent of participants had injected in the month prior to interview. Many participants continued to use heroin and other drugs and practice some risky behaviour.

Urban and rural groups did not differ in the magnitude of health outcomes as measured by the OTI mean Total Health Score (urban: 13.98, SD 7.72; rural 15.43, SD 7.48, p=0.31) and psychological adjustment score (urban: 8.10, SD=7.40; rural: 9.61, SD=8.76, p=0.51). However, factors significantly associated with health outcomes in the study groups differed. In the urban group, having to pay for their methadone dose was significantly associated with poorer health outcomes, while in the rural group, being female, using a greater number of other drugs in the month prior to interview and being unsatisfied with their programme were significant factors.

Being an urban or rural client was not significantly associated with injecting while on treatment. The factors significantly associated with injecting were similar for the two study groups. These included living with someone who injected, number of drugs used in the month prior to interview and employment being the main income source in the last six months prior to interview.

Like health outcomes, there was no significant difference between the two study groups in the magnitude of BBV risk due to injecting as measured by the BBV TraQ injecting risk scores (rural=7.75, SD 9.68; urban=5.78, SD 8.93; p=0.42). Factors that were significantly associated with injecting with a BBV risk were similar for both study groups (unlike health outcomes). These were younger age, frequency of injecting in the month prior to interview, number of takeaway doses, number of missed doses per week, and methadone dose. Being a rural client was also significantly associated with injecting with a BBV risk.

Overall, 70 per cent (n=76) of all participants who had provided a blood sample (n=110) had positive HCV serology. A higher proportion of rural participants were positive as compared to urban, but this difference was not significant (urban=63%, rural=76%, p=0.16). For HIV, all but one participant (108 of 109) had negative serology. Factors significantly associated with having a HCV positive serological status were being older (40+ years), having a tertiary education, having injected methadone, previous incarceration, and not being on methadone treatment while in prison. Overall, validity of HCV positive self-reports (sensitivity=87%, positive predictive value=83%, positive likelihood ratio=2.12) was better than validity of HCV negative self-reports (specificity=59%, negative predictive value=64%, negative likelihood ratio=0.23). Validity of HCV self-reports (positive and negative) were better for rural participants, but not significantly different to urban participants. Duration between last serological test and provision of self-report appeared to affect the validity of self-report.

Conclusion/Implications

Although the magnitude of health and BBV risk outcomes were not significantly different for urban and rural study groups, the factors influencing these outcomes differed and were either dependent on treatment policy or client characteristics and behaviour. Common factors contributing to poorer outcomes within both study groups should be considered in the planning and delivery of methadone treatment services in general. Risk factors that differed should be considered within urban and rural programmes. Risk factors relevant to client characteristics should be addressed at the individual level during enrolment and review. Results from the study suggest that validity of HCV self-report continues to be poor and reasons should be investigated further. Increased education and more frequent testing may be needed within programmes that target IDUs.

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Preface

This thesis evolved out of working with the SNSW Public Health Unit (PHU), between April 1998 and March 2001, where I coordinated the Sexual Health and HCV programmes. The HCV programme was introduced as a new national programme with the release of the National HCV Strategy in 1999. It was included into the portfolio of Sexual Health programmes throughout Australia even though HCV has not been conclusively shown to be transmitted sexually. This arrangement although appropriate for resource management purposes, made delivery of HCV services to IDUs who were the main target group difficult. IDUs accessed the sexual health services for procuring clean injecting equipment through the Needle and Syringe Programmes (NSPs). For issues related to drug use and dependency, they accessed the Alcohol and other Drug (AOD) services. For HCV services to be delivered and utilised appropriately I developed linkages with the SNSW AOD programme, and thus became closely involved with the methadone treatment programme.

Delivery of HCV services within SNSW were further complicated by rural area specific issues such as availability and access to services, cost to the client, client confidentiality, and stigmatisation associated with injecting drug use. These issues were emphasised more within the methadone treatment programme where policy and service delivery varied according to jurisdictional priorities and was not always flexible to the needs of the client. Trying to implement and manage the new HCV programme instigated my interest in rural health service delivery. The research for my PhD gave me the opportunity to examine if differences in delivery of urban and rural methadone treatment programmes affected outcomes.

While working with the SNSW PHU, I became involved in a study researching the effect of withdrawal of large bore syringes from NSPs on methadone injecting in NSW. The study recruited methadone injectors from urban and rural areas. I coordinated the rural arm of the study and as an extension to the study I examined the accuracy of HCV self-reported status in this group by comparing it to serological antibody status. The study found that only 64 per cent of participants who reported their status as positive were serologically positive, while only 54 per cent of participants who reported their status as negative were serologically negative. The research for my PhD also gave me the opportunity to examine the accuracy of HCV self-reported status as a true indicator of actual status further, and compare it for urban and rural IDUs.

Thesis outline

The thesis has eight chapters in which I aim to take the reader through the study in a systematic way. I begin the thesis with an introduction to the history of heroin dependency, BBV transmission, and methadone treatment globally and in Australia.

In Chapter 1, I explain the Australian health system structure to enable better understanding of methadone treatment service provision and delivery. This background assists with explaining the aims and rationale for my study. I also describe my study locations and the management and service delivery of the programmes within these locations in this chapter.

In Chapter 2, I provide a literature review into the origins and effectiveness of methadone treatment particularly in relation to health and BBV risk outcomes. This includes a review of previous studies that examined accuracy of BBV self-reported status.

Methods used to conduct the study including study design, instruments used, sampling, recruitment, data collection and analyses processes are described in Chapter 3.

Chapters 4, 5, 6, and 7 present the results of my study in relation to the aims. Chapter 4 describes and compares socio-demographic characteristics, treatment characteristics, client risk characteristics (previous and current), BBV status and client satisfaction and outcome perceptions for the two study groups. Any differences identified were taken into consideration for measurement and comparison of health and BBV risk outcomes for urban and rural methadone clients. These results are presented in Chapters 5 and 6, which also describe the instruments used for measurement of health and BBV risk outcomes. Chapter 7 presents results of the validity study of HCV self-reported status and uses HIV as a comparator. Chapter 7 also identifies factors associated with being HCV positive as diagnosed through serological status and compares this to factors identified through HCV self-reported status.

Chapter 8 brings together all the results and discusses them in the broader context of public health and implications for future policy and service delivery.

I discuss the implications of the results and compare them to other relevant studies through a summary and/or discussion section at the end of each chapter.

"All things appear and disappear because of the concurrence of causes and conditions. Nothing ever exists entirely alone; everything is in relation to everything else".

Buddha

Chapter 1

Introduction, aims, rationale, and locations for the study

In this chapter I describe the history of heroin dependency, BBV (HIV, HBV and HCV) aetiology, prevalence and transmission risk, the history of methadone treatment, and service provision and delivery of methadone treatment in Australia. The chapter also details the aims and rationale for the study, describes the locations of the study and service provision and delivery of methadone treatment within the locations.

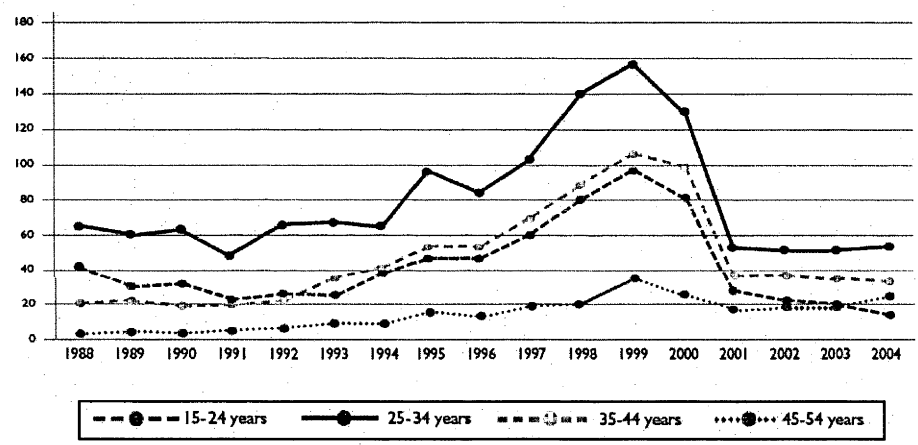
1.1: History of heroin dependency in Australia

Illegal heroin use in Australia escalated in the 1970s [1]. A review of methadone treatment in Australia conducted in 1995 indicated that there were approximately 60,000 heroin dependent users [2]. In 2000, Hall and colleagues estimated the prevalence of dependent or daily heroin users in Australia to be between 67-92,000, with a median estimate of 74,000 users. The population prevalence was calculated at 6.9 per 1,000 persons aged 15-54 years [3]. As part of the Australian National Drug Strategy (NDS), house-hold surveys to monitor trends of alcohol and other drug usage have been conducted every two to three years in Australia since 1985. The survey conducted in 1998 indicated that one per cent of males and 0.6 per cent of females aged 14 years or older injected illicit drugs in the 12 months preceding the survey, and one per cent of persons aged 14-19 years injected in the month prior to the survey. Twenty eight per cent of illicit injectors in the 1998 house-hold survey reported overdosing at least once after injecting heroin in that period [4]. The survey conducted in 2001 indicated that although heroin use in Australia is relatively low, it is a significant cause of death, injury and illness for younger people and in the last decade was the third commonest cause of death in the 25-35 year age group [5]. The most recent survey conducted in 2004 indicated that heroin had been used by 1.4 per cent of the population aged 14 years and over with the highest proportion of users being in the 20-29 year age group. Males were more likely to have used heroin than females [6]. Results from these surveys are best interpreted with caution as these surveys are dependent on an individuals' willingness to participate. Participants may not always provide accurate information due to the sensitive nature of these surveys and the possibility of identification. Another limitation is that many drug users are not always in regular house-holds and the results may be underestimated.

The rate of opioid related overdose deaths increased steadily between 1964 to 1997, with a study showing that mortality rates increased 55-fold from 1.3 to almost 71.5 per million for persons aged 15-54 years. The study also showed that death rates increased more substantially for the older birth cohorts with an incidence rate ratio of 20.70 (95% CI, 13.60-31.46) for the 1940-44 birth cohort as compared with the 1975-79 cohort indicating that older dependent users were more at risk of death related to overdose [1].

There was an exponential increase in mortality between 1995-1999 with approximately 500 deaths per annum [7]. A report published by the National Drug and Alcohol Research Centre (NDARC) showed that mortality rates have since decreased, and there were 347 deaths recorded in 2004 (31.3 per million population) [8]. This decrease was attributed to a shortage of heroin in the early 2000s [9]. Although there has been a reduction in opioid related mortality, rates amongst older injectors (45-54 years) continue to increase. Males comprise the majority of deaths (up to 78%) and the highest proportion of deaths (43%) continue to occur in the 25-34 year age group [8].
Figure 1.1 illustrates mortality rates related to opioid overdose between 1988 to 2004 for persons aged 15-45 in Australia.

Figure 1.1: Rate of accidental deaths due to opioids per million by age group: Australia 1988-2004



Courtesy of NDARC 'Opioid Overdose Deaths in Australia: 2004 Edition'

Australia has experienced similar problems associated with heroin dependency to the rest of the world in relation to health, BBV transmission, crime, and social problems. Australia, however, has been fortunate in relation to transmission of HIV and the related health care and social support issues being much less prevalent in comparison to some other countries. This is due to the introduction of harm minimisation policies (such as NSPs) in the early to mid 1980s, and the availability of treatment and support services for IDUs. In 1986, Drucker noted that approximately 50 per cent of IDUs were infected with HIV in New York city [10]. He outlined the health and social consequences associated with this rate of infection and the implications this would have on health care utilisation and need [10].

Quantifiable costs associated with illegal drug use in Australia were estimated to be $1,700 million in 1992; law enforcement cost at $450 million and net health costs at $43 million [11]. A further report published in 2002 estimated costs for 1988-99 to be $59 million for health and $2,500 million for law enforcement [12]. There are many social costs that cannot be quantified. For the heroin dependent individual this includes diminished quality of life, financial hardship, employment instability, broken relationships and stigmatisation in the community. For the general community there are costs associated with drug related crime including financial loss and sometimes physical harm [13].

1.2: BBV (HIV, HBV and HCV) transmission and prevalence amongst IDUs in Australia

The three viruses that are of major concern for blood borne transmission amongst IDUs are HIV, HBV and HCV [14-17]. HIV and HBV are also known to have other routes of transmission apart from blood. HIV is transmitted through sexual intercourse and vertical transmission from mother to baby during pregnancy, while HBV is known to be transmitted through sexual intercourse and during the perinatal period (four weeks after delivery) [18, 19]. HCV has been shown to be transmitted most effectively through blood with uncertainty about sexual transmission [20, 21]. Transmission of BBVs can occur while injecting drugs, through the sharing of injecting equipment, and other unhygienic and un-sterile practices [22-24]. Transmission of BBVs through injecting drugs is now recognised as a major public health problem [25-27].

With the advent of HIV and AIDS in the 1980s, the non-availability of a vaccine for HIV, the high mortality rate associated with AIDS and the high possibility of transmission of the virus through injecting drug use, many countries recognised IDUs as a serious threat to contributing to increased prevalence not only through blood borne transmission but also through sexual transmission to the general population. For this reason, many developed countries introduced policies and programmes for IDUs to have access to sterile injecting equipment at no cost, with the aim of minimising sharing of injecting equipment and preventing transmission of HIV [28-31].

This was a policy adopted by Australia in the early stages of the HIV and AIDS epidemic, and for the past two decades Australia has been very successful in keeping the prevalence of HIV amongst injecting drug users to a minimum with only one per cent of the population infected [30, 32, 33]. Methadone treatment has assisted further as it is administered orally and decreases risk of transmission through injecting. The policy has also assisted with minimising other BBV transmission (HBV and HCV). In countries that did not adopt policies to provide clean injecting equipment, the prevalence of HIV is higher amongst IDUs in comparison to countries that did [34]. For example, in Russia which did not adopt the policy, HIV prevalence in 2004 was found to be anywhere between 3-14 per cent amongst IDUs [35, 36].

The global prevalence of HBV varies widely and there are three demarcated prevalence zones: high, medium and low. Despite vaccination programmes being available, global incidence of HBV continues to rise and is mainly due to transmission in high risk groups such as IDUs. Australia is considered to be a low prevalence zone and minimal data is available about the true prevalence of HBV in the general population [37, 38]. A recent study conducted in 2005 to gain information about seroprevalence of HBV in the Australian general population revealed that only two per cent of the sample (45/2115 persons) either had current infection or were chronic carriers of the virus. However, the adjusted Odds Ratio (OR) for HBV infection was significantly increased in persons who had injected drugs between 1980 and 1990 (4.4-fold), persons who had household contact with someone diagnosed with HBV between 1980 and 1990 (3.9-fold) and persons who had never been vaccinated for HBV (2.8-fold) [38]. These results indicate that, although the prevalence in Australia for HBV may be low, HBV transmission still poses a risk for IDUs and there is a continuing need to check and immunise IDUs against the virus.

HBV vaccination has been included into the Australian National Immunisation Programme (NIP)[1] as a routine childhood vaccine since 2000, as recommended by the National Health and Medical Research Council (NHMRC). Prior to this (since 1988) it was only available as a routine childhood vaccination to Australian children whose ethnic origins were from highly endemic areas for HBV [39].

[1] All vaccines on the NIP are funded through the Pharmaceutical Benefits Schedule and are provided free of charge to eligible people.

HBV vaccination for IDUs has been recommended by the NHMRC immunisation guidelines, but is not provided free of charge. Although vaccination is available and recommended, many IDUs may not be immunised either due to the vaccine not being available during their childhood or due to the schedule. This makes them vulnerable to acquiring HBV. A recent study amongst 118 Australian drug and alcohol users found that only 21 per cent had immunity to HBV determined through serology. Of these 118 participants, 22 per cent were current IDUs and 48 per cent had injected in the past [40].

Even with the provision of clean injecting equipment, the prevalence of HCV is high amongst IDUs in Australia, with an estimated 60-90 per cent being diagnosed with the virus [17, 41]. One of the reasons for this could be that although HCV was only identified in 1989 (after introduction of NSPs), the virus existed prior to this as one of the collective group of non-A non-B hepatitis viruses, and knowledge about transmission of the virus was limited [42, 43]. By the time HCV was identified, its aetiology established, and programmes for provision of clean injecting equipment were instituted in Australia, the virus had already spread amongst IDUs and was common in this population [44]. This is supported by a recent Australian study that was conducted amongst IDUs in opioid replacement therapy. The study showed that persons above 40 years had higher HCV prevalence as compared to persons in the 19-30 year age group (93.9% vs. 60.8%). This suggests that the virus has been present in the Australian IDU population for many years and older IDUs who have been injecting for longer were more likely to have been exposed to it [45].

1.3: Methadone treatment for heroin dependency in Australia

Methadone has been used in Australia for treatment of heroin dependency since 1969. It was first prescribed for heroin dependency by a physician from the United Kingdom (UK), Dr. Stella Dalton, who was practising as a General Practitioner (GP) in New South Wales (New South Wales) [2, 46]. By 1970, most Australian States and Territories offered methadone as a treatment for heroin dependency.

1.3.1: History

The use of methadone treatment for heroin dependency grew gradually between 1969 to the early 1980s when there were approximately 3000 clients nationwide [13]. With an apparent rise in illness, death, social instability and crime associated with heroin dependency, and the advent of HIV in the early 1980s, methadone was endorsed as an effective treatment by the Australian Government in 1985 [2]. National Guidelines to provide a framework for jurisdictions to formulate policies and procedures for methadone treatment were endorsed by the Australian Health Ministers conference of 1985 [2, 13]. The Guidelines were endorsed as National Policy in 1993 to provide a common set of standards for methadone treatment within Australia; this policy was revised in 1997 [2, 13]. The number of clients on methadone increased rapidly from 6,500 in 1989 to 17,000 clients by mid-1995 [2, 13]. There were approximately 32,000 methadone clients Australia wide in June 2001, with an average annual growth rate of 14 per cent since 1985 [46]. Currently (in 2007), there are an estimated 38,000 people receiving opioid replacement therapy [47].

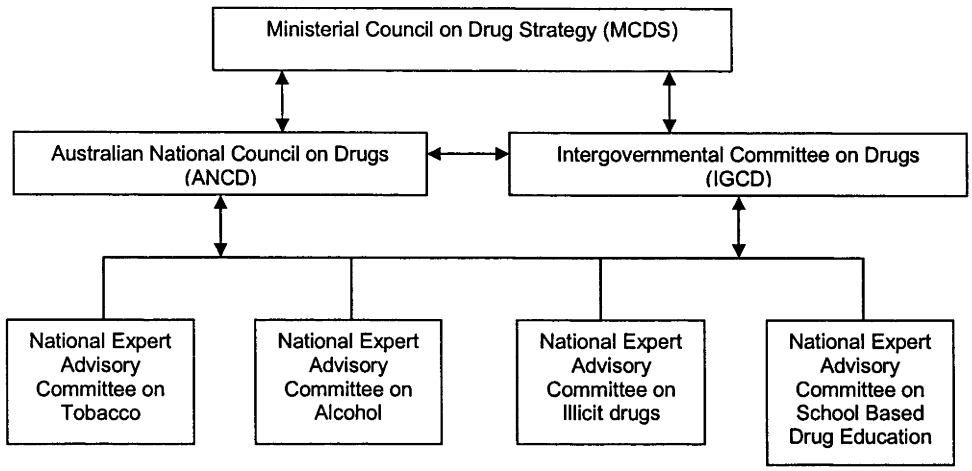
Since I commenced this study other forms of opioid replacement therapy have been registered as treatments for heroin dependency in Australia. Buprenorphine in tablet form (subutex) was registered in October 2000, while a combination of buprenorphine and naltrexone as a sublingual tablet (suboxone) was registered in 2005. Methadone however, still continues to be used as the main opioid replacement therapy in Australia.

1.3.2: Australian Government Framework for methadone treatment

Australia has a Federal system of Government, with the Constitution establishing a Commonwealth Government and six State and two Territory governments. The Australian Health Care System follows this pattern of governance giving the Commonwealth Government certain powers in specified fields of Health, and the State and Territory Governments powers in other areas. The Commonwealth Government has a leadership role in policy making, particularly in the areas of Public Health, Research and Health Information Management. State and Territory Governments are responsible for delivery and management of public health services, such as acute care services and a wide range of public and community health services including the methadone treatment programme. State and Territory Governments are also responsible for liaison with health care providers and the regulation of health professionals. The Australian health care system contracts the provision of health services both at the Commonwealth and State and Territory levels through a large network of health providers in the private and non-government sector. Consultation and administration of the health care system is managed between the Commonwealth and State and Territories through the Australian Health Ministers Council (AHMC). There are several ministerial advisory councils with representation from the Commonwealth and State and Territory Governments on various health issues that are responsible for development of policy and strategies that inform the AHMC [48, 49].

Based on this system of health care, the Commonwealth Government is responsible for the formulation of national strategic directions, national policy and clinical guidelines for methadone treatment, under the auspices of the NDS. States and Territories are responsible to adopt the broad policy context framework and principles of these guidelines for service delivery and regulation of service provision. There is a National Structure in place that provides the information and advice necessary to inform national strategic direction and policy. This structure is presented in Figure 1.2. All alcohol, tobacco and other drug treatment policies fall under this structure and are the responsibility of the various committees that form this structure. Policies and guidelines for methadone treatment are developed under the auspices of this structure.

Figure 1.2: Australian National Drug Strategy Structure



Adopted from the National Drug Strategic Framework 1998-99 to 2002-03

There are three key strategic documents which provide the guiding principles and philosophies under which treatment for heroin dependence is delivered. These are:

1) The National Drug Strategy (currently 2004-2009) [5].
2) The National Pharmacotherapy Policy for People Dependent on Opioids (2004) [46].
3) The National Policy on Methadone Treatment (1997) [13].

The NDS is the ultimate responsibility of the Ministerial Council on Drug Strategy (MCDS), which receives advice from the Australian National Council on Drugs (ANCD) and the Inter Governmental Committee on Drugs (IGCD). The ANCD represents stakeholders interested in drug strategy and involves the private and non-government sector, and the general community. The IGCD represents stakeholders and experts from the Commonwealth and State and Territory Governments [5].

The National Pharmacotherapy Policy for People Dependent on Opioids was produced under the auspices of the NDS and was prepared by the methadone subcommittee of the IGCD. This policy provides States and Territories with guidelines for the different types of treatment available for heroin dependency in Australia. Opioid replacement therapies currently recognised and used in Australia for heroin dependency under these guidelines are methadone, buprenorphine and naltrexone [46].

Methadone is the most commonly used treatment for heroin dependence in Australia and is administered orally [13]. Injectable methadone and heroin have not been used and are not available in Australia for the treatment of opioid dependency unlike the UK [50]. There is a range of options available to manage heroin dependence in addition to opioid replacement therapies. These include in-patient and out-patient withdrawal services, day programmes, therapeutic communities and self-help groups [13].

The National Policy on Methadone Treatment is also produced under the auspices of the NDS and is the key document for methadone treatment objectives and principles. States and Territories provide and deliver methadone treatment services according to the broad policy context and framework set out in these guidelines [13].

1.3.3: The goals and objectives of the methadone treatment programme

The goal of methadone treatment and the objectives of the programme in Australia as established by the National Policy on Methadone Treatment (pg 6) are quoted below [13].

> The goal of methadone treatment is to reduce the health, social and economic harms to individuals and the community associated with unsanctioned opioid use.

> The objectives of methadone treatment are:
> - To reduce harmful opioid and other drug use;
> - To improve the health of clients;
> - To help reduce the spread of blood-borne communicable diseases associated with injecting opioid use;
> - To reduce deaths associated with opioid use;
> - To reduce crime associated with opioid use; and
> - To facilitate an improvement in social functioning.

1.3.4: Service delivery and regulation

The methadone treatment programme is regulated through the Australian Health System. Service delivery of methadone treatment in Australia is the responsibility of States and Territories and jurisdictional policy is developed based on national polices and guidelines. Some aspects of the programme are funded at the national level, while others are funded at the State and Territory level. Service delivery occurs through a combination of public and private sector providers; most clients are treated either completely or partially through the public health system [13].

Clients in most States and Territories are inducted into the programme through the public sector, where assessment and treatment schedules are drawn up by Medical Officers employed by public sector methadone clinics. Dosing also occurs through the public sector until the client is considered stable, after which they can be transferred into the private sector. Clinical assessment and management in the private sector is usually conducted by GPs who are registered as methadone prescribers, and dosing occurs at participating community pharmacies. Criteria for induction into the programme and transfer between public and private sectors can vary according to jurisdictional guidelines within States and Territories [13].

The prescription and administration of methadone is highly controlled and most people on the programme have to access their dosing site to get their regular dose. Methadone treatment requires daily dosing, and until deemed stable clients are required to present at their dosing centre on a daily basis. Dosing times are restricted and can vary between sites. Most clients pay a nominal fee (either on a weekly or daily basis) for their methadone. There are some instances where clients may get their methadone free, for example at the commencement of the programme during a short induction period. Once clients are relatively stable they may be eligible for Takeaway Doses (TAs). The criteria for eligibility for TAs and the number of TAs once again vary according to jurisdictional guidelines. Payment for assessment services and methadone also varies between jurisdictions [13].

It is recommended by the National Policy on Methadone Treatment that clients be encouraged to have testing for HIV, HBV and HCV at the time of induction into the programme. The availability and access to support systems such as counsellors, case managers, social welfare services and follow-up support after treatment completion is also recommended but is at the discretion of jurisdictional policy [13].

1.3.5: Current state of play

Methadone treatment in Australia has been proven to be successful in improving health status, minimising harm from injecting and reducing some BBV transmission amongst opioid dependent users [51, 52]. Treatment programmes have grown immensely since commencement in 1969. Programmes have seen many changes in relation to service provision and delivery with the aim of maximising outcomes for clients. A review of the administration and service delivery of the methadone treatment programme in Australia in 1995 indicated that treatment philosophies and principles were similar between States and Territories and were basically dictated by national policy. There were, however, considerable differences in development and delivery of programmes between States and Territories [2]. Growth and changes to methadone treatment programmes within different jurisdictions have occurred at different rates and within different aspects of the programme. Changes have included a shift from methadone withdrawal to maintenance treatment, a shift from being a completely public programme to having a combination of service provision through public and private sectors, and an increase in the number of available places and decrease in waiting lists to be admitted to programmes [2].

Although there have been several changes that have enhanced the methadone treatment programme in Australia over the years, there have been difficulties in meeting treatment needs for all dependent heroin users [51]. This could be associated with jurisdictional policy relating to service provision and delivery, and rural area specific issues. There has been minimal evaluation of these changes and about the way differences in service delivery could affect outcomes for rural clients.

The methadone treatment programme and NSPs do not seem to have had an impact on transmission and incidence of HCV (unlike HIV and HBV) in Australia [24, 53]. Dore and colleagues estimated an incidence of 10-20/100 person years and prevalence of 50-55 per cent amongst IDUs in 2003. Levels of HCV transmission were found to be particularly high in both younger IDUs and incarcerated IDUs [54]. A more recent study in Sydney, NSW which followed up 215 HCV negative IDUs at 3-6 monthly intervals, observed a total of 61 seroconversions with an incidence of 45.8/100 person years. [55]. Depending on future IDU patterns and practices, it is projected that there could be 300-800,000 infected people in Australia by 2020 [17].

Reasons for the continuing transmission of HCV even with successful harm reduction strategies are not completely understood. Crofts suggested in 1999, that the higher prevalence and infectiousness of HCV (in comparison to that of HIV), combined with risk factors related to injecting (including contamination of equipment other than needles and syringes, such as tourniquets, spoons, water and swabs) as contributing factors [24]. Lack of accurate knowledge of HCV status and aetiology could also be contributing factors. Studies conducted amongst methadone treatment clients in the UK and the United States (US) indicated that clients lacked knowledge about their status, risk factors for transmission, consequences of infection and treatment [56, 57]. A study that I was involved with while working in SNSW PHU in relation to methadone injecting amongst a rural population, found that accuracy of HCV self-report was relatively low amongst participants. Forty four of 64 participants in this study provided a blood sample, of whom 66 per cent (n=25) were serologically positive for HCV. Sixty per cent (n=15) reported their positive status correctly, while 54 per cent (n=7) reported their negative status correctly [58]. This study suggested that knowledge of actual HCV status amongst IDUs can be inaccurate.

These issues instigated my interest in whether policy and service delivery in rural areas could affect methadone treatment outcomes for rural clients differently to urban clients, whether lack of knowledge of HCV status amongst IDUs could be a contributing factor to continuing HCV transmission, and whether rural IDUs knowledge was different to that of urban IDUs. This formed the basis for my PhD and the development of the following aims.

1.4: Aims of the study

1) To measure and compare health status and BBV risk (HIV, HBV, and HCV) between urban and rural methadone clients, and to identify factors that affect these outcomes.
2) To establish the validity of HCV self-reported status amongst IDUs by comparing it to serological status, and to compare HCV self-report validity between urban and rural areas.

1.5: Rationale for comparing health and BBV risk outcomes for urban and rural methadone programme clients

There are two perspectives from which conclusions about effectiveness of methadone treatment can be drawn: 1) from the perspective of the general community and 2) from the perspective of the heroin dependent individual. The general community would be interested in methadone treatment effectiveness in decreasing drug use and antisocial behaviour including crimes related to drug use. From the heroin dependent individual's perspective, one would be interested in decreasing the chance of acquiring BBVs through injecting and improving health and social well-being [44]. As I am interested in comparing outcomes for urban and rural individuals on the programme, I have chosen to concentrate on health and BBV risk outcomes. In addition to this, these are the two outcome areas that I have clinical experience and knowledge in. I have chosen to focus on BBV risk outcomes related to injecting risk practices as methadone treatment aims to minimise BBV transmission by decreasing injecting.

The benefits of methadone maintenance treatment are at their optimum when programmes are easily available, accessible and clients are retained on treatment as long as possible [13, 44, 59]. Factors that have been shown to influence programme entry, participation and retention include: number and/or location of treatment programmes, cost to clients, opening hours of dosing centres, methadone dose, assessment procedures, attitudes of treating clinicians, and relevant access to other allied health and social welfare support services [13, 44]. The National Policy on Methadone Treatment stipulates four principles that should be part of treatment programmes to optimise benefits of treatment: availability, access, acceptability and quality of care [13]. These four principles can be compromised in rural areas as shown in other rural health outcomes studies (mental health, dental health, sexual health and youth health) [60-65].

The 1996 Australian census estimated that 14 per cent of the Australian population lived in rural areas [66]. In 2002, 14 per cent of opioid maintenance therapy patients in NSW were classified as rural clients [67]. Access to services has been shown to be the major barrier for better health outcomes for rural populations. This was recognised in 2002 at a joint conference of the World Health Organization (WHO) and the World Organization of Family Doctors (WONCA) which initiated 'The Global Initiative on Rural Health' and the 'Health for All' vision for rural people [68].

Limited access to methadone treatment for rural people could be due to decreased availability of services, smaller choice of service provider, and longer travel time and distance to services. Confidentiality and stigmatisation are also issues that could contribute to poorer access for rural people resulting in poorer health outcomes [69, 70]. It has been shown that people will travel longer distances in rural and small communities to seek treatment if confidentiality is an issue [71]. These issues have been shown to affect the rural young to a greater extent, and health seeking behaviour in relation to sexual health and drug use (including alcohol, tobacco and illicit drugs) [72, 73].

Cost of services in rural areas can be a contributory factor to health seeking behaviour and outcomes [74, 75]. Cost for rural clients that could affect methadone treatment outcomes might include the cost of the service, cost associated with travel, and costs of seeking other allied health services support if these are not provided through the programme. Cost in its own right could compromise compliance and retention on the programme.

At the time of commencement of my study in 2000, there had been very little research conducted into evaluating outcomes for rural clients on methadone treatment. An article written in 1998 by Richards highlighted some strengths and weaknesses of methadone treatment in rural Australia based on his experience as a rural GP in Victoria. Lack of proper public transport systems, confidentiality and lack of support from health professionals and the community were identified as factors that contributed to barriers for effective treatment outcomes. Richards highlights that rural IDUs and methadone treatment clients faced greater barriers to accessing harm minimisation and treatment services than their urban counterparts [76]. Another article in 2002 by Edwards and Donnermeyer suggested that due to very little research conducted in rural areas, methadone treatment policy and delivery had been based on research conducted in urban centres [77].

From my own experience working with a rural PHU between 1998 to 2001, I noticed that availability, access, cost and confidentiality of services were relevant to outcomes for clients in the sexual health and methadone treatment programmes. Jurisdictional policy and service delivery of methadone treatment in this rural area may have further compromised outcomes for clients.

As methadone is at present the most preferred and cost effective option for treatment of heroin dependency, it is important to evaluate its effectiveness particularly where optimal level of service provision can be compromised such as in rural areas. My study takes this first step to investigate if differences in relation to sociodemographics, risk practices, and service delivery and policy, affect outcomes for rural methadone clients in comparison to urban clients.

1.6: Rationale for establishing validity of HCV self-report amongst IDUs

The term validity is used in reference to the validity of a screening test to pick up actual disease as used in clinical epidemiology. In my study validity of HCV self-reported status refers to the accuracy of self-reported status as a screening test to determine whether a person is truly HCV positive as indicated by serology [78, 79].

HCV has emerged as a major health issue amongst IDUs globally and in Australia. Injecting drug use has been shown to be a major risk factor for acquiring HCV as it is primarily transmitted through blood. Studies have shown that 60-80 per cent of IDUs in Australia are HCV positive [17, 80-82]. State and Territory PHUs received approximately 160,000 notifications of HCV infections between 1990-2000 making it the most commonly notified communicable disease in Australia [54]. It has been estimated that there were 242,000 Australians living with hepatitis C by the end of 2003 with 16,000 new infections occurring every year. The evidence suggests that 80 per cent of past infections and 90 per cent of currently occurring infections in Australia are associated with unsafe injecting drug use [17].

Seventy five per cent of people infected with HCV will develop chronic disease and the 25 per cent who clear the virus will still have detectable antibodies present indicating past exposure [17]. Common symptoms of chronic HCV are lethargy, nausea, headaches, joint pains and depression. Symptoms can take many years to develop. An estimated 7-20 per cent of persons with chronic HCV will develop cirrhosis over a 20-40 year period if therapeutic intervention is not sought. Another four per cent may develop hepatocellular carcinoma or liver failure [17, 54]. Currently, HCV-related liver disease is the primary reason for liver transplants in Australia. People co-infected with other BBVs such as HIV and HBV have been shown to progress more quickly to develop liver disease [17].

Past infection with HCV does not provide immunity from being re-infected [17, 20]. There are six major genotypes of HCV with several subtypes, and re-infection with a different genotype can occur [83]. It has been shown that IDUs can be infected with several genotypes at the same time [84]. There is no vaccine available for HCV. Treatment has been available for a few years and the effectiveness is improving, but only a small proportion (<10%) of people with HCV access treatment [47, 85]. Reasons for this are not clearly understood, but access issues (such as location of clinics), side effects of treatment and lack of knowledge of the criteria to be eligible for treatment and their outcomes may be deterrents [17, 20, 85].

In addition to physical illness, people infected with HCV suffer many social and economic consequences of the illness [86]. Due to physical symptoms, many people are forced to reduce working hours. As HCV is known to be strongly associated with injecting drug use, many infected people can be discriminated against [17, 87].

Due to the health and social consequences associated with HCV it is important for IDUs to have accurate knowledge of their status. Lack of accurate knowledge of HCV status could be a reason for the high incidence and transmission of HCV that is continuing to occur in Australia and also a reason for not seeking treatment and support. It could also be responsible for unnecessary stigmatisation by the general community. In addition to this, many studies investigating socio-demographic and risk factors associated with HCV use self-reported status as an indicator of HCV status.

At the commencement of my research, I found only five studies that had investigated knowledge about HCV status amongst IDUs: two in Australia [88, 89], and three overseas [56, 57, 90]. The objectives of these studies were mainly to identify risk factors for HCV, but some findings suggested that knowledge of actual HCV status may be poor. For these reasons I decided to examine the validity of HCV self-reported status as an indicator of true status amongst a sample of IDUs in Australia further. I also decided to compare accuracy between urban and rural IDUs, as the accuracy of HCV self-reported status in the NSW rural methadone injectors study was poor. I chose to measure the validity of HIV self-report as a comparison to HCV self-report as when HIV was discovered there was a huge momentum towards education, testing and harm minimisation, and people at risk were made very aware of the consequences of HIV and AIDS.

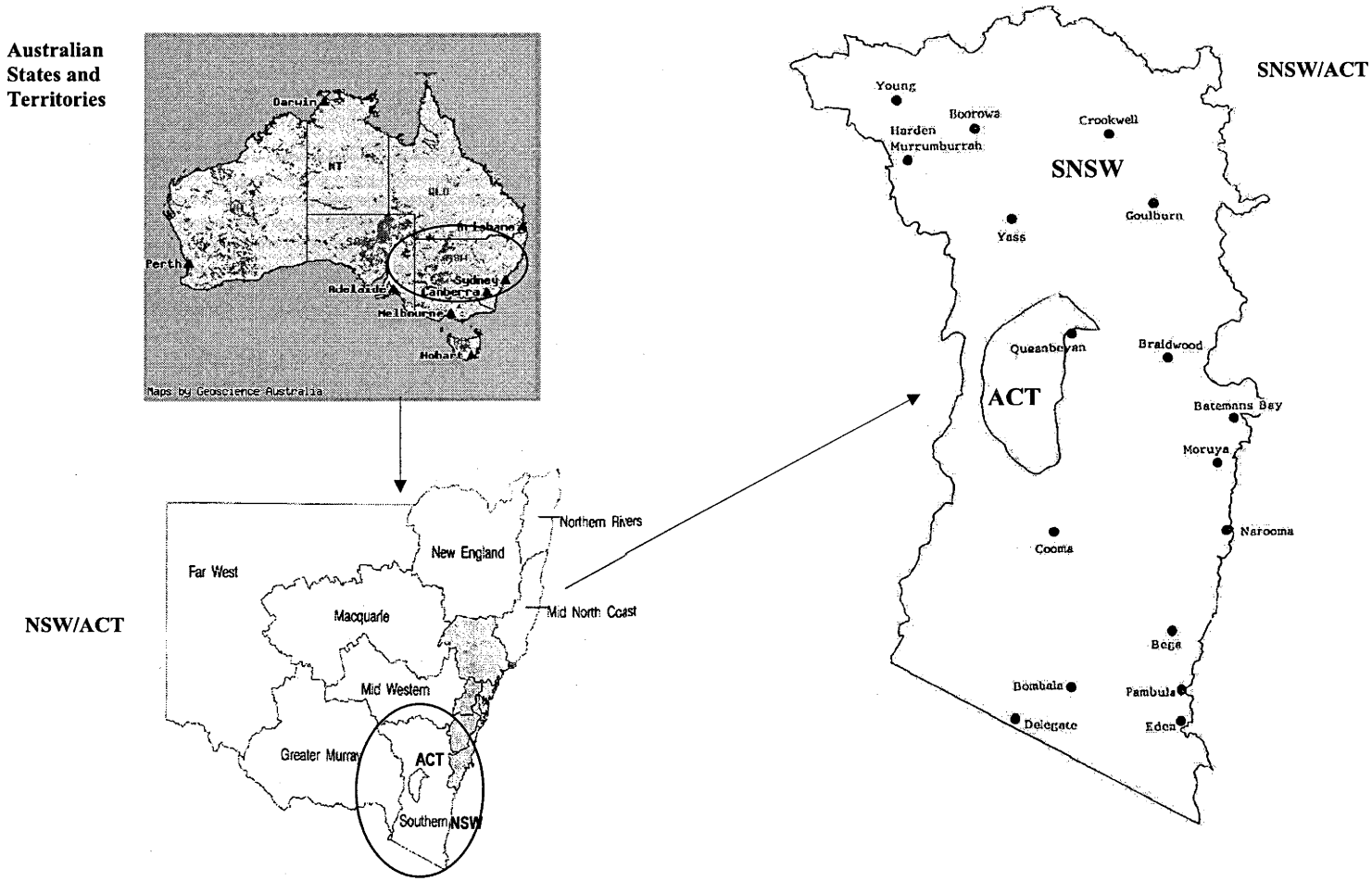
1.7: Locations for the study

Having worked closely with the SNSW methadone treatment programme and gaining knowledge of the practicalities of delivering the programme within the area, I chose this area to represent the rural group for my study. The ACT programme was chosen as the comparable urban study group as it had a similar population size to SNSW and was located within the boundaries of SNSW. Geographical location of the two study areas are represented in Figure 1.3.

At the time of data collection (2002), the ACT had a population of 307,053 [91]. SNSW had a population of 239,993 within three statistical subdivisions; these being the Southern Highlands (population 68,045), South Coast (66,731) and Southern Tablelands (population 105,217) [91]. The SNSW population was spread out in population groups of 5,000 persons upwards. The largest population group was in the city of Queanbeyan (population 41,378), which is within the Southern Tablelands and shares a boundary with the ACT.

Although the two areas were similar in population size and located within the same regional area of Australia, they varied in relation to some aspects. The ACT had a higher average annual income of $55,000 per annum compared to $35,000 per annum in SNSW. The two areas also differed geographically with SNSW being spread over a large and diverse area with mountain ranges and coastal areas, with a three hour travel radius from its administrative centre, Queanbeyan. In contrast, the ACT although elevated 570 metres above sea level is basically flat with a 30 minute travel radius from the city centre with all residents closely located to central services. The two areas also varied in terms of health service provision, delivery and management, based on policy that applied within their State and Territory governments and for reasons specific to urban and rural areas. These factors have been considered in the comparison of the two groups in relation to my research questions.

Figure 1.3: Geographical location of study sites



1.8: The ACT and SNSW methadone programme structure

The methadone programmes in both the ACT and SNSW were managed and delivered according to national frameworks with State and Territory policy articulating service delivery within these frameworks. The National Drug Strategic Framework 1998-99 to 2002-03 provided the national framework under which the two programmes developed strategies for delivery of AOD Programmes [4]. The National Policy on Methadone Treatment provided the guidelines for delivery of the methadone treatment programme within the overall national framework [4, 13].

The ACT and SNSW programmes were managed through a combination of the public and private health systems. Each programme had three tiers (Tier 1, Tier 2, and Tier 3). Clients were registered into these tiers dependent on whether they were a new client or not, and for existing clients their stability in their current programme. Clients could be moved in and out of the tiers depending on their stability and adherence to criteria within each tier. Movement between tiers was also dependent on the availability of places within the tiers. Table 1.1 (at the end of the chapter) compares service delivery and management of the two programmes and the three tiers within the programmes.

1.8.1: Tier 1 (Public)

Tier 1 was completely managed through the public health system and all services were delivered through the public sector. All persons who were new to the methadone programme were registered into this tier for assessment and management of their opioid dependence. Clients were clinically assessed and managed through public methadone clinics and were dosed at public outlets based at the public clinics, hospitals or community health centres. Cost of clinical assessment and management was covered by the public health system (Medicare system) and was thus free to the client. Most new clients were dosed on a daily basis in this tier and payment for methadone depended on jurisdiction programme policy. If there was a payment for methadone this was a flat rate that was to be paid on a weekly basis.

1.8.2: Tier 2 (Partly Public/Partly Private)

Tier 2 was partly public and partly private in relation to client assessment, management and delivery of the service. Clinical assessment and management of clients was conducted through the public system similar to Tier 1, but dosing was conducted through the private sector at community pharmacies registered with the programme as service providers. All clients in Tier 2 paid a weekly fee for methadone which was a flat rate not dependent on dose. In some instances payment was partly subsidised by the programme. In most instances clients could only be registered in Tier 2 after being stabilised in Tier 1.

1.8.3: Tier 3 (Private)

Tier 3 was referred to as the private tier where client assessment, management and delivery of services were completely through the private health sector. All clients who were registered with Tier 3 were most likely to enter the programme through Tier 1 for initial clinical assessment and management. They would either have progressed through Tier 2 into Tier 3 or on some occasions directly from Tier 1 to Tier 3 depending on their stability. GPs registered as methadone prescribes (GP prescriber) on a State and Territory Registry were responsible for clinical assessment and management of clients in this tier. Tier 3 clients had to pay for their clinical assessments, according to general practice rates; some GP prescribers bulk-billed [2] through the Medicare system, which meant no out-of-pocket expense for the client. Clients dosed at community pharmacies and paid for their weekly methadone dose on a similar basis to Tier 2 clients.

1.8.4: TA and transfer policy

The availability and number of TAs per week depended on the tier the client was in, stability of the client, time on the programme and TA policy within each programme. Tier 2 and 3 clients were more likely to get TAs on a regular basis as they were usually more stable than Tier 1 clients. Transfer between State and Territory programmes required negotiation and availability of an appropriate place on the programme in which a client was transferring into. Clients moving away temporarily or travelling for a period longer than for which they could get TAs also required a transfer to another programme.

[2] The Medicare system in Australia pays a rebate for a GP consultation. Most GP consultations (and some other medical services) are above this rate, meaning an out-of-pocket expense to a client. In some instances a GP will only charge the cost of the rebate which is referred to as bulk-billing. This means no out-of-pocket expense to the client.

1.9: The ACT programme

The first formal ACT methadone treatment programme started in 1979 as a completely publicly managed and delivered programme at the Woden Valley Hospital. Between 1986 to 1994, the number of clients on methadone increased from 64 to 323 [2]. For many years the programme had approximately 80 places (A. Faden 2007, [ACT Methadone Programme] pers.comm., 10 January). In 1993, the programme was still completely run through the public sector and there were three dosing points, one in Woden Valley Hospital (south-side of Canberra), one in Civic (north-side of Canberra, city centre) and one operating out of a pharmacy in Queanbeyan [3] [92]. In 1995, the methadone programme instituted dosing through the private sector via community pharmacies. All clinical assessment of clients was still conducted through the public sector by two medical officers employed by the ACT Department of Health and there were no private methadone prescribers. Ninety per cent of cases dosed at the clinics in Woden and Civic, while the rest dosed at five community pharmacies and the pharmacy at Queanbeyan that were approved for dosing [2].

By 2002 when I conducted my study, the ACT programme had considerably expanded since 1993 and had a total of 755 places available at any one time. The programme had evolved to having three tiers with public and private sector management and service delivery components. Tier 1 had a total of 270 places, Tier 2 had 330 places and Tier 3 had 155 places. Strictly speaking a potential client had to be a resident of the ACT (residential address with ACT postcode) to be eligible to register on the programme.

At the time of the study the ACT had two public methadone clinics, one based in Civic in the north-side of Canberra and one based at The Canberra Hospital (TCH) in Woden in the south-side of Canberra (the old Woden Valley Hospital). The clinic in the north-side provided some clinical assessment and management services, and provided a public outlet for dosing in the north side. This clinic closed down during the course of my study, which left the ACT with one public clinic and dosing outlet for the entire population. The south-side clinic provided the bulk of the clinical assessment and management services, particularly with assessment of new clients, and provided a public outlet for dosing. It also functioned as the administrative centre for the management of the ACT programme.

[3] Queanbeyan centre was part of the ACT programme as the SNSW programme did not exist at this time.

1.9.1: ACT Tier 1

All new clients were initiated into the programme through Tier 1. All Tier 1 clients were clinically assessed and managed at the public clinic in TCH, Woden. Services were bulk-billed through the Medicare system with no cost to the client. Clients were provided with prescriptions for methadone at regular intervals based on their clinical assessment by medical officers within the clinic. Clients in this tier received their daily methadone dose at the public clinic in Woden at two designated time periods; one in the morning and one in the afternoon. Methadone was provided cost-free for the first six months in this tier, after which all clients paid $15.00 per week, regardless of magnitude of dose.

Clients in this tier were allowed a maximum of two TAs per week. The number of TAs per week was dependent on the length of time the client had been on the programme, results of random urine tests for opioids and other drugs, indicating stability of the client. Clients were not allowed TAs in the first three months, after which they were allowed one TA if they had four clear random urine tests in the first four months of treatment. If clients progressed over the next four months with clear random urine tests, they would be eligible to have two TAs per week.

1.9.2: ACT Tier 2

Once clients were stabilised in Tier 1, they could be moved into Tier 2. Clients in this tier were clinically assessed and managed by medical officers in the public clinic at TCH with no cost to the client, similar to Tier 1. Dosing of clients in this Tier was through the private health sector at community pharmacies registered as service providers with the ACT programme. Community Pharmacies had fixed time periods for dosing similar to the public clinic. Most dosing pharmacies had only one time slot per day, which was usually as soon as the pharmacy opened in the morning. The cost of methadone dosing (regardless of magnitude of dose) was $30.00 per week; the client paid $15.00 and the ACT programme subsidised the remaining $15.00 payment. Clients were allowed TAs if four of six random urine tests were drug free, and were allowed a maximum of three TAs per week dependent on stability.

1.9.3: ACT Tier 3

Clients in Tier 3 were clinically assessed and managed through GPs who were registered with the ACT programme as prescribers. Most clients were usually charged a fee to see the GP prescriber for assessment and provision of prescriptions due to the limited level of bulk-billing within the ACT. Clients in this tier dosed at community pharmacies with a similar set-up as Tier 2 clients. Payment policy for these clients was that they paid the full $30.00 per week for methadone, but in practice, they paid $15.00 per week like all other tiers (with a subsidy of $15.00 from the ACT methadone programme). TA policy was also the same as for clients in Tier 2.

1.9.4: ACT programme policies common to all tiers

Case managers were allocated to ACT Tier 1 and 2 methadone clients on a needs basis when they had complex clinical assessment management issues; this arrangement was extended to Tier 3 clients in some instances. ACT methadone programme clients were also subject to a missed dose policy. If a client missed one or two doses consecutively, a quick assessment was made by the dosing staff. If there were no significant issues and the client appeared stable, they would continue to be dosed. If a client missed three or more doses consecutively, they would need to be reviewed by a medical officer for re-assessment of dose. If a client missed seven doses consecutively (i.e. a week of dosing), they would be removed from the programme and would need to be assessed as a new client to re-enter the programme.

There was a total of 18 community pharmacies that dosed methadone clients and a total of 23 GP prescribers through the ACT at the time of my study. All clients (regardless of which tier they were in) were registered with the public programme. There were two databases for registration purposes; one database for Tier 1 and a second database for Tier 2 and 3 clients. Tier 2 and 3 clients were on one database for purposes of registration with community pharmacies.

1.10: The SNSW programme

The SNSW methadone programme is a relatively new programme, having commenced in 1994. The methadone programme was introduced to NSW in the 1970s but the programme was not rolled out to smaller centres and rural areas until some time later. This does not mean that methadone treatment was not available within SNSW until 1994. Prior to 1994, there were approximately 20 clients being case managed by AOD service workers in one of SNSW's cities (Goulburn). These clients were prescribed methadone by a GP in Campbelltown on the outskirts of Sydney (about 175kms from Goulburn). There were a handful of GPs in the south-coast who had patients on methadone as well. This system of being managed by GPs continued on as Tier 3 of the SNSW programme when it commenced in 1994, but without any formal links (B. Callahan [SNSW Methadone Programme] 2007, pers.comm., 15 January).

In 2002, the SNSW methadone programme had a total of 300 places. The programme had three tiers with a combination of public health and private health sector management and service delivery. The three tiers had 100 places each and to be eligible to enter the programme a client had to be a resident of SNSW (SNSW residential postcode). This was similar to the ACT's residential criteria.

1.10.1: SNSW Tier 1

Unlike the ACT programme, clinical assessment, management and prescribing methadone for clients Tier 1 was done by medical officers from the private sector who were contracted by the programme (most being GPs, others being locum medical officers). These medical officers conducted assessment and prescription clinics for the SNSW programme at the Queanbeyan public clinic. Rooms in the public clinic were rented by the medical officers, and clients were bulk-billed for the service (i.e. no cost to them). The end result was similar to the ACT programme with clinical assessment and management being provided by default through the public health system. Clients were dosed at public dosing outlets based within community health centres (CHC) and one hospital through the area. Methadone was completely subsidised by the programme and provided free of charge in Tier 1. Unlike the ACT programme, clients in this tier were not eligible for any TAs. This was different to the rest of NSW's TA policy [93]. This was mainly put in place to decrease demand for dosing within the public system (B. Callahan [SNSW Methadone Programme] 2002, pers. comm., 15 March).

1.10.2: SNSW Tier 2

Clients entered Tier 2, once stabilised in Tier 1, similar to the ACT programme. Clinical assessment, management and prescription of methadone in this tier were as per Tier 1. Dosing of clients was at community pharmacies, thus making this part of service delivery through the private system. In contrast to the ACT programme, clients in this tier did not receive a subsidy for the cost of methadone and paid the full-cost for their weekly dosing, which was $35.00 per week. Clients in this tier were eligible for a maximum of four TAs per week dependent on their time on the programme and stability. Clients were not eligible for TAs in the first three months on the programme. After this they were eligible for a maximum of two TAs between 3-12 months on the programme, a maximum of three TAs between 12 months to two years on the programme and a maximum of four TAs after two years on the programme.

1.10.3: SNSW Tier 3

Unlike the ACT program, clients could register into Tier 3 in SNSW directly without having to go through Tier 1. As Tier 3 of the programme had no formal links to the SNSW programme (due to the history of its development), these clients were the sole responsibility of the GP prescriber managing them. They could enter and exit the programme without having to register with the SNSW methadone programme. These clients could approach a GP prescriber within the area and at the discretion of the prescriber could be initiated into the programme. This arrangement was developed to particularly assist persons seeking treatment for opioid dependence in areas within SNSW where there was limited access to the public programme. Clinical assessment and management was provided through the private health sector without subsidy from the programme and the client usually paid the full cost for it. Similar to Tier 2 clients, clients in this tier dosed at community pharmacies and paid the full-cost of methadone of $35.00 per week with no subsidy from the programme. The number of TAs a client received per week was at the discretion of the GP prescriber managing the client. Clients in this tier were only registered on the NSW Pharmaceutical Registry for identification and provision of methadone at nominated community pharmacies.

1.10.4: SNSW programme policies common to all tiers

All clients in Tiers 1 and 2 of the SNSW programme were allocated case managers routinely for the time that they were on the programme regardless of whether they had complex management issues or not. This was in contrast to the ACT programme. Tier 3 clients did not have access to case managers. In rare instances this could be negotiated between a GP prescriber and the SNSW programme. If there was a prolonged need for a case manager, a transfer from Tier 3 to Tier 1 or 2 would most likely be negotiated. The SNSW programme also had a missed dose policy which was similar to the ACT programme policy.

At the time of the study, there were eight public dosing outlets in SNSW which included seven community health centres and one hospital. There were 25 community pharmacies through the area that dosed methadone clients and eight GP prescribers registered with the programme.

Management and service delivery policies for the ACT and SNSW methadone treatment programmes are described and compared in Table 1.1.

Table 1.1: Comparison of ACT and SNSW methadone programme service delivery and management structure

Policy	ACT (urban study group)	SNSW (rural study group)
Overall Programme*		
- Number of public dosing outlets	1	8 (7 community health centres and 1 hospital)
- Number of community pharmacies	18	25
- Number of GP Prescribers	23	17 (9 had patients had time of study)
- Missed dose policy	1-2 doses = assessment by dosing staff, continue dosing 3 or > = assessment by medical officers 7 = off programme	1-2 doses = assessment by dosing staff, continue dosing, 3 or > = assessment by medical officers, 7 = off programme
- Registration	All Tiers registered with the ACT programme	Tiers 1&2 registered with the SNSW programme
Tier 1		
- Clinical assessment	Public clinic medical officer	Private sector medical officer contracted by programme
- Cost of clinical assessment	Nil (as covered through the clinic)	Nil (covered through bulk-billing)
- Dosing	Public clinic outlet	Community health centre and one hospital
- Cost of methadone	Free for first 6 months, then $15.00per week	Free
- TA	No TAs for first three months, maximum two TAs	Nil
- Case Manager	On a needs basis	Routine for the period of time on the programme
Tier 2		
- Clinical assessment	Public clinic medical officer	Private sector medical officer contracted by programme
- Cost of clinical assessment	Nil (as covered through the clinic)	Nil (covered through bulk-billing)
- Dosing	Community Pharmacy	Community Pharmacy
- Cost of methadone	$30.00 per week (client paid $15.00 and $15.00 subsidised by the programme)	$35.00 per week (no programme subsidy)
- TA	Maximum three TAs	Maximum 4 TAs, time dependent
- Case Manager	On a needs basis	Routine for the period of time on the programme
Tier 3		
- Clinical assessment	GP prescribers (private sector)	GP prescribers (private sector)
- Cost of clinical assessment	As per GP charges	As per GP charges
- Dosing	Community pharmacy	Community Pharmacy
- Cost of methadone	$30.00 per week (client paid $15.00 and $15.00 subsidised by the programme)	$35.00 per week (no programme subsidy)
- TA	Maximum 3 per week	At GP's discretion
- Case Manager	On a needs basis	No access

* *Relevant to all tiers*

1.11: Summary

Australia has an identified problem of heroin dependency and associated health and social problems. Prevention of BBV transmission related to injecting drug use is an integral part of public health policy and harm reduction.

Methadone has been identified as an effective treatment to curtail heroin use and assist with reducing health and social problems associated with heroin dependency. Methadone treatment services are delivered under the auspices of State and Territory Policy within the broad contextual framework of the NDS, The National Pharmacotherapy Policy for People Dependent on Opioids and the National Policy on Methadone Treatment. All States and Territories are required to provide access to methadone treatment which includes assessment and clinical management, access to suitable dosing centres, support systems such as crisis counselling, appropriate referrals for other medical services and the need to provide a confidential and informative service. Criteria and policy of service provision may differ according to State and Territory and jurisdictional policy. For this reason, availability, access, cost and support services may vary between jurisdictions. Differing service delivery policy, along with rural specific issues such as availability, access, cost and confidentiality of services, can contribute to differences in outcomes for urban and rural methadone clients.

HCV has emerged as a major health issue for Australian IDUs. Due to its high prevalence HCV poses a greater threat than HIV and HBV amongst IDUs. Lack of accurate knowledge of HCV status could affect HCV transmission amongst IDUs and treatment seeking behaviour. Findings from studies investigating demographic and risk factors associated with HCV using self-report as an indicator of HCV status may also be compromised due to this. For these reasons it is important to ascertain the validity of HCV self-report amongst IDUs.

The two methadone programmes chosen as study groups for urban and rural comparison of health and BBV risk taking behaviour outcomes were the ACT and SNSW. The two study areas were comparable in terms of population size, but differed in terms of annual average income and geography.

The management of the urban and rural programmes was basically similar, with both programmes having three tiers for service delivery and management. Services in Tier 1 in both areas were completely managed and delivered through the public sector, even if the mechanisms for service delivery differed in the two areas. Tier 2 for the two programmes was also similar with services being partly public and partly privately managed and delivered. Tier 3 for the two areas, although completely delivered through the private sector, differed in relation to its links to the Area programme. There were differences identified in relation to access to service delivery and policy such as access to TAs, cost of methadone, and allocation of cases managers.

Both programmes continue to be managed and delivered in the same way to date. (A. Faden 2007, [ACT Methadone Programme] pers.comm., 10 January; B. Callahan [SNSW Methadone Programme] 2007, pers.comm., 15 January).

1.12: Implications of the study

Through this thesis I aim to contribute towards knowledge about urban and rural outcomes for opioid users on methadone treatment and a better understanding of HCV self-report accuracy amongst IDUs.

It is envisaged that results from this study will:

1) Identify if there are differences in health and BBV risk outcomes for urban and rural methadone clients and identify the factors associated with these outcomes.
2) Provide further information about validity of HCV self-report amongst IDUs.
3) Inform policy making and service delivery for methadone treatment clients and IDUs not on treatment according to urban and rural needs.

Chapter 2

Literature review

In this chapter I present a literature review about the inception of the methadone programme, its goals and expected outcomes, its effectiveness in curtailing heroin use and improving health and decreasing BBV risk behaviours. I also include an overview of literature on rural health and BBV risk outcomes and research findings on accuracy of HCV and other BBV self-report.

2.1: History of heroin dependency

Heroin (diacetylmorphine) is a semi-synthetic drug derived from opium. The opium poppy was cultivated as early as 3400 BC in lower Mesopotamia and was used for many reasons including medicinal, cultural and social[4] reasons. Morphine, the principle active opiate extracted from the opium poppy was known for its 'addictive" properties from early times of use [94, 95]. Heroin was synthesised from morphine in 1874 by a British chemist C.R. Alder Wright, by combining morphine with acetic anhydride acid after experimenting with combining morphine with various acids. This compound was further analysed by F.M. Pierce who confirmed that its properties included production of analgesia, euphoria and a sense of well-being [95]. Heroin was released as a medicinal product by the pharmaceutical company Bayer in 1898 and was marketed as a cough medicine for children as a supposed non-'addictive' substitute for morphine until 1910 [96, 97]. Heroin was also marketed as a treatment for morphine 'addiction' prior to the discovery that it was in fact 'addictive' as it is converted to morphine in the brain [97].

Heroin mimics endorphins which are produced regularly by the body and induce a sense of well-being and attenuate pain [98]. When heroin is introduced to the body, the body responds by reducing the production of endogenous endorphins as heroin substitutes their effect [99]. Frequent use can lead to tolerance of its effects, and the need for higher doses to experience its effects. As heroin replaces endogenous endorphins, the body can also become dependent on it. Once a stage of dependency is reached, non-use of the drug can cause severe withdrawal effects within 6-24 hours of the last dose [99].

Withdrawal effects include sweating, malaise, anxiety, depression, cramping, muscle and bone aches, sleep problems, cold sweats, nausea, vomiting, diarrhoea, priapism in males (persistent and intense penile erection) and genital hypersensitivity in females. Sometimes symptoms can be severe enough to be life threatening if not treated; for example dehydration from vomiting and diarrhoea [99] .

[4] By social use, I refer to non-dependent heroin use to experience a euphoric state.

Heroin can be injected (intramuscular, subcutaneous, and intravenous) smoked, snorted or consumed orally. The onset of its effect depends on route of administration. Intravenous injection results in an almost immediate rush and a state of euphoria and is the most common route of administration [100]. International studies have shown that about 55 per cent of users inject it [100, 101]. Injecting is more common in Australia, and a recent study in 2006 showed that 86 per cent of study participants injected their opioids [67].

In the early 1900s heroin became popular as a social drug due to its euphoric properties [102]. As heroin use and the likelihood of dependency and its associated consequences increased, many countries passed laws to monitor its production and availability for medicinal purposes only. By the mid-1920s most countries had made the production of heroin for non-medicinal purposes illegal and by the 1930s heroin trafficking became more prevalent because of these laws. In the 1940s most western countries declared heroin to be a controlled substance due to its high level of non-prescribed use, and high potential for dependency and associated health risks.

Making heroin a controlled substance increased the potential for black market supplies and as is the case with all black market supplies, the cost of heroin soared. This became an issue particularly for users who were dependent on the drug [103]. Maintaining a heroin dependency needed large sums of money on a regular basis which led many users to a life of crime and sex work. The bulk of a dependent individual's finances went towards maintaining their heroin dependency, which led to other social issues such as unemployment, lack of proper housing, nutrition and antisocial behaviours. Heroin dependency also led to many health issues such as malnutrition, infections related to injecting and general poor health [97, 104-107]. The illegality of use made it difficult for dependent persons to seek help for these problems. The 1950s and 60s saw a huge increase in heroin dependent individuals in the US with the numbers continuing to rise in the 1970s along with the health and social issues that accompanied it [97, 104, 108].

2.2: The inception of methadone treatment to combat heroin dependency

The main opium supply for manufacture of heroin in the US and Europe between the 1940s to the 1970s was from Iran. In the 1940s due to World War II and temporary trade disruptions (including the engagement of Iran in anti-opium policies under pressure from the US) heroin trafficking was virtually eliminated in the US and parts of Europe. Due to this allied effort threatening heroin supply from Iran, the Germans developed methadone in their laboratories in 1939, alongside many other synthetic opioids (including pethidine) for medicinal purposes. Methadone was known initially as Amidon and was not used extensively in the early years of discovery. This new synthetic opioid was recognised to have strong analgesic properties and a long duration of action. It was given the name methadone in 1947, but only marketed as a drug in 1949 and patented in 1953. It has been marketed under other names including Dolophine, Phenadone and Physeptone [97, 109].

The health and social problems associated with heroin use and dependency became widely recognised in the US in the 1950s, and a number of abstinence related treatment programmes were developed to combat it [97]. In the early 1960s, Marie Nyswander a New York based psychiatrist who had worked in these abstinence based programmes, and her husband Vincent Dole (a biochemist), noticed that there were limited results achieved through abstinence in relation to health and social well-being for heroin dependent users. In an initial trial of treating 307 heroin dependent individuals with methadone, they observed that individuals not only stopped their heroin-seeking behaviour, but did remarkably well in relation to health and social well-being without counselling support even though available. This observation made them question the theory of 'addictive' personalities contributing to heroin dependency. They considered it more likely to be associated with a metabolic deficiency that could be managed by administering a sufficient amount of an appropriate substitute opioid [110]. Based on this argument they decided to substitute heroin with other opioids in the quest to treat heroin dependency and carried out trials using different opioids [111].

In 1964, after numerous trials using short acting opioids, Dole and Nyswander found that methadone had the best outcome amongst heroin users in curtailing use, and improving health and social well-being [112, 113]. The advantages of methadone were that it could be taken orally and had a longer half-life then most other synthetic opioids. This meant that it needed to be administered only once a day (one dose in 24 hours).

Dole and Nyswander noticed that with this one dose in 24 hours, heroin dependent persons were able to regain control of their lives, improve their health and nutrition, social circumstances and move away from a life of crime and sex work [113].

With the success of this first trial of methadone treatment in reducing heroin use, criminal activity and improving health, its use to curtail heroin dependency and associated problems became quite common, and the methadone treatment programme was born [44]. Since then, methadone treatment has been adopted in many countries to treat heroin dependency. There have been many changes to the management of the programme over the years in relation to objectives, dosage and support services provided for rehabilitation [44, 114].

The use of methadone became even more important with the advent of HIV in the early 1980s as one of the transmission routes for HIV was identified to be through blood, thus making injecting drug use a major risk category for transmission [115]. The role that methadone treatment could play in preventing transmission of BBVs in general became even more obvious in the latter part of the 1980s with the identification of HCV, which was shown to be most effectively transmitted through blood [20]. With these two milestones in the 1980s, the importance of using methadone as an oral opioid substitute for decreasing heroin injecting and managing dependency became even more magnified. The importance of keeping the prevalence of HIV low amongst IDUs to prevent transmission to the general population through other routes (i.e. sexual and vertical) was also a factor in driving the need to decrease injecting drug use related to heroin dependency [44].

Over the years methadone has been used to treat heroin dependency both as a withdrawal and maintenance treatment. The ultimate aim of withdrawal programmes was abstinence from use of heroin, and this was to be achieved through administering decreasing doses of methadone over the course of treatment. In contrast methadone maintenance programmes aim to reduce heroin dependency to enable a dependent user to improve their health and social well-being [44]. Research has shown that heroin dependent users on methadone withdrawal programmes are more likely to relapse to heroin use, and that methadone maintenance programmes are much more effective in reducing heroin use and allowing for a return to normal life [51, 116-118]. Most methadone treatment programmes in Australia today are maintenance programmes.

2.3: The effectiveness of methadone treatment

The main goal of methadone treatment is to improve health status, and psychological and social well being of the opioid dependent person [119]. The initial aim of methadone treatment was to reduce heroin use and associated crime, which is why methadone treatment programmes were supported by governments and the public [44]. From the heroin dependent individual's point of view, the aim is to improve health and social functioning (e.g. housing, employment, relationships) and decrease the chances of acquiring BBVs [44]. Effectiveness of methadone treatment is usually measured under five outcome headings: 1) decreased drug use, 2) decreased BBV risk, 3) improved physical and psychological health, 4) decreased criminal activity and 5) improved social adjustment and functioning [13, 120]. Researchers have studied the effectiveness of methadone in achieving single outcomes or a combination of outcomes.

Research since the inception of methadone treatment has shown that methadone is particularly effective in reducing heroin use and associated crime. There are three Randomised Controlled Trials (RCT) quoted in most methadone literature assessing the effectiveness of methadone treatment in relation to decreased heroin use and crime, two of which are reviewed here [121, 122]. The third study is not reported here as it concentrates on the effect of methadone dose and retention in the programme [123].

The first RCT was conducted by Dole and colleagues in 1969 [121]. The study was conducted amongst 32 male prisoners who had been dependent on heroin for at least four years and were eligible for release over a four month period at the time of commencement of the study. The prisoners were randomly assigned to methadone treatment and non-treatment groups with 16 participants in each group. Of the 16 prisoners randomly assigned to the methadone treatment group, 12 took part in the study and commenced on methadone before leaving jail. The 16 prisoners in the non-treatment group were put on a waiting list. The two groups were followed up after 12 months of release from prison; there was one member in each group lost to follow-up. Of the 12 participants in the methadone treatment group, none returned to daily heroin use (although 10 of 12 had used heroin at least once since their release) and only three returned to jail. In contrast, all 16 participants in the control group had returned to daily heroin use and prison. The non-treatment group had a 2.67 times greater risk of being re-imprisoned and four times greater risk of returning to daily heroin use as compared to the treatment group [121].

A previous publication by Dole and Colleagues reported results of their first trial conducted in 1965, which indicated that methadone curtailed heroin use, decreased crime and increased social functioning [111]. The results were cautiously accepted and supported by the medical fraternity but did not receive support from law enforcement agencies and the general community [44, 97]. The RCT conducted later in 1969 showed similar results but had a greater impact on law enforcement agencies and community groups as it showed a clear association between methadone use and decreased incarceration suggesting a decrease in crime.

The second RCT was conducted in 1981 by Gunne and Gronbladh in Sweden, and compared patients on methadone in an in-patient setting with intensive vocational rehabilitation, and persons with referral to drug-free treatment [122]. The criteria for entry into the study were similar to the RCT conducted by Dole and colleagues in 1969, with participants having to be opioid dependent for at least four years and having tried rehabilitation before. The study design was such that participants were recruited into the two groups until a statistically significant difference was elicited between outcomes for the groups. Outcomes were assessed at the end of two years. In total, 36 persons were recruited to the study, 17 of whom were placed in the methadone treatment group. When the two groups were compared, 12 of the 17 participants in the treatment group no longer used other opioids. In the non-treatment group only one participant had ceased using opioids; two had died and two were in prison [122].

Similar results were seen in an Australian observational study, which compared crime rates while on treatment as opposed to when not on treatment as one of its objectives [124]. Three hundred and four methadone clients from three different private clinics were recruited into the study and interviewed on three occasions over a twelve month period. Crime rates on treatment and off treatment were measured through self-report and by checking police records on the three interview occasions. Crime rates through self-report while on treatment were one-eighth the level of when the person was not on treatment (i.e. prior to entry into their current treatment programme). Police records corroborated self-report results. Participants who had committed crimes while on treatment were more likely to have used illegal drugs, particularly cannabis. The study concluded that crime rates are lower while on methadone treatment than when dependent on illegal opioids [124].

Results from these three studies indicate that participants on methadone treatment had decreased their heroin use and associated crime as compared to participants who were not on methadone treatment.

Improved social functioning is another recognised outcome of methadone treatment [97, 125]. The RCT conducted by Dole and colleagues in 1969 showed improved social functioning for participants who were in the methadone treatment group. Of the 12 participants in the methadone treatment group, six were employed or studying [121]. In the Gunne and Gronbladh study of 1989, 12 of the 17 participants in methadone treatment were either employed or studying [122]. A more recent study published in 1999 by Dore and colleagues examined the effectiveness of methadone treatment by comparing outcomes for 112 clients before and after six months in treatment in a New Zealand clinic. The study found that during treatment the number of clients on government benefits reduced by almost 30 per cent, employment rates doubled from 19 to 40 per cent (including attendance at educational programmes) [126].

Cost effectiveness of methadone treatment for heroin dependency is another factor that makes it attractive to governments as well as to the general community [44, 97]. A literature review into the cost-effectiveness of methadone maintenance as a health care intervention for heroin use was conducted in 1999 [127]. The aim was to measure the mortality associated with opioid use. Life-years of survival were used as the measure of treatment benefit. Cost effectiveness was calculated through cost for every life-year saved. The study found that providing opioid dependent persons with access to methadone incurred an additional treatment cost of $5915 for every year of life saved (incremental cost-effectiveness ratio of $5915 per life-year gained). This ratio is much lower than many other medical therapies and well below the $50, 000 threshold for every life year saved used for judging cost-effectiveness of a treatment [127].

2.3.1: Effectiveness of methadone treatment in improving health outcomes and decreasing BBV risk

Dole and Nyswander, recorded an improvement in appearance, attitude and general health amongst heroin dependent individuals with their first trial of methadone treatment in the 1960s [97, 113]. It has been shown that heroin dependent individuals entering methadone treatment suffer from both physical and psychological health problems [44]. Physical health problems include infectious diseases such as respiratory illness, dermatological problems, sexually transmissible infections, BBVs, infective endocarditis, osteomyelitis and septicaemia. BBV risk associated with heroin dependency is related to HCV, HIV and HBV. Additional health problems that have been noted to be associated with heroin dependency are malnutrition, dental caries, menstrual irregularities, accidents, overdose and injecting associated risks such as emboli and cellulitis [128, 129]. Most common psychological disorders seen in heroin dependent individuals are mood disturbances and personality disorders, but can range to severe psychiatric disorders. Whether psychological problems are a cause or consequence of illicit drug use, still remains unclear [130, 131].

Many health and BBV risk problems are directly related to risky injecting behaviour (such as sharing equipment) leading to transmission of an infection (e.g. BBVs, endocarditis, pneumonia, septicaemia) [44]. Other health problems are related to the physical act of unhygienic and unsafe injecting as a route of drug administration (e.g. localised infection around the injecting site, collapse of veins, and emboli) [129]. By replacing heroin with methadone, the need to inject and use heroin and the associated financial strain has decreased. This is turn has assisted with improving the physical, mental, psychological and social health of these individuals as defined by the WHO [104, 132].

The following summary of studies show that methadone treatment is effective in improving health outcomes, decreasing mortality associated with heroin dependency, and decreasing injecting and associated BBV risk.

2.3.1.a: Effectiveness of methadone treatment in decreasing mortality

Gearing and Schweitzer measured changes in mortality rates amongst heroin dependent individuals as part of an evaluation of long-term methadone maintenance treatment [133]. The evaluation was done in four cohorts and conducted amongst 17,500 patients admitted to New York city methadone treatment programmes between 1964 and 1971. Ninety per cent were still in treatment after one year, while 80 per cent remained after two years and 75 per cent after 3 years. The study found that mortality rates of people who remained in treatment (7.6 deaths per 1000) were lower than those observed among methadone clients who had left treatment (28.2 per thousand), and were not much higher than the general New York population at that time (5.6 per thousand).

A case control-study conducted amongst 4200 methadone treatment clients in Rome between 1980 to 1988, found that those who left treatment were over three times more likely to die from heroin overdose than those who stayed in treatment (OR=3.55, CI: 1.82-6.90) [134]. The risk was higher for those who left treatment in the first 12 months. These individuals were eight times more likely to die from an overdose (OR=7.98, CI: 3.40-18.73). In the following 12 months, those who left treatment were two times more likely to die from overdose as those who remained (OR=2.54, CI: 1.25-5.15).

Heroin dependent individuals in Australia have also been shown to have higher mortality rates than the general population. This is usually associated with overdose [1]. A long-term follow-up study of a cohort of 307 study heroin dependent persons admitted to methadone treatment in Australia, showed that those who left treatment were there times more likely to die than those in treatment (CI: 1.45-5.61) [135].

2.3.1.b: Effectiveness of methadone treatment in decreasing injecting

Ball and Ross (1991) investigated the effectiveness of methadone treatment in decreasing frequency of injecting and sharing of equipment. A total of 633 male patients from six methadone maintenance programmes in the US were recruited over a three-year period [136]. Of 506 patients interviewed at the end of the study period, 388 remained in treatment. Of these, 36 per cent had not injected since the first month on methadone treatment, 22 per cent had not injected in the past year and 13 per cent had not injected in the one to 11 months prior to interview. The rate of injection in the remainder was less than before entry into treatment.

An Australian study conducted by Baker and colleagues in 1995 compared injecting and sexual risk-taking behaviour among IDUs who were currently, previously and never enrolled in methadone treatment [137]. All participants had to have injected in the six months prior to interview to be eligible to enter the study. The OTI was used to measure injecting and sexual risk [120]. Results indicated that the three groups were similar for age, age at first injection and number of years at school. IDUs who were currently on methadone treatment had significantly lower ($p<0.001$) injecting risk behaviour than the group who had been on methadone treatment previously, and the group who had never been in treatment. IDUs on current treatment also differed significantly from the other two groups in the frequency of injecting ($p<0.001$) and cleaning of injecting equipment with bleach ($p<0.01$). For sexual risk behaviour there was no difference between the IDUs on methadone treatment and the other two study groups.

The study by Dore and colleagues (1999) examining effectiveness of methadone treatment amongst clients in a New Zealand clinic, found that of 89 clients injecting opioids daily prior to treatment, 64 per cent reported no opioid use in the three months prior to review (at six months after commencement of treatment). Sharing of injecting equipment was also reduced by almost 90 per cent [126].

2.3.1.c: Effectiveness of methadone treatment in decreasing BBV transmission

Methadone treatment has been shown to be very effective in decreasing new HIV infections [44]. There have been two prospective cohort studies conducted in the US that examined the effectiveness of methadone treatment in reducing HIV transmission through injecting. In the first study, 255 heroin injectors (inclusive of injectors in treatment and not in treatment) were followed over a period of 18 months to determine incidence of HIV in the two groups [138]. One hundred and fifty two injectors in treatment were recruited from a methadone clinic in north-central Philadelphia and 103 injectors not in treatment were recruited from surrounding areas. HIV serology and other behavioural assessments were conducted at six monthly intervals over the follow-up period and results were available for 89 per cent of the sample. At baseline, the HIV seroprevalence rate for the total sample was 12 per cent; 10 per cent for injectors on methadone and 16 per cent for injectors not on methadone. Seroconversion rates were calculated for the HIV-negative injectors in both groups. At the end of the follow-up period, injectors on methadone showed a seroconversion rate of 3.5 per cent, while injectors not on methadone showed a seroconversion rate of 22 per cent.

Moss and colleagues conducted the second cohort study, which aimed to examine HIV seroconversion rate, risk factors for seroconversion, and changes in risk behaviour over time amongst IDUs admitted to methadone treatment in San Francisco between 1985-1990 [139]. A total of 2351 heterosexual IDUs were recruited into the study, of whom 681 were HIV sero-negative at first visit. At the end of the study period, results showed that of these 681 participants, those who stayed in methadone treatment for over a year were almost three times less likely (risk ratio of 2.7) to have sero-converted for HIV as opposed to those who had stayed in treatment for less than one year.

Some countries that were initially opposed to methadone treatment for heroin dependency (as it was seen as supporting continued drug use), changed their position to combat escalating HIV prevalence amongst IDUs when studies showed that methadone treatment assisted with decreasing incidence of HIV. Drucker in his 'Notes from the Drug Wars: On the European Front' describes France as an example of this phenomenon, where 20-40 per cent of heroin injectors were infected with HIV and the need to use methadone in this group to decrease injecting and minimise transmission of HIV was finally recognised [140].

With HCV, methadone treatment has not been as effective in minimising new infections as most methadone clients are already HCV positive when they start on treatment [44]. This could be due to the higher infectiousness and higher prevalence of HCV amongst IDUs as compared to HIV. The higher infectiousness of HCV may mean that transmission could occur with exposure to smaller amounts of contaminated blood [24, 55, 82]. The higher prevalence of HCV amongst IDUs also means that transmission of the virus can occur with fewer risk exposures compared to HIV. The lack of knowledge about the aetiology and transmission of HCV until the late 1980s may have also promoted unsafe injecting practices [7, 44, 53]. In addition to this, as discussed in Chapter 1, a person who is HCV positive can be re-infected with a different genotype and can thus have multiple infections unlike HIV [83, 84]. Due to its high prevalence amongst IDUs, the higher infectiousness, and the potential for re-infection with other genotypes, methadone treatment may be ineffective in preventing new infections of HCV but may be more effective in minimising re-infection with a different genotype.

This literature review indicates that methadone maintenance treatment over the years has been effective in improving health outcomes and decreasing mortality, in reducing injecting and transmission of HIV associated with heroin dependency.

2.4: Factors associated with health and BBV risk for rural IDUs

At the time of commencement of my study there was very little research that had been conducted into investigating factors that could be associated with health outcomes and BBV risk amongst rural IDUs (such as drug use and associated risk factors, access to, and delivery, of harm minimisation services). This paucity of research in rural areas has been recognised in recent years. Two studies in 2005 and 2006 have aimed to specifically compare risk practices between urban and rural IDUs related to injecting, and explore the relationship with service delivery in rural areas [67, 141].

The first study conducted by Day and colleagues (2005) aimed to compare patterns of drug use, associated harms, and service access and utilisation among rural and urban IDUs in Australia [141]. The study was conducted in NSW, where 164 rural and 96 urban IDUs were recruited. Urban and rural participants were found to be similar for sociodemographic factors such as age, gender, education and employment. Range of drugs used and drug use patterns were also similar for urban and rural participants. However, rural participants were less likely to have used heroin on a daily basis as compared to urban participants (rural: 2%; urban 10%), and were more likely to have injected morphine in the six months prior to interview (rural: 50%; urban: 21%). Rural participants were also less likely than urban participants to have used NSPs (rural: 36%; urban: 80%), and reported that access to NSPs and other drug treatment services was an issue [141].

The most recent study in 2006 by Lawrinson and colleagues examined if there were regional differences amongst entrants to opioid treatment in NSW in relation to sociodemographics, injecting practices and risk behaviours related to other substance use [67]. A total of 1512 consecutive entrants to opioid maintenance therapy in NSW were enrolled into the study between November 2000 and July 2003. There were three study groups; urban, regional and rural methadone treatment clients as designated by the NSW Department of Health (the demarcation between these groups is population dependent).

Data for this study were collected using the Brief Treatment Outcome Measure (BTOM)[5] when clients first entered into their methadone treatment programme. Results indicated that there were some sociodemographic differences between the study groups, with rural participants being significantly more likely to be older ($p=<0.001$), to have dependent children ($p<0.001$) and to be unemployed ($p<0.001$) in comparison to their urban and regional counterparts. Rural and regional participants were significantly more likely ($p<0.001$) and almost two times more likely to have shared injecting equipment as compared to urban participants (urban: 16%, regional: 31%, rural: 29%). The researchers conclude that there is a need to investigate the reasons for these differences in BBV risk, so that harm reduction and treatment services can be developed accordingly [67].

These two recent studies conducted after commencement of my study, suggest that there are differences between urban and rural IDUs in relation to sociodemographics, BBV risk exposures and access to harm minimisation and treatment services. The studies highlight that these differences need to be investigated further and taken into account when planning and delivering treatment services for heroin dependency. The findings from these two studies corroborate and support my study objectives to investigate if there are differences in outcomes for urban and rural methadone treatment clients and the factors affecting them. The differences identified in these two studies were included as possible factors that could affect health and BBV risk outcomes for urban and rural methadone clients in my study.

[5] The BTOM is a relatively new validated questionnaire that collects baseline information about dependency issues, BBV exposure risk, drug use, health/psychological functioning and social functioning at the commencement of opioid replacement therapy. Information is collected for client behaviour for the three months prior to interview.

2.5: Validity of HCV self-reported status

As discussed in Chapter 1, 60-80 per cent of IDUs in Australia are positive for HCV and it has been projected that there could be between 300,000 to 800,000 IDUs living with HCV by 2020 (1.5-4% of the Australian population). HCV is associated with many health and social consequences that impact on daily living and quality of life.

A literature search conducted at the time of commencement of my study found five previous studies that compared HCV self-report with serology [56, 57, 88-90]. These studies had other main objectives but blood samples were collected for BBV serology and information on self-reported status was also gathered. Four studies compared serology done at the time of the study with participant's recall of previous tests [57, 88-90], while the fifth study compared serology done within two years of the interview date and self-report [56]. Two studies were conducted amongst prisoners [88, 90]; one study amongst IDUs [89]; and two studies amongst methadone programme clients [56, 57]. The five studies used different population groups, and validity of self-report per se was not actively measured. I calculated the validity of HCV self-report from results published in the studies using clinical epidemiology measures, including sensitivity, specificity, positive and negative predictive values (PPV and NPV), and positive and negative likelihood ratios (PLR and NLR) [78]. These validity measures are summarised in Appendix 1.

Both prison studies were conducted for the purpose of determining BBV prevalence based on serology and to identify associated risk factors for BBV amongst prisoners. The first prison study was conducted amongst Irish prisoners and measured seroprevalence for HCV, HBV and HIV through salivary antibody status [90]. The second prison study was amongst Australian prisoners in NSW and serology was done through blood samples. Participants were asked to provide self-report of BBV status and the study provided the proportion of correct positive self-reports [88]. The study amongst Australian IDUs was a multi-city study comparing seroprevalence for HCV, HIV and HBV, associated risk factors and the effectiveness of available harm minimisation strategies between cities. Serology and self-reports for HCV, HBV and HIV were compared [89]. The first study amongst methadone programme clients was conducted amongst English methadone clients who were still injecting opioids and aimed to examine the accuracy of self-report of HBV and HCV status compared to serology [57]. The second study amongst US methadone clients compared HCV self-report with results of serology performed within two years of the self-report [56].

All five studies were conducted in differing settings with different study groups, and sociodemographic descriptions are presented in Table 2.1. The validity study amongst rural methadone injectors in NSW in 2000 was included as the sixth study in this description [58]. For these comparisons the entire study samples were used and not just the samples that aimed to compare HCV serology to self-report. The comparison found some sociodemographic differences between the study groups.

Studies conducted amongst methadone treatment clients had higher mean ages [56-58]. The male to female ratio was much higher amongst the prison studies [88, 90]. Only three studies (Australian IDUs study, the English methadone programme study and the NSW rural methadone injectors study) had information on education level [56, 58, 89]. A large proportion (72%) of the participants in the Australian IDUs study had not completed secondary school [89], while two-thirds in the English methadone programme study and the rural methadone injectors study had [56, 58]. All of the participants in the studies (other than the prison studies) had injected drugs. This was to be expected as they were studies amongst IDUs or methadone clients. These differences may affect risk exposure for HCV but would not affect the validity measurement of HCV self-report as this is dependent on testing and presumed knowledge of the individual.

Table 2.1: Sociodemographic characteristics of participants in the HCV self-report validity studies reviewed

Demographic Characteristics	Butler et al N=789	Thornton & Barry N=1205	Loxley et al N=872	Best et al N=106	Stein et al N=306	Southgate et al N=64
Year of study	1999	2000	1995	1999	2001	2001
Study Group	Prisoners	Prisoners	Injecting Drug Users	Methadone maintenance clients	Methadone maintenance clients	Rural methadone injectors
Country of study	Australia (NSW) (27 correctional centres)	Republic of Ireland (9 prisons)	Australia (Perth, Sydney, Melbourne, Adelaide)	United Kingdom (London)	United States (Providence, Rhode Island)	Australia (Southern NSW)
Mean age (range) in years	33.5 (18-67)	25 (NR)	28.5 (14-58)	36 (21-54)	40*	30 (16-43)
Sex						
male	83% (n=657)	95% (n=1148)	64% (n=562)	65% (n=69)	56% (n=171)	63% (n=40)
female	17% (n=132)	5% (n=57)	35% (n=306	35% (n=37)	44% (n=135)	37% (n=24)
transgender	0	0	0.5% (n=4)	0	0	0
Level of Education	NR	NR		NR		
< Yr 12			72% (n=629)		39% (n=119)	38% (n=24)
completed Yr 12			27% (n=239)		61% (n=187)	62% (n=40)
Employment	NA	NA		NR		
employed/student			26% (n=224)		40% (n=122)	77% (n=49)
unemployed/home duties			74% (n=646)		60% (n=184)	23% (n=15)
On methadone programme	NR	37% (n=185)	29% (n=256)	100% (n=106)	100% (n=306)	73% (n=47)
Previous imprisonment	58% (n=457)	NR	37% (n=324)	NR	NR	63.2% (n=36)
Ever injected	44% (n=349)	43% (n=509)	100 % (n=872)	100% (n=106)	100% (n=306)	100% (n=64)

*NR: Not Recorded, NA: Not Applicable, *Mode*

2.5.1: Validity of HCV self-reported status from the six studies

Findings in the published papers of these studies were used to measure validity of HCV self-reported status. Results are based on the sample in each study where both HCV self-report and serology were available. Some studies did not have all the necessary information to calculate all parameters of validity. Table 2.2 presents results for HCV self-report and serology status for participants of the six studies. For all studies, a greater proportion of participants were serologically positive than compared to self-report and a smaller proportion were serologically negative as compared to self-report.

Table 2.2: Comparison of correct self-reports (positive and negative) for the HCV validity studies reviewed

Study	+ve self-report		+ve serology		-ve self-report		–ve serology	
	n	%	n	%	n	%	n	%
Thornton & Barry (Irish prisoners) (n=304)	229	**75**	246	**81**	75	**25**	58	**19**
Butler et al (NSW prisoners) (n=738)	NA*	**NA**	288	**39**	NA	**NA**	NA	**NA**
Loxley et al (Australian IDUs) (n=599)	319	**53**	367	**61**	280	**47**	232	**39**
Best et al English methadone clients (n=79)	58	**73**	66	**84**	16	**20**	8	**10**
Stein et al (US methadone clients) (n=149)	104	**70**	132	**89**	45	**30**	17	**11**
Southgate et al (Australian rural methadone injectors) (n=38)	21	**55**	25	**65**	17	**45**	13	**34**

* *NA: Not Available*

Results of the validity analysis of HCV self-report for the six studies reviewed are presented in Table 2.3. This table has been reported once again in Chapter 7 inclusive of validity results from my study to compare and discuss the results from my study with these six studies. The proportion of participants who reported their status as positive and were HCV positive as elicited through serology (sensitivity) ranged between 60-90 per cent. These results suggest that between 10-40 per cent of people who are infected with HCV can report a false negative status. The positive predictive value ranged between 70-100 per cent suggesting that up to 30 per cent of people who are HCV positive can self-report a positive status when actually serologically negative. The likelihood of self-reporting a positive status when serologically positive as opposed to when negative (as measured by the PLR) ranged between 1.30 to 7.43. This suggests that people who are HCV positive are between one to seven times more likely to report a positive status when actually positive as compared to those who are negative.

The proportion of participants who truly did not have HCV and reported their negative status correctly (specificity) ranged between 54-100 per cent for the five studies where specificity could be calculated. Of these, three of the four studies had specificity of greater than 80 per cent; the NSW rural methadone injectors study had a very low specificity at 54 per cent in comparison. Taking into consideration the low specificity in the NSW methadone injectors study, the results suggest that up to 46 per cent of persons who are not infected with HCV can provide a false positive result. The negative predictive value had a very wide range, between 33-74 per cent, suggesting that predicting a correct negative result can vary widely for persons who are HCV negative, and can be as low as 33 per cent. The likelihood of self-reporting a negative HCV status while positive as opposed to when negative also varied widely and ranged between 0.13 to 0.74. This suggests that the likelihood of a negative self-report in persons who were HCV positive in comparison to those who were HCV negative could be up to three of four persons (0.74). This is a very high proportion of incorrect negative self-reports.

Results of these validity calculations for HCV self-report (positive or negative) from the six studies suggest that knowledge and awareness of HCV status is poor amongst people at risk of acquiring HCV. The results also suggest that validity of positive self-report is better than negative self-report.

Table 2.3: Validity of HCV self-report for the studies reviewed

Validity Measure	Butler et al N^=738	Thornton & Barry N^=304	Loxley et al N^=599	Best et al N^=74	Stein et al N^=149	Southgate et al N^=38
Year of study	1999	2000	1995	1999	2001	2001
Study Group	Prisoners	Prisoners	Injecting Drug Users	Methadone maintenance clients	Methadone maintenance clients	Rural methadone injectors
Sensitivity (CI)*	65% (60-71)	89% (84-92)	80% (76-84)	80% (77-94)	77% (69-84)	60 % (39-78)
Specificity (CI)	Not calculable	81% (68-90)	89% (84-93)	100% (60-100)	88% (62-98)	54% (26-80)
PPV (CI)	Not calculable	95% (91-98)	92% (89-95)	100% (92-100)	98% (93-100)	71% (48-88)
NPV (CI)	Not calculable	63% (51-73)	74% (68-79)	50% (26-75)	33% (20-49)	41% (19-67)
PLR (CI)	Not calculable	4.70 (2.13-7.22)	7.43 (4.60-10.27)	Not calculable	6.57 (-2.18-15.32)	1.30 (0.4-2.19)
NLR (CI)	Not calculable	0.13 (0.09-0.19)	0.22 (0.18-0.27)	0.12 (0.04-0.20)	0.26 (0.16-0.35)	0.74 (0.22-1.27)

*^Participants for whom serology and self-report were available, *Confidence Intervals*

I compared associations of possible risk factors with HCV serological and self-reported status in the NSW rural methadone injectors study [58]. This could not be done for the other studies reviewed due to lack of availability of results for this comparison. I did this to examine if the risk factors found to be significantly associated with HCV as determined by serology were the same as those elicited through self-report. I considered this to be important as one in four studies have been shown to use HCV self-report as an indicator of HCV status. The analysis conducted with HCV serological status (n=44) showed that men were significantly more likely to test positive than women, and those who had been in prison were significantly more likely to test positive ($p<0.05$). When the same analysis was conducted based on HCV self-reported status (n=64), these associations were no longer significant ($p>0.05$).

2.6: Summary

In this chapter I reviewed available literature about heroin dependency, the advent of methadone treatment to curtail heroin dependency and the accuracy of HCV self-reported status. Research has shown that methadone is effective in improving health, decreasing mortality, and decreasing BBV transmission associated with heroin use and injecting. Although there has not been an evaluation comparing methadone treatment outcomes for urban and rural clients in Australia, there has been recent research which suggests that rural IDUs and entrants to methadone treatment differ in relation to sociodemographic characteristics, risk behaviours and access to, and utilisation of harm minimisation treatment services, which could affect outcomes. The few studies that have examined the accuracy of self-report of BBVs prior to and after commencement of my study, suggest that the validity of HCV self-report is poor.

Chapter 3
Methods

In this chapter I describe the study design, ethical considerations, sampling methods, recruitment processes, data collection and handling, data analyses and limitations associated with the methods used.

Most alcohol and other drug research has been conducted using opportunistic or convenience sampling particularly with IDUs. As convenience sampling can introduce selection bias and confounding into study results, I attempted to recruit participants into this study through the use of random sampling [79]. Although this had limited success (as will be shown in this chapter), by using this methodology I explored the possibility of increasing validity of AOD research results by attempting to decrease selection bias. The outcomes of using random sampling in my study indicate that it is very difficult to do in research amongst IDU populations for logistic reasons and due to the unpredictable nature of IDU lifestyles.

Another feature of my study design was the use of verbal consent in the presence of an appropriate witness to gain informed consent from participants. This assisted in increasing the chances of participation by removing the need to identify individuals for random sampling.

I consider the attempt to increase validity of results and participation in my study by using these two methods to be a major contribution towards AOD research methodology.

3.1: Study design

The first aim of my study was to investigate if there was a difference in health and BBV risk outcomes for urban and rural methadone clients, and identify factors that were associated with these outcomes. The best study design to explore this was a cross sectional study design where data were collected at one point in time [79]. This study design was also suitable for my second aim to examine the validity of HCV self-report as compared to serology at one point in time. The study design was also the most practical in terms of time and resources available for a PhD thesis.

3.2: Instruments used for data collection

I developed a partly self-administered and partly interviewer administered questionnaire to collect data required for the study. The questionnaire was mainly quantitative (close ended questions) with questions developed specifically for the study. It included two validated questionnaires; the OTI [120, 142] and the BBV TraQ [143]. There were three parts to the questionnaire, the first part concentrated on gathering socio-demographic data and specific information on programme policy and service delivery factors that could be associated with the outcomes of interest (health, BBV risk, and validity of HCV self-report status). Most of the questions in this part were developed for the purpose of my study. Some questions from a short questionnaire used for a study conducted by Dr Gabriele Bammer in 1993 investigating the feasibility of controlled availability of opioids in Australia (ACT 1993 Feasibility study) were included in the first part, as they were relevant to the first aim of my study [92]. The second two parts consisted of the two validated questionnaires which were used to measure health and BBV risk outcomes. A finger prick blood spot test was used for serological diagnosis of HCV and HIV status of the participants [144].

3.2.1: The Questionnaire (Appendix 2)

The three parts to the questionnaire are described below.

Part I: General questions

Part 1 of the questionnaire was self-administered. There were four sections to this part.

Section 1: General questions

Included questions regarding socio-demographics, participant methadone treatment and programme management characteristics, participant perceptions of outcomes and satisfaction related to being on methadone treatment.

Section 2: Prison history

Collected data on prison history of participants and whether drug use and risk practices for BBV transmission occurred whilst in prison.

Section 3: Drug history

Collected information on drug use history, including first drugs used and injected, age when regular drug use commenced, and injecting practices. This section also collected information on methadone injecting.

Section 4: Serostatus

Participants were asked to self-report their perceived status for HIV, HBV, HCV and Hepatitis A Virus (HAV); details of when their last serological tests were done were also collected. Immunisation details were collected for HBV.

Part II: The BBV TraQ [143]

The BBV TraQ is a validated questionnaire developed by Fry, Rumbold and Lintzeris in 1998 under the auspices of the Turning Point Alcohol and Drug Centre [143]. It was developed for the sole purpose of measuring BBV risk. The TraQ measures risk in three domains; injecting risk, sexual risk and skin penetration risk (e.g. tattooing, body piercing and sharing of razors or toothbrushes). Additionally, it measures protective behaviours that may be used to minimise a risk practice while injecting. One of the criteria for use of the BBV TraQ is that participants need to be current injectors, which is described as having injected in the month prior to interview.

The BBV TraQ uses a numerical scale that calculates scores for each domain, and a total BBV risk score that combines the scores for the three domains. These scores indicate the magnitude of risk experienced by an individual in the three risk domains by quantifying it through the numerical score. Individual scores and group mean scores can be calculated within each domain as well as for the total BBV risk score. A zero score indicates no risk and any score above zero indicates risk; the higher the score the greater the risk.

I used the BBV TraQ as the questionnaire of choice for measuring BBV risk. Although my main focus was on risk associated with injecting, I also measured BBV risk from sexual and other skin penetration practices to examine how much of BBV risk amongst methadone clients in my study groups was contributed from these sources. The reasoning for using the BBV TraQ, and further description of how it measures BBV risk is described in Chapter 6 (results chapter measuring and comparing BBV risk).

Part III: The OTI

The OTI is a validated questionnaire which was developed in 1991 by Darke et al under the auspices of the National Drug and Alcohol Research Centre (NDARC) at the University of New South Wales [120] . The OTI was designed to measure and evaluate the outcomes of methadone treatment based on the five expected outcome measures described in Chapter 1. The OTI has also been extensively used for research purposes widely through Australia and other countries, including in a modified form in the UK [137, 142, 145-150].

The OTI has seven sections, six of which measure expected outcomes from methadone treatment as listed in the goals of treatment (Chapter 1). The first section gathers demographic information about participants. Sections II to VI measure outcomes related to drug use, BBV risk (injecting and sexual practices), social functioning (including housing, employment and relationships), involvement in crime, and health (general and in specific systems). Section VII uses the General Health Questionnaire-28 (GHQ-28) to measure psychological adjustment [151]. As demographic details were collected in Part 1 of my study questionnaire, the demographics section in the OTI (Section I) was not used in my study questionnaire. OTI information was collected from Sections II to VII only, which were re-labelled as I to VI for the purposes of my study.

The OTI also uses a numerical scale to measure the expected outcomes similar to the BBV TraQ. For sections relating to drug use history, BBV risk, crime, health and psychological adjustment (GHQ-28), risk or dysfunction is measured for the month prior to interview. For social functioning risk is measured for the six months prior to interview. A participant will have a numerical score for each of the section outcomes and a total score combining all section outcome scores (OTI total score). Mean scores can be calculated for study groups (group mean scores) in each section and for the OTI total score. Like the BBV TraQ a zero score indicates no risk or dysfunction in relation to the expected outcome, any score above zero indicates risk or dysfunction, and the higher the score the greater the risk or dysfunction.

I used the OTI to measure health outcomes in my study. The health section consisted of eight health areas/systems, and outcomes were measured through the presence or absence of symptoms within these. Scores for the eight areas/systems can be calculated and a Total Health Score (THS) can be calculated by combining the eight areas/system scores. Like the BBV TraQ, THS scores indicate the magnitude of health risk or dysfunction experienced by an individual. Although information was collected for all sections of the OTI, only measurement scores for health outcomes (THS scores) are presented in this thesis. Details of the measurement process for health outcomes are explained further in Chapter 5 (results chapter measuring and comparing health outcomes). Appendix 3 describes OTI measurement of all the outcome sections. Although the OTI measures BBV risk, I chose not to use the OTI for my study for reasons explained in Chapter 6.

3.2.2. Finger prick blood spot

Capillary blood collected through a finger prick blood spot test was used to establish serological HCV and HIV status. Venous blood samples were not collected as interview locations did not have appropriate facilities for collecting or storing large amounts of blood. Blood collected was stored on blotting paper at room temperature and couriered to the pathology laboratory for analysis at regular weekly intervals. Blood samples were tested for HCV antibody using a modified third generation enzyme immunoassay (Abbott HCV 3.0, Chicago II). HIV antibody was detected using Genetic Systems HIV-1 ELISA tests. These assays have been shown to have a high correlation with venous blood samples [144].

The National Centre for HIV Epidemiology and Clinical Research (NCHECR) in Sydney provided the test kits for serology and carried out the analysis. This support was provided to my study as the results of HCV and HIV status would contribute to the on-going Australian NSP Survey conducted by NCHECR [33].

3.3: Outcome measures

1) **Health**: Health outcomes were measured through group mean scores for urban and rural study groups in the following categories as calculated by the OTI.
   a. THS (Sum of systems score).
   b. Each systems score:
      - general health,
      - injection related problems,
      - cardio/respiratory,
      - genito-urinary,
      - gynaecological,
      - musculo-skeletal,
      - neurological,
      - gastrointestinal systems,
      - GHQ scores for psychological adjustment.
   c. Factors associated with THS within urban and rural study groups.

2) **BBV risk**: BBV risk was measured through group mean scores for urban and rural study groups in the following categories as calculated by the BBV TraQ.
   a. Total BBV score (sum of injecting, sexual and skin penetration risk score).
   b. Each section score:
      - injecting risk,
      - sexual risk,
      - other skin penetration risk.
   c. BBV risk in injectors and non-injectors.
   d. Factors associated with BBV risk due to injecting within urban and rural study groups.

3) **Validity of HCV self-reported status**: In my study, validity of HCV self-reported status refers to the accuracy of self-reported status as a screening test as used in clinical epidemiology, to determine whether a person is truly HCV positive as indicated by serology [79]. Validity of HCV self reported status compared to serological status was calculated for urban and rural study groups using the following epidemiological validity measures:
   a. sensitivity and specificity,
   b. positive and negative predictive values,
   c. positive and negative likelihood ratios.

   Validity of HIV self-reported status was measured as a comparator to validity of HCV self-reported status.

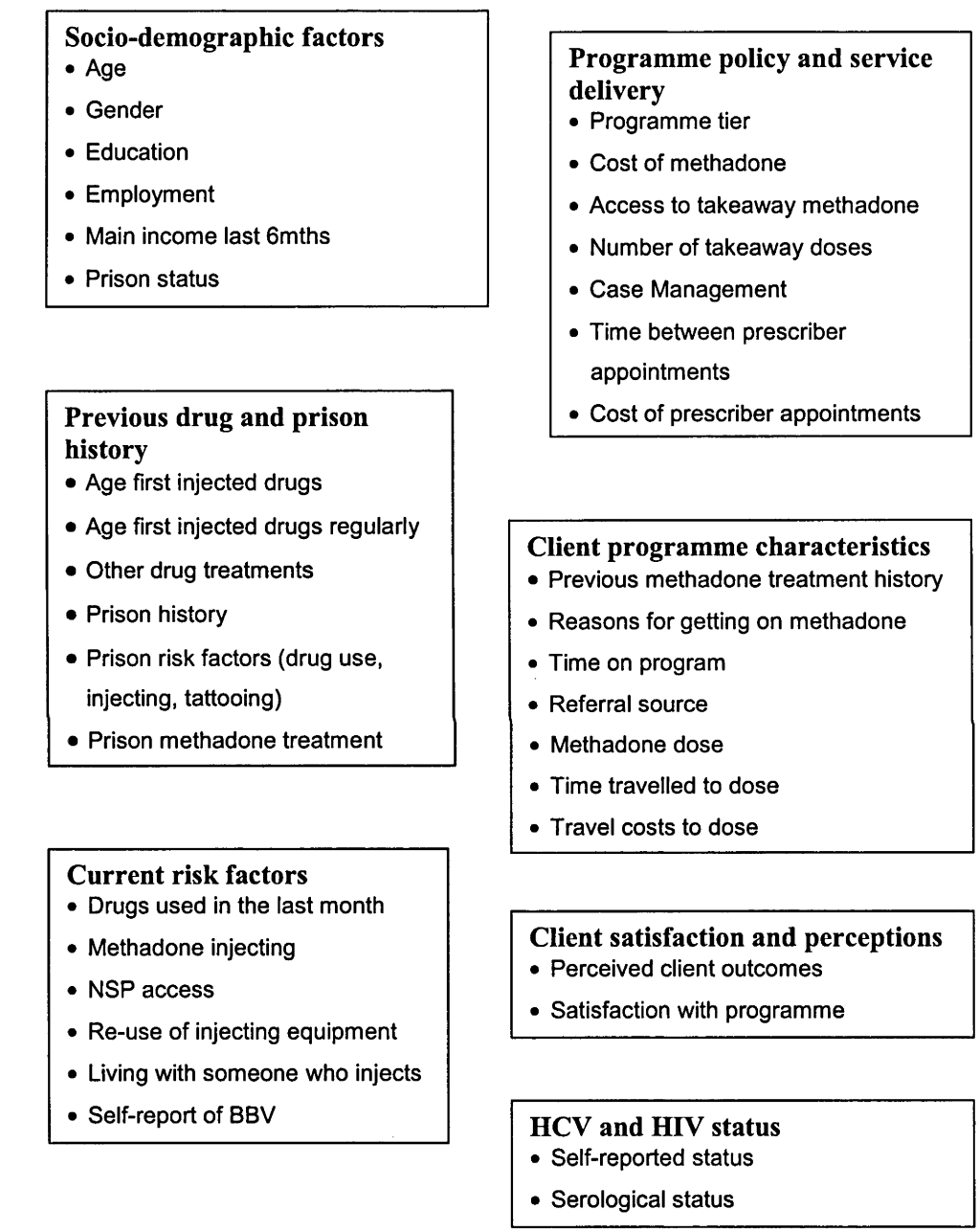
3.4: Factors that could be associated with study outcomes

Factors that could be potentially associated with the outcomes of interest in my study (health, BBV risk, validity of HCV self-report) were identified from previous studies and through my experience working with the SNSW PHU and methadone treatment programme. They were categorised under the following broad headings for which information was collected.

- Socio-demographic characteristics
- Participant risk factors
  - Previous drug and prison history
  - Current risk factors
- Methadone programme policy and service delivery
- Client programme characteristics
- Client satisfaction and perception of outcomes
- HCV self-reported and serological status
- HIV self-reported and serological status

Actual factors within these categories are outlined in Figure 3.2.

Figure 3.1: Factors that could be associated with study outcomes



3.5: Ethics Committee approval and ethical considerations

As this study involved two methadone programmes, ethics approval had to be obtained from the Ethics Committees responsible for the two programmes. Approval was also needed from the Australian National University (ANU) Human Research Ethics Committee (HREC), as the study was being conducted under the auspices of ANU. Ethics applications were prepared and submitted to the following three bodies at the end of September 2001:

- ANU HREC,
- ACT Department of Health and Community Care HREC,
- South Western Sydney Area Health Service HREC (proxy for SNSW Area Health Service).

Approval from all three committees was granted by the end of February 2002.

3.5.1: Main conditions for approval granted by Ethics Committees

1) All three HRECs required that the study should not have access to, collect or keep any identifying details that would allow a participant in the study to be traced. This was done to protect confidentiality and prevent identification of participants under the Federal Privacy Act 1988 [152].

2) A second ethical issue raised was the dissemination of HIV and HCV blood test results as a diagnosis. All three HRECs agreed that this could not be done for two reasons. Firstly, although the finger prick blood spot test used was recognised to have a high correlation with assays of venous blood samples, it was designed for research purposes only. A venous sample would be needed for confirmatory diagnosis and the participant would need to have pre and post test counselling as required by law [153]. Secondly, to disseminate results to participants, records of their identity and contact details would have to be kept, which was not allowed under the conditions granted for the study by the three HRECs. All HRECs required that participants be made aware of this and alternatives for diagnostic testing be provided. Every participant was given an information sheet (Appendix 4) at the time of the interview explaining the study, the process of the interview, protection of their identity and that results of blood tests would not be given to them. Participants were given the opportunity to have diagnostic testing done through their respective methadone programmes.

3) Informed verbal consent

Acquiring written consent from participants was not possible, as HRECs required that no identifying information of the client be kept. Instead, verbal consent was gained with a clinic/community health centre staff member present as a witness. This process for consent was included in the information sheet (Appendix 4) given to participants at the beginning of the interview and was read out to participants in the presence of the witness after the study had been explained. The witness was present until participants consented verbally to taking part in the study. The verbal consent process has been used in other AOD studies and is seen to be acceptable to fulfil ethics committees criteria in keeping the identity of participants anonymous [154]. Verbal consent was documented on the information/consent sheet and stored with the completed questionnaire. The study record number of participants was also noted on this information sheet and a copy of the sheet was given to participants. If a participant wished to withdraw from the study at any time, they were asked to call me or the ANU HREC Secretariat, quote their record number and asked to be removed from the study.

3.6: The sample

As mentioned in the introduction, most AOD research has used convenience sampling to maximise recruitment and increase sample sizes. One of the reasons for lesser numbers of individuals recruited into AOD research is the fear of being identified. Many studies require admission of illegal activity such as illicit drug use and criminal activity on the part of participants to be able to measure risk or outcomes. Acknowledgement of performing illegal activities could compromise participants' eligibility to remain on treatment programmes and also increase the chance of being identified by law enforcement agencies. There may also be social and professional implications such as loss of employment and stigmatisation by the community. These issues are particularly relevant amongst IDUs who are in general a hard to reach group. Thus research with IDUs grasps every opportunity to recruit participants into studies, and convenience sampling makes this much more possible through recruiting all voluntary and self-referred participants.

Convenience sampling has both advantages and disadvantages. The advantages are that larger numbers can be recruited and participants do not need to be identified for recruitment purposes. A major disadvantage is that the sample may not be a representative sample of the study group and could thus introduce selection bias and confounding into the study results [79]. For these reasons I designed a random sampling strategy to recruit a representative sample for my study.

3.6.1: Sampling frame and method

A multistage process of stratified systematic simple random sampling was used to minimise bias and confounding associated with recruitment of the study sample. Sampling of participants for the study was conducted from the ACT and SNSW methadone registers. As HRECs' approvals required that identifying factors of the client could not be accessed, sampling was done with a de-identified register. The sample was initially stratified by study group (urban and rural), then by methadone programme tier, followed by systematic selection of every *nth* client within each tier to add up to the required sample size within each study group. Equal numbers were selected from each programme tier to ensure equal representation from all tiers. Table 3.1 illustrates the sampling frame and method and how participants were to be selected into the study.

Table 3.1: Sampling frame and method

Sampling Frame	**Urban:** ACT Methadone Treatment Programme Clients **Rural:** SNSW Methadone Treatment Programme Clients **Three tiers of the programmes** - Tier 1: Public (public programme management and dosing) - Tier 2: Partly public/partly private (public programme management/ pharmacy dosing) - Tier 3: Private (GP management/pharmacy dosing)
Sampling Method	**Multistage sampling** - Stratified by urban/rural - Stratified by tier of programme - Systematic simple random sample (every **nth** client from each Tier of the programme, to have equal numbers from each tier)
Eligibility Criteria	**Determined by the programme the client was registered on** - ACT client for urban sample - SNSW client for rural sample

3.6.2: Sample size calculations

Group mean scores as measured by the OTI in the ACT 1993 feasibility study conducted by Bammer and colleagues were used as baseline health scores to calculate the sample size required to elicit a 20 per cent difference in health outcome scores between urban and rural study groups at the $p \leq 0.05$ level with 80 per cent power [92]. The ACT 1993 study group mean score for health status was 14.6 (SD: 7.3)

Group mean scores from the validation study of the BBV TraQ were used for calculation of sample size required to elicit a 20 per cent difference in total BBV risk and injecting risk scores between urban and rural study groups at the $p \leq 0.05$ level with 80 per cent power. I used the standard deviations (SD) of total BBV risk and injecting risk scores from the ACT 1993 study as measured by the OTI instead of the BBV TraQ. This was done as participants in my study were methadone treatment clients and the ACT 1993 study was conducted amongst methadone treatment clients. The BBV TraQ validation study was conducted amongst IDUs not on methadone treatment and by using the BBV TraQ SDs for sample size calculations, risk may have been overestimated for participants in my study.
The following were the mean scores from the BBV TraQ validation study and SDs as measured by the OTI in the ACT 1993 study:

- Total BBV risk: Group mean score=29.4; SD=6.6.
- Injecting risk: Group mean score=16.1; SD=3.9.

STATA statistical software package was used for sample size calculations [155]. Using the baseline mean scores and SDs from previous studies, the following sample sizes were required to establish a 20 per cent difference ($p \leq 0.05$ level, power=80%) between urban and rural study groups for health outcomes and BBV risk associated with injecting:

- Total BBV risk: 20% difference in group mean scores = 20 per group
- BBV risk (injecting): 20% difference in group mean scores = 24 per group
- Health Status: 20% difference in group mean scores = 100 per group

To calculate the sample size required to determine the validity of self-reported HIV and HCV status, a 95 per cent confidence interval length of 0.2 for sensitivity and specificity was used for precision. Based on these calculations a sample size of 100 per group was required.

A final sample size of 100 per comparison group was reached for the study. To have equal representative samples from each of the three tiers of the two programmes, at least 34 clients from each of the tiers were required to be sampled to make up a total of 100 participants per study group. Systematic sampling was going to be based on the number of methadone clients registered within each tier of the programme at the time of sampling.

3.7: Random sampling for selection of participants into the study

Sampling, recruitment and data collection processes for the two study groups were done separately and at different times. The processes commenced within the ACT in April 2002. Sampling, recruitment and data collection processes for SNSW were planned to occur after those of the ACT and to commence in July 2002. Figure 3.2 outlines the stratified systematic random sampling process, recruitment process and final study numbers.

3.7.1: Procurement of a de-identified database for random sampling

To enable random sampling, I had to obtain a de-identified database to keep in line with the confidentiality requirements of the HRECs. All clients in the ACT were listed on one of two ACT methadone programme registers (public and community programme registers), which were maintained by the programme. These registers were used for sampling to select clients into the urban study group. ACT Tier 1 clients were kept on a separate register to Tier 2 and 3 clients. This was because Tier 1 clients were managed as public clinic clients, while Tier 2 and 3 clients were grouped and managed as community programme clients, as they were dosed through community pharmacies. The ACT methadone programme coordinator produced a de-identified database by removing all identifying variables such as name, address, phone number and workplace. This database was sorted by tier. Each client was assigned a database number in place of his or her name. The database numbers were sequential for the entire database and were not sequential within each tier. I was provided with a copy of this de-identified database for the purposes of random sampling.

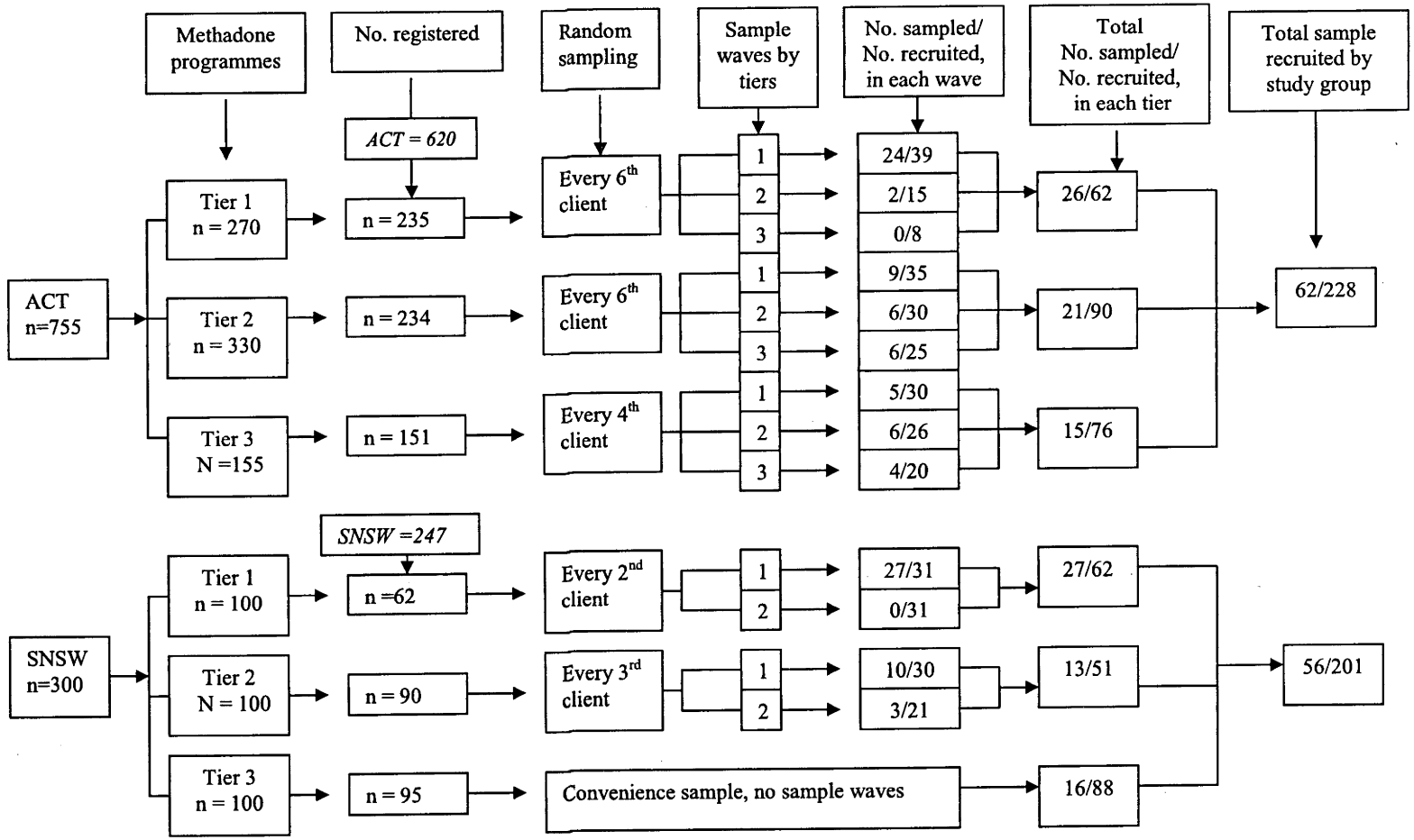
Only Tier 1 and 2 clients were listed on the SNSW methadone programme register. As Tier 3 clients could get on the programme directly at the discretion of GP prescribers, they were not on the SNSW programme register and were only registered on the NSW Department of Health's Pharmaceutical register (as explained in Chapter 1). The process that was used to procure a de-identified database for sampling in the ACT was replicated for Tiers 1 and 2 in SNSW.

Sampling for Tier 3 clients in SNSW proved to be more complicated as these clients were not registered with the SNSW programme. The methadone coordinator could not access a client list from the NSW Pharmaceutical Department of Health's register to enable Tier 3 clients to be added to the Tier 1 and 2 database for sampling, as these were private patients. Procuring a de-identified database for random sampling of Tier 3 clients could only be done with the assistance of GP prescribers.

There were two options considered for random sampling of Tier 3 clients within SNSW. The first was for the GP prescribers to provide a list of clients registered at their practices to the SNSW methadone coordinator to collate and add to the Tiers 1 and 2 de-identified database. This was only possible if clients gave their consent. Getting consent from Tier 3 clients could only be done when the clients visited the GP as contact details of clients kept in GP practices were not reliable. Client GP visits were usually at three monthly intervals or greater and this timeframe for the purposes of the study was not reasonable.

The second option was for GP prescribers to compile a list of their clients in alphabetical order and do the random sampling process for the study by selecting every *nth* client as required to produce a total Tier 3 sample of 34 clients. Although this process did not provide a random sample similar to that of Tier 1 and 2 of SNSW and the ACT, there would still be an element of randomisation within each GP practice. This was seen as being the best option at obtaining a SNSW Tier 3 database for random sampling without compromising confidentiality and the process of random sampling.

Figure 3.2: Summary of sampling and recruitment processes



3.7.2: Random sampling process for selecting clients into the study

Random sampling to select participants into the urban study group (ACT) was done on 2 April 2002. There was a total of 620 clients (three tiers combined) registered for treatment on the day of sampling, out of a total of 755 available places on the programme.

Random sampling to select participants from Tiers 1 and 2 for the rural study group (SNSW) was done on 1 July 2002 after completion of recruitment and data collection in the ACT as planned. There was a total of 152 clients registered for treatment in the two tiers on the day of sampling, out of a total of 200 available places on the programme. The number of Tier 3 clients registered in SNSW at this time was 95, out of a total 100 available places (this information was accessed from the NSW Department of Health by the methadone coordinator). Due to the complexity of access to a Tier 3 client list, sampling of this tier was left until Tiers 1 and 2 sampling, recruitment and data collection was completed. The distribution of clients by tiers in the two study areas at the time of sampling to select participants into the study is displayed in Table 3.2.

Table 3.2: Numbers on the ACT and SNSW programme by tier at time of sampling

Tier	Urban study group (ACT)			Rural study group (SNSW)		
	Total places	No. registered	% Places occupied	Total places	No. registered	% Places occupied
Tier 1	270	235	**87**	100	62	**62**
Tier 2	330	234	**62**	100	90	**90**
Tier 3	155	151	**97**	100	95	**100**
Total	755	620	**82**	300	247	**82.3**

To recruit the required sample size of 100 for the urban study group with equal sampling of approximately 34 in each tier, the following clients were systematically selected from each Tier in the ACT:

Every 6th client was selected in Tier 1; with 39 of 235 clients selected.

Every 6th client was selected in Tier 2; with 39 of 234 clients selected.

Every 4th client was selected in Tier 3; with 37 of 151 clients selected.

A total of 115 clients were selected from the ACT programme through this process.

In SNSW, systematic random sampling as per the ACT process was done for Tiers 1 and 2. The following clients were selected into the rural study group to have approximately 34 participants from each tier:
Every 2nd client in Tier 1 was selected; with 31 of 62 clients selected.
Every 3rd client in Tier 2 was selected; with 30 of 90 clients selected.
In total, sixty-one clients were selected from Tiers 1 and 2 through the sampling process to represent Tiers 1 and 2 of the rural study group.

Sampling of SNSW Tier 3 clients was done by enlisting the assistance of GP prescribers and their practice managers. Out of 17 GP prescribers in SNSW, there were nine GPs who managed Tier 3 clients in their practices at the time of the study. All nine GPs were contacted and sent information detailing the study with a covering letter from the director of the SNSW AOD Programme. Two GPs had no patients registered for treatment at the time of sampling, one refused to participate and one had withdrawn from the programme. This left five GPs who were on the programme and willing to participate in the study. Of the 95 clients on the NSW pharmaceutical register, the five GPs who were willing to participate had 88 clients between them, while the GP who had refused to participate in the study had seven patients at that point in time. This meant that 93 per cent of Tier 3 clients could be accessed through the five GPs willing to participate in the study. I visited these five GP to finalise details of random sampling of clients within their practice for recruitment into the study. A total of 35 clients were selected through this process in Tier 3.

Randomly selected clients were to be contacted by the methadone coordinators in each programme to be recruited into the study. For this to occur, clients selected needed to be identified by the methadone coordinators. Every client randomly selected was allocated a sample number, separate to his or her database number. The sample number was allocated sequentially within tiers unlike the database number. This number indicated which tier selected clients belonged to, and their chronological number in the random sampling process within the tier (example: second client randomly picked in Tier 1 would have a sample number of 1[2]). The sample number along with the database number allowed for the methadone coordinators to identify clients for recruitment into the study according to tier.

3.7.3: 'Sample waves' and non-respondents

It was intended that all clients who were selected through the sampling process to be recruited into the study were to be given one month to respond to the invitation to participate. If they did not respond within this period they were to be deemed as non-respondents. Clients who refused at the time of invitation were also classified as non-respondents. To ensure that enough numbers were recruited and random selection into the study was maintained, the next person to the non-respondent on the methadone register replaced the non-respondent. These new samples were to be created on a monthly basis as this was the timeframe for selected clients to respond and were termed 'sample waves' for the purpose of this study. The sample number remained the same for participants in each sample wave.

3.7.3.a: Non-respondents

Non-respondents were asked to fill in a non-respondent questionnaire (Appendix 5), with 14 questions relating to demographics, selected programme characteristics, satisfaction with the programme and why they did not wish to participate. This was done to establish if non-respondents differed to respondents in the study. Non-respondent response was very poor. Overall there were only 19 non-respondents who participated, 17 of 156 non-respondents in the ACT and two of 145 non-respondents in SNSW. Non-respondent numbers and participation rates by tier are presented in Table 3.3.

Table 3.3: Non-respondent participation rate

Tier	Urban (ACT)			Rural (SNSW)		
	No. sampled	No. recruited	Participation rate (%)	No. Sampled	No. recruited	Participation rate (%)
Tier 1	26	9	**35**	35	1	**3**
Tier 2	69	3	**4**	38	1	**3**
Tier 3	61	5	**8**	72	0	**0**
Total	156	17	**11**	145	2	**1**

As the response was so poor and sample size was small, further analyses of non-respondents would not have been useful.

3.8: Recruitment

Advertising of the study through posters (Appendix 6) was timed to occur a month prior to recruitment and data collection commencing in the two study areas. Posters were distributed to all methadone clients in the urban and rural study areas at their point of dosing, informing them about the study and that they may be randomly selected to participate. The poster was not an open invitation, but was intended to raise awareness and provide information to potential participants of the study. Copies of these posters were sent to all ACT and SNSW public methadone clinics and medical officers, community pharmacies, CHCs, other AOD services and all participating GP methadone prescribers in the two study areas.

As randomly selected participants had to be identified to be recruited, and due to Ethics Committees' requirements that the study could not have access to identifying details of clients, the methadone programme coordinators of the urban and rural programmes were to recruit selected participants into the study. Recruitment sheets for the coordinators to use were created for each tier in each study group with the randomly selected clients' database number and sample number (Appendix 7). A third column on the recruitment sheet indicated whether the randomly selected client was willing to participate or not.

The coordinators in each programme area used the recruitment sheets to cross reference the selected participants against their identification details on the methadone registers. Once selected participants were identified, the coordinators were to contact them, briefly describe the study and invite them to participate. Contact was to be made through client details available on the register. A schedule of interview times was organised. If a selected client agreed to participate the coordinators were to set up interviews according to the convenience of the client, and time slots available on the schedule (Appendix 8). This recruitment process was applicable to all urban participants and Tier 1 and 2 participants of the rural study group. Selected Tier 3 clients of the rural study group were to be contacted through the practice managers of their GP methadone prescribers.

Each participant was to be given AUD15.00 as re-imbursement for out of pocket expenses (such as bus fares and childcare) related to participating in the study. The poster did not advertise this as it was perceived that advertising a monetary re-imbursement would encourage unnecessary self-referral for participation in the study.

3.8.1: Recruitment process in the ACT

Advertisement of the study to recruit urban participants commenced in the ACT in the first week of March 2002. Recruitment started with Tier 1, and as per the recruitment plan, the methadone coordinator tried to contact and recruit selected clients through contact details available in the methadone registers. This process was not successful as contact details of many clients were not recorded or incorrect. Consequently another strategy was needed.

It was decided that the best way to contact Tier 1 clients was through their dosing centres, which were the Civic Methadone Clinic (north-side) and TCH Methadone Clinic (south-side). The Tier 1 recruitment sheet along with interview schedules were sent to these dosing points for selected clients to be recruited by dosing staff. If the client agreed to participate they were asked to choose a time from the interview schedule. If they declined they were asked to fill in the non-respondent questionnaire. The non-responders were replaced with the next client on the database by the methadone coordinator. The sample number for the new client selected remained the same but the database number changed and the sample sheet was modified accordingly.

Recruitment of clients for Tiers 2 and 3 ran into the same problem as Tier 1. Once again it was decided that the best method for recruitment was at the point of dosing, which in the case of Tiers 2 and 3 was at community pharmacies. The recruitment sheets created for Tiers 2 and 3 were not usable any more for the new recruitment strategy as each selected client had to be identified by the pharmacy they dosed at. A recruitment sheet of selected clients with database number, sample number and pharmacy where they dosed was compiled for Tiers 2 and 3 from the de-identified database (Appendix 9).

Recruitment sheets for each pharmacy were compiled combining Tiers 2 and 3 clients onto the one sheet with a blank column for client name to be entered by the methadone coordinator (Appendix 10). The methadone coordinator identified randomly selected clients by database number, filled their names on the sheet and forwarded it to the nominated pharmacy for recruitment when they came in to dose. To protect the identity of the clients the study did not have access to these lists. Selected clients were to contact me on a mobile number and identify themselves by their sample number to make time for an interview. Information sheets detailing these processes were given to selected clients at the time of recruitment (Appendix 11). This recruitment strategy maintained the confidentiality of the client since no identifying details were accessible.

All randomly selected clients were given one month to respond after which they were deemed as non-respondents and were replaced with the next person on the database within their tier for recruitment into the study.

As the methodology for recruitment had changed significantly, HRECs needed to be informed and for me to seek permission to use the new methods for recruitment. As the same recruitment issues were envisaged in SNSW as well, and to ensure that methodology was consistent in both study groups, all three HRECs were contacted at the same time to seek permission to modify recruitment processes in both study areas. All HRECs gave permission for the new recruitment process to be adopted immediately. Permission was also obtained from the ACT and SNSW Pharmacy Guilds, and the ACT and SNSW methadone programmes, to use participating methadone pharmacies and public programme dosing outlets as recruitment points.

3.8.2: Recruitment process in SNSW

All clients on the SNSW methadone programme were sent the poster advertising the study through their dosing points in June 2002, a month before data collection began. All Tier 3 clients were also sent the poster advertising the study through participating GP practices. All public clinics, participating pharmacies and GP prescribers were sent the poster and further information detailing the study and processes involved, by the SNSW methadone coordinator.

Recruitment of Tier 1 and 2 randomly selected participants was done as per the process used to recruit for the urban study group through public dosing points. Selected clients called me directly to make appointments (similar to clients in Tiers 2 and 3 in the urban study group). As it was going to cost more than the cost of a local phone call (since SNSW was out of the ACT region), all clients recruited through SNSW pharmacies were sent a phone card via their dosing point to ensure that participants did not have any further out-of-pocket expenses, and to maximise the chances of recruitment into the study. Selected clients were given an information sheet detailing all these processes by the recruiting pharmacist (similar to those used in the ACT) (Appendix 12). Similar sampling sheets to those used for the ACT were created for SNSW Tiers 1 and Tier 2 recruitment processes.

Randomly selected Tier 3 clients were to be recruited by practice managers at the GP practice that the client attended. Contact details for SNSW Tier 3 clients were also found to be unreliable and the practice managers had to recruit clients when they visited the practice. As clients' visits were at three monthly intervals or more, recruiting only selected participants into the study was not going to be possible within the timeframe for data collection. For this reason, any client who visited the GP practice was invited to participate, which made the Tier 3 sample in the rural study group a convenience sample. There was still an element of randomisation to this process, as clients did not self-refer themselves into the study. Practice managers made the appointment with the client at the time of the visit, based on a schedule I had provided them with. All rural Tier 3 clients were also supplied with phone cards to enable them to contact me to schedule an appointment. An information sheet with these details was given to recruited clients (Appendix 13).

As per the ACT recruitment strategy randomly selected participants in SNSW were also given one month to respond before a new sample wave was created. Non-respondents were asked to fill in the non-respondent questionnaire.

3.9: Data collection

Two research assistants were employed for 10 hours per week, to assist with the data collection process. The research assistants were employed to collect data only within the urban study area and areas with minimal travelling time in the rural area, which was mainly Queanbeyan. I conducted all other interviews in SNSW outside of the ACT/Queanbeyan region; thus in total there were three people (including myself) collecting data. A training session was conducted a week prior to the commencement of data collection, to familiarise the research assistants with the questionnaire, the process of administering the questionnaire, blood sample collection, ethical considerations and personal safety issues. All interviewers were trained to collect finger prick blood samples and were provided with gloves, disinfectants and sharps disposal bins that fit into a backpack for easy carriage.

3.9.1: Locations used for data collection in the ACT

Appropriate interview locations had to be identified to ensure easy access, comfort and confidentiality for participants, and at the same time provide personal safety for interviewers. Public places such as coffee shops would have been suitable for administration of the questionnaire but were not considered suitable for blood sample collection.

As the urban study area (ACT) is divided by Lake Burley Griffin into the south-side and the north-side it was decided that the study would have a centrally located interview venue within each area to maximise access for clients. The best option for the south-side location was at TCH clinic dosing point for the following reasons:

- it was centrally located,
- it had private interview rooms that could be made available for the study,
- public transport stopped in front of the clinic,
- the clinic was open on weekends enabling interviews on weekends,
- the clinic was a secure location for interviewers as desk phones and Duress alarms[6] were provided and fitted in each interview room,
- there were hand washing facilities and sharps disposal equipment within the rooms.

The Civic methadone clinic was chosen as the interview point for the north-side for similar reasons. However, soon after data collection commenced in mid-April 2002 the north-side clinic shut down (in the first week of May 2002). To ensure access for the north-side participants, a non-governmental organisation, Canberra Alliance for Harm Minimisation and Advocacy (CAHMA), which had a drop in centre for drug users in the north-side was approached to request use of their premises. CAHMA was centrally located in the ACT Business District (ACT CBD). CAHMA staff were willing to support the study and provided a room to use for interview purposes during centre opening hours, which were normal business hours (Monday to Friday). Most methadone clients were familiar and comfortable with the centre, which provided privacy and helped to maintain confidentiality, security and easy access for both interviewers and participants. The only disadvantage of this location was that it was closed on weekends.

[6] A Duress alarm system is a network of transmitters linked to a central location within large facilities and is designed to provide a means of alerting security personnel to potential personal safety problems within the site. Every patient consultation room in TCH had a Duress alarm.

3.9.1.a: Changes and problems with recruitment and data collection in the ACT

Once data collection commenced, it became apparent that most selected clients were not going to keep their interview times. Selected clients turned up for interviews at unscheduled times either due to confusion with timeslots or just forgetting interview times. As selected clients were interested and were turning up but not necessarily at the appointed time, it was decided that rather than having set appointment slots, interviewers would be available between 9.30 am and 4.30 pm, most days at both interview locations (north and south). This was to allow selected clients to come in for the interview according to their convenience.

The first week of data collection for Tier 1, with interviewers being available at all times (first week in April 2002), was a dismal failure as there was not a single interview conducted in the first four days of the week. When the process was reviewed it came to light that some recruiting staff at dosing points were not aware of the study, were not briefed that there was an interviewer available through the day, or were just forgetting to recruit as dosing times could be very busy. This could have been due to a number of staff working part-time or being casual workers, or working different shifts, thus missing briefing meetings. It was decided that receptionists at the clinics who were fulltime workers and worked normal business hours including dosing times, were probably more likely to be able to recruit clients consistently. This process worked more efficiently and numbers interviewed in Tier 1 increased substantially in the weeks following (mid April-June 2002). The recruitment plan for Tiers 2 and 3 clients continued as planned and recruitment was done by pharmacists at dosing points, and selected clients called me directly to make an appointment.

3.9.2: Locations used for data collection in SNSW

As clients in SNSW were so widely dispersed, there needed to be many locations for interviews for ease of access, to minimise travel time, and have sufficient privacy for participants to feel that their confidentiality was protected. For interviewers the locations needed to be accessible, secure and practical to conduct interviews. As CHCs are available in most rural towns, it was decided to use their facilities in SNSW for interviews. These locations were the most practical as they had confidential private interview rooms, with phones, Duress alarms and hand washing facilities (needed for blood sample collection).

Permission was sought and granted by the SNSW Health Services to use interview rooms in the CHCs as necessary. Clients from all tiers were interviewed at these locations. For Queanbeyan clients, interview rooms in the AOD clinic were used instead of the CHC, as this was more accessible for clients and was also the dosing point for Tier 1 clients.

As recruitment and data collection for SNSW was done after the ACT processes were almost completed, lessons learned in the ACT made the processes in SNSW flow more smoothly and according to plan. The main problem with recruitment and data collection in SNSW was the limited numbers available in Tier 1 for random selection into the study (i.e. every second client was selected to have approximately 34 clients in the study). There were a few minor logistic problems, such as selected clients who had received phone cards, not knowing how to use them. Recruiting staff were asked to inform clients on how to use them.

Data collection for both study groups was stopped on the 30th November 2002 even though the required sample size was not reached. This was done for the following reasons:

- There were no more clients to be sampled in Tier 1 of SNSW (Tier 1 had only 50% of places full and all 62 clients were approached through two sample waves).
- It was getting difficult to recruit more participants and in the last few weeks of data collection, there were only one or two interviews being conducted.
- Time limit in terms of completing a doctoral study.

3.10: Data coding and entry

Data were directly coded on the questionnaire. Data from the coded questionnaire were entered into an Access database, which had four tables, representing the four parts of the questionnaire. I entered all data onto the Access database after all data collection was completed. Where possible screen input validation checks were incorporated for questions. Data already entered were re-checked against each questionnaire. This ensured that the error rate in data entry was minimal.

3.11: Data storage

Once an interview was completed, the questionnaire and blood sample were sealed in an interview package and stored under lock and key at the National Centre for Epidemiology and Population Health (NCEPH). All questionnaire packages were only opened to mail the blood samples to NCHECR for analysis at weekly intervals. The interview packages were then re-sealed and locked at NCEPH. All data (questionnaires and databases) will be stored under lock and key at NCEPH for at least seven years after completion of the PhD, as per ANU requirements.

3.12: Data analysis

Data were transferred from the Access database to SPSS and STATA databases for analysis, which were used interchangeably [155, 156]. Missing variables were removed for analysis but are presented in final tables. There were three types of analyses conducted. These are described in detail below.

1) Descriptive analysis (Chapter 4)

Pearson chi-square two sided tests ($p \leq 0.05$) were used to measure and compare factors that could be associated with outcomes for urban and rural study groups. Where numbers were less than five in any cell, a Fishers exact test was used.

2) Measurement and comparison of health and BBV risk outcomes for urban and rural study groups (Chapters 5 and 6)

As the samples were independent, t-tests were used to compare the mean score of health outcomes (THS) and BBV risk outcomes (BBV TraQ risk scores) for the study groups, where sample sizes were large enough and the test statistic had an approximate normal distribution (>30 degrees of freedom) [157]. A non-parametric test (Mann-Whitney test) was used for comparison of mean scores when sample sizes were small and normal distributions could not be assumed.

Factors identified as having a potential association (Figure 3.2) with health and BBV risk outcomes were entered into stepwise (backward elimination) multiple regression models to identify the best combination of factors that were significantly associated ($p \leq 0.05$) with the outcomes within the two study groups. Linear regression analysis was used where the outcome was an approximately continuous variable and logistic regression analysis was done where the outcome variables of interest were binary.

As there were several factors identified as having the potential to be associated to the outcomes, I first used univariate analyses to examine the association of individual factors with the outcomes within each study group, to select a subset of factors to enter into the stepwise regression model. I chose a p-value of 0.10 as the cut-off to maximise the chances of picking up significant associations. All factors that were significantly associated with outcomes at the $p \leq 0.10$ in this univariate analyses were entered into the stepwise (backward elimination) multiple regression models. Possible confounders were entered into the model regardless of whether or not they were significantly associated with the outcomes in the univariate analysis.

β coefficients in the linear regression models represent the change in mean score of the outcomes associated with factors. Odds Ratios (ORs) in the logistic regression models represent the strength of the association between factors and the outcomes. These measures also indicate the direction of the association between factors and outcomes (positive measures=detrimental relationship, negative measures= beneficial relationship). P-values and confidence intervals (CI) indicate whether the associations were significant or not. Likelihood Ratio tests (LR tests) were used to determine if categorical factors (> two categories) were significantly associated with outcomes as a whole factor. The variance of outcome scores within the study groups explained by factors significantly associated with the outcome is indicated by R^2 in the univariate analysis and adjusted R^2 in the multivariate models [157].

3) Validity of HCV and HIV self report (Chapter 7)

There were two parts to this analysis. The first part aimed to determine validity of HCV self-reported status as an indicator of true HCV status and compared it for urban and rural individuals. This was done by calculating sensitivity, specificity, PPV and NPV, and PLR and NLR for HCV self-reported status as a screening test for true status as determined by serology (Appendix 1). Validity of HIV self-reported status was used a comparator.

The second part of the analysis compared factors associated with HCV serological status as opposed to self-reported status to examine if significant associations differed. As this analysis was not aimed at comparing urban and rural factors associated with HCV, the study samples were combined to have greater power to pick up any significant associations that may exist. Univariate analyses were used for this purpose with level of significance set at $p \leq 0.05$, as these were final analyses.

3.13: Numbers recruited, response and participation rates

A total of 118 participants were recruited into the study; 62 in the ACT and 56 in SNSW. Tables 3.4 and 3.5 describe the recruitment and response rates and the final sample numbers by study groups and tier. Recruitment rate for the purposes of my study is the proportion of the sample size needed for the study, while response rate is the proportion of randomly selected participants who took part in the study.

There were three waves of sampling conducted in the ACT; sampled on the 02/04/2002, 27/05/2002 and 05/07/2002. There were two sample waves in SNSW for Tiers 1 and 2, sampled on the 01/07/2002 and the 10/09/2002 respectively. Only two sample waves were created in SNSW for Tiers 1 and 2 due to lack of numbers in the tiers. There was a total of 40 clients recruited from Tiers 1 and 2 into the rural study group from these sample waves. There were 16 clients recruited from Tier 3 in SNSW through GP practices into the rural study group. Although sample waves were to be created on a monthly basis, for logistic reasons participants were given longer to respond.

Table 3.4: Numbers recruited by tier and by study group

Tier	Urban study group (ACT)			Rural study group (SNSW)		
	No. Needed	No. recruited	Recruitment rate (%)	No. Needed	No. recruited	Recruitment rate (%)
Tier 1	34	26	**76**	34	27	**79**
Tier 2	33	21	**64**	33	13	**39**
Tier 3	33	15	**45**	33	16	**48**
Total	100	62	**62**	100	56	**56**

Table 3.5: Response rate by tier and by study group

Tier	Urban study group (ACT)			Rural study group (SNSW)		
	No. sampled	No. recruited	Response rate (%)	No. sampled	No. recruited	Response rate (%)
Tier 1	62	26	**42**	62	27	**44**
Tier 2	90	21	**23**	51	13	**25**
Tier 3	76	15	**20**	88	16	**18**
Total	228	62	**27**	201	56	**28**

Recruitment into the study was lower than was needed for the required sample size of 100 participants per study group. Overall the recruitment into both study groups was greater than 50 per cent. The achieved recruitment rate of 62 per cent (n=62) into the urban study group and 56 per cent (n=56) into the rural study group was only possible because of creating sample waves to replace non-responders. Recruitment rates in Tier 1 were higher than those of Tiers 2 and 3 for both study groups. This may have been due to better compliance on the part of drug and alcohol staff recruiting at Tier 1 dosing points. Recruitment rates into Tiers 1 and 3 were similar for both study groups but Tier 2 rates were higher for the urban study group as compared to the rural study group. Tier 2 and 3 recruiting in the ACT and Tier 2 recruiting in SNSW received poorer compliance from pharmacists as compared to public dosing points. Although recruitment for Tier 3 in SNSW was complex and dependent on clients presenting at GP practices to be recruited, recruitment rate for Tier 3 in SNSW was similar to that of the ACT.

The overall response rates for urban and rural study groups were approximately the same at 27 and 28 per cent respectively. Response rates for the three tiers were comparable between study groups. The response rates in Tier 1 for both study groups was almost approximately double that of Tiers 2 and 3. Lack of Tier 2 and 3 recruiting compliance and interest on the part of community pharmacists may have contributed towards poor response rates in these tiers.

3.14: Sources of bias and confounding

3.14.1: Selection bias

Random sampling was used as a method to minimise selection bias into the study. This was however, compromised due to the following reasons:

- Tier 1 in SNSW had a total of 62 clients only at the time of sampling. As at least 34 participants were required from each tier, this meant that with two sample waves, all Tier 2 clients in SNSW had been selected and asked to participate in the study, making this a convenience sample.
- Not being able to include SNSW Tier 3 clients on to the same database as Tier 1 and 2 clients and having to recruit Tier 3 clients into the study as they presented at GP practices, made Tier 3 sampling of the rural study group a convenience sample.

- Knowledge of re-imbursement of $15.00 for out-of-pocket expenses through word-of-mouth communication amongst methadone clients (even though not advertised through the study), may have introduced an incentive for randomly selected clients to participate.

Although serious attempts were made to minimise selection bias, due to the issues noted above there was a certain degree of self-selection and convenience sampling introduced into the study.

3.14.2: Measurement Bias

Measurement bias can occur in a study through recall bias (inaccurate responses from participants), interviewer bias, and measurement and analysis of outcomes [79]. These biases were reduced in my study at two levels: firstly through the study design used and secondly through analytical methods used. Recall bias was decreased through the use of a cross sectional study design and most questions were limited to behaviours affecting outcomes in the one-month prior to interview. The use of validated questionnaires, training interviewers in the use of the questionnaire, and standardisation of information collected and recorded decreased the likelihood of interviewer bias. Measurement bias was also decreased through the measurement of outcome variables being standard through the use of validated questionnaires.

The use of a de-identified database for sampling and the use of verbal consent to participate assisted in lowering measurement bias. As the questionnaire covered some illegal activities (such as illicit drug use and other criminal activities), if identification was required from participants, they may have provided inaccurate responses due to fear of their methadone treatment being compromised or being pursued by the legal system.

3.14.3: Potential Confounders

Information was collected for potential confounders identified through literature (e.g. age, sex, socio-economic status) and other confounders identified at the time of the study (e.g. tiers of programmes as they were managed differently). Methods used to control for these confounders were through the study design (random sampling) and analysis (stratification and inclusion of potential confounders in multiple regression models).

3.15: Validity of study results

Internal validity of results depends on controlling for sources of error; these being chance, bias and confounding [79]. Sampling, recruitment, and data collection and analysis methods used in the study were designed to minimise these sources of error to increase internal validity of results.

3.16: Generalisability

The final sample size recruited was smaller than required and mainly a convenience sample. This may not have been truly representative of urban and rural participants of the areas chosen for the study, or Australian urban and rural methadone clients in general. However, 13 per cent of the total study population was recruited (118 of 867 registered methadone clients in both programmes), with 10 per cent recruited in the urban programme (56 of 620 registered clients) and 23 per cent in the rural programme (56 of 247 registered clients). These proportions of the actual study populations recruited should provide a representative sample of urban and rural methadone clients, thus improving the generalisability of results.

3.17: Limitations:

The limitations of the methods employed were that random sampling was not completely achieved and this may have contributed to selection bias. The sample size needed to elicit significant differences was also not reached which may have resulted in actual significant differences not being detected.

3.18: Summary

This chapter described the methods used to address the aims of the study. A cross-sectional study design was considered to be the most appropriate and a random sampling strategy was used to minimise selection bias. A questionnaire that was partly self-administered and partly interviewer-administered was used to collect relevant data. The OTI and BBV TraQ were part of the questionnaire and were used to measure health and BBV risk outcomes respectively. A finger prick blood spot test was used to collect blood for HCV and HIV serology. Ethics approval was sought from ANU, ACT and SNSW HRECs.

Random sampling was used to decrease selection bias, but there were several problems encountered with the sampling and recruitment processes. Random sampling was not achieved properly due to issues normally associated with AOD research and logistic factors (such as available numbers on the programmes for sampling, and time). The required sample size to elicit significant differences between study groups for health and BBV risk outcomes was not reached.

An Access database was created to enter data. Data were transferred to SPSS and STATA for analysis. A combination of univariate and multivariate analyses were employed to measure and compare health and BBV risk outcomes for the two study groups. Standard clinical epidemiology validity measures were used to measure validity of HCV self-reported status as a screening test for true HCV status as indicated by serology. The methods employed were not completely successful in minimising selection bias but were able to minimise measurement bias.

The smaller sample size and not achieving random sampling properly may have affected the representativeness of the sample, which in turn could affect the generalisability of the results. However, approximately 13 per cent of the overall study population was recruited into the study, which should provide a representative sample for generalisability of the results to other urban and rural methadone treatment groups in Australia. Validity of study results was increased by minimising bias and confounding both in the study design and analysis wherever possible.

The following chapters (Chapters 4, 5, 6 and 7) provide the results of the study by application of these methods. Relevant results are in the process of being submitted to participating organisations.

RESULTS

"However beautiful the strategy, you should occasionally look at the results"
Winston Churchill

Evaluation is

'The process of determining whether an item or activity meets specified criteria.'
(sparc.airtime.co.uk/users/wysywig/gloss.htm)

And aims to

'(1) Assess the effectiveness of an ongoing program in achieving its objectives,
(2) Relies on the standards of project design to distinguish a programme's effects from those of other forces, and
(3) Program improvement through a modification of current operations'.
(www.ojp.usdoj.gov/BJA/evaluation/glossary/glossary_e.htm)

Chapter 4
Description of the sample

In this chapter I describe and compare the urban and rural study groups in relation to sociodemographic characteristics, previous and current drug use history and risk factors, methadone treatment characteristics and other factors that could affect health and BBV risk outcomes (as described in Chapter 3). These analyses were done to examine if the two study groups differed in relation to these factors. Results for the whole sample as well as comparisons between urban and rural samples are also reported.

4.1: Socio-demographics

Table 4.1 presents socio-demographic comparisons for the two study groups. Overall, the majority of participants (44%) were aged between 30-39 years and 59 per cent were male. Only four participants (3.3%) identified as being of Aboriginal or Torres Strait Islander background[7]. Although only small proportions of participants had completed Year 10 and Year 12, completion of tertiary education was relatively high at 35 per cent. Only twenty one per cent of participants were employed either full-time or part-time. Twenty five percent were unemployed. Fifty per cent were on government pensions (relating to home duties and sickness benefits) and four per cent identified as students. A high proportion of participants (66%) lived in rented accommodation. These factors were not significantly different between urban and rural samples.

The main source of income in the six months prior to interview was the only socio-demographic factor found to be significantly different for the two study groups. The urban study group was more likely to have been in paid employment as compared to the rural study group ($p=0.01$). Interestingly this did not contribute to a significant difference in employment status at the time of the study.

[7] In order to maintain anonymity no further information related to Indigenous status will be presented.

Table 4.1: Sociodemographic characteristics of study groups

Characteristic	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
Age group							
< 20	1	1.6	0	0	1	0.9	
20-29	17	27.9	11	20.0	28	24.1	0.32
30-39	28	45.9	23	41.8	51	44.0	
40 +	15	24.6	21	38.2	36	31.0	
Total	**61[a]**	**100**	**55[a]**	**100**	**116[b]**	**100**	
Sex							
Male	35	56.5	34	60.7	69	58.5	
Female	27	43.5	22	39.3	49	41.5	0.64
Total	**62**	**100**	**56**	**100**	**118**	**100**	
Education completed							
Under Year 10	11	18.0	18	33.3	29	25.2	
Completed Year 10	14	23.0	12	22.2	26	22.6	0.25
Completed Year 12	13	21.3	7	13.0	20	17.4	
Tertiary	23	37.7	17	31.5	40	34.8	
Total	**61[a]**	**100**	**54[b]**	**100**	**115[c]**	**100**	
Employment at time of study							
Unemployed	16	25.8	13	23.2	29	24.6	
Employed (fulltime/part-time/casual)	15	24.2	10	17.9	25	21.2	0.75
Student	2	3.2	3	5.4	5	4.2	
Other (home duties/sick leave)	29	46.8	30	53.6	59	50	
Total	**62**	**100**	**56**	**100**	**118**	**100**	
Accommodation type							
Own accommodation	9	14.5	11	19.6	20	16.9	
Rented accommodation	43	69.4	35	62.5	78	66.1	0.70
Other (boarding house, live with parents/govt housing/shelters)	10	16.1	10	17.1	20	16.9	
Total	**62**	**100**	**56**	**100**	**118**	**100**	
Main income last 6mths							
Paid employment	18	29.5	6	10.7	24	20.5	
Non-employment sources (Government benefits/ dependent on spouse/illegal sources)	43	70.5	50	89.3	93	79.5	**0.01**
Total	**61[a]**	**100**	**56**	100	**117[a]**	**100**	

[a] One missing value, [b] two missing values, [c] three missing values

The socio-demographic characteristics of participants in my study were similar to those found in the first Australian national census of clients of AOD treatment agencies conducted in 1990 as well as the most recent census of 2001 [158, 159]. For 6175 clients surveyed in the first census, the mean age was 34 years, 66 per cent were male and the majority were not in paid employment. There were 10 per cent who identified as Aboriginal or Torres Strait Islander people [158]. In the most recent census of 2001 the mean age of clients was 33 years, 63 per cent were male and the majority (82%) were unemployed or in unpaid employment [159]. Opioid dependency was the second most common reason for being in treatment after alcohol in both surveys.

Education levels were not reported in the two censuses. A high proportion of my study participants had completed tertiary education (35%) and this could possibly be explained by the inclusion of TAFE (Technical and Further Education) qualifications in the tertiary education category. The ACT population having higher levels of education may also explain the urban study group having a higher level of tertiary education in comparison to the rural study group (38% vs. 32%). The 2001 census data indicate that 46 per cent of ACT residents had a tertiary qualification (inclusive of TAFE and university degrees) [160].

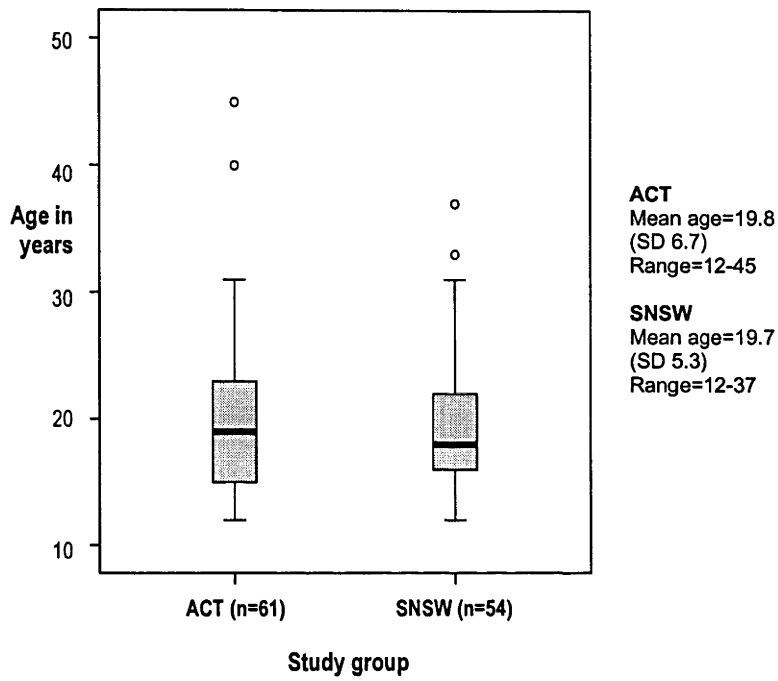
4.2: Previous drug injecting history

In this section I compare drug injecting history for the two study groups. This includes age of first injection, age of starting to inject regularly, first drug injected and methadone injecting.

4.2.1: Age of first drug injection

The mean age of first drug injection for the overall sample was 19.8 years (SD 5.7, range 12-45) with a median age of 19.0 years. The mean age of first injection for the urban sample was 19.8 (SD 6.7, range 12-45) with a median age of 19.0 years. The mean age of first injection for the rural sample was 19.7 (SD 5.3, range 12-37) with median age of 18.0 years. There was no significant difference in mean age of first injection between the study groups (p=0.42). The mean age and age range of first injection are represented in Figure 4.1.

Figure 4.1: Mean age and age range of first drug injection for study groups



The mean age of first drug injection in my study (19.8 years) was slightly higher than another Australian study amongst IDUs in Sydney between 1996-2000 (mean age 18.8 years) [161]. It was slightly lower than another Australian study in 2005 conducted amongst 399 heroin users also in Sydney (mean age 21.0 years). It was also lower than the NDS household survey of 2004 (mean age 21.0 years) [6, 162].

4.2.2: Age of starting to inject drugs regularly

The mean age of starting to inject regularly for the total sample was 21.6 years (SD 5.7, range 12-40), with a similar median age of 21.0 years. The mean age of regular injecting for the urban sample was 22.2 (SD 5.8, range 12-40) with a median age of 21.0 years; for the rural sample it was 20.9 (SD 5.6, range 12-37) with a median age of 19.0 years. There was no significant difference between urban and rural study groups for mean age of starting to inject regularly (p=0.24).

When categorised into age groups, 80 per cent of the participants started injecting drugs regularly between the ages of 16-29 years. A higher proportion of rural participants (46%) started injecting regularly in their teenage years (16-19 years), while a higher proportion of urban participants (50%) started injecting regularly in their twenties. This difference was not statistically significant (p=0.16). These results are summarised in Table 4.2.

Age group when first injected regularly	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
10-15	6	10.3	4	7.4	10	8.9	0.16
16-19	15	25.9	25	46.3	40	35.7	
20-29	29	50.0	20	37.0	49	43.8	
30 and above	8	13.8	5	9.3	13	11.6	
Total	**58[a]**	**100**	**54[b]**	**100**	**112[c]**	100	
Mean age of starting to inject regularly	22.2 ± 5.8 (range 12-40)		20.9 ± 5.6 (range 12-37)		21.6 ± 5.7 (range 12-40)		0.24

Table 4.2: Age group of starting regular drug injecting

[a] Four missing values, [b] two missing values, [c] six missing values

Overall, the mean age of starting to inject regularly was approximately a year and a half higher than that of first injection. Rural participants appeared to commence regular injecting within a shorter period after their first injection (about one year) compared to urban participants (a little over two years after their first injection).
(Rural: first injection 19.7 years, regular injecting 20.9 years; Urban: first injection 19.8 years: regular injecting 22.2 years).

4.2.3: Drug first injected

For the overall sample, heroin was the first drug ever injected by a large proportion of participants (46%), followed by amphetamines and methamphetamines [8] (38%). Table 4.3 summarises and compares type of drug first injected for the urban and rural study groups. Urban participants seemed more likely to have injected amphetamines and methamphetamines as their first drug ever injected (44%), with heroin following closely (43%). In comparison, heroin was the first drug ever injected for almost half of the rural participants (49%), followed by amphetamines (31%). Rural participants had a higher frequency of injecting other drugs such as ecstasy, benzodiazepines and steroids. There was no significant difference between choice of first drug ever injected between urban and rural participants (p=0.29).

4.2.4: Methadone injecting history

The methadone injecting history of the two study groups is also summarised in Table 4.3. Although methadone was the least likely drug of choice for first drug ever injected, two thirds (67%) of the total sample had injected it at some point during their drug injecting careers. This pattern was similar for urban and rural participants (p=0.51).

Table 4.3: Drug first injected and methadone injecting history

Characteristic	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
Drug first injected							
Heroin	26	42.6	27	49.1	53	45.7	0.29
Amphetamines	27	44.3	17	30.9	44	37.9	
Other drugs *	8	13.1	11	20.0	19	16.4	
Total	**61[a]**	**100**	**55[a]**	**100**	**116[b]**	**100**	
Ever injected methadone							
Yes	39	63.9	39	69.6	78	66.7	0.51
No	22	36.1	17	30.4	39	33.3	
Total	**61[a]**	**100**	**56**	**100**	**117[a]**	**100**	

[a] *One missing value,* [b] *two missing values*

* Urban: cocaine = 2, methadone = 1, other opioids = 1, ecstasy, benzodiazepines, steroids = 4
Rural: cocaine = 1, methadone = 0, other opioids = 3, ecstasy, benzodiazepines, steroids = 7
Total: cocaine = 3, methadone = 1, other opioids = 4, ecstasy, benzodiazepines, steroids = 11

[8] Other amphetamine type substances such as ecstasy and cocaine are grouped under 'other drugs'.

The practice of injecting methadone while on methadone treatment has been identified to be prevalent in Australia since the mid 1990s. An Australian study in 1995 found that of 312 heroin IDUs surveyed, 50 per cent had injected methadone at least once while on a methadone programme [163]. A more recent study conducted between 1999-2000 found that of 205 methadone injectors recruited, 80 per cent (n=164) were on methadone treatment. This study also found that the mean age of first injecting methadone was 26 years and the mean age of first injecting any drug was 18 years [58].

There are not many studies that have been conducted overseas in relation to methadone injecting. Robinson and colleagues conducted a study in New Zealand which aimed to identify patterns of methadone injecting, and reasons and perceived risks of this behaviour over a two month period between December 1995 to January 1996 [164]. Nineteen of 36 possible methadone injectors were recruited through a NSP, 17 (89%) of whom had been in methadone treatment for an average duration of four years. Of the 19 recruits, 26 per cent (n=5) had injected methadone daily, 16 per cent (n=3) had injected three times a week, 26 per cent (n=5) had injected one to two times a week and 32 per cent (n=6) had injected less than weekly in the three months prior to interview. The main reasons for injecting methadone stated by the participants were to get an immediate effect of the drug (80%), and 'needle fixation'[9] (47%) [165]. These reasons were supported by another study in Australia by Sunjic and Howard in 1996 [166]. From other available overseas reports, it appears that methadone injecting is not as common as it appears to be in Australia. For example, a recent Swiss survey on methadone injecting amongst methadone treatment clients of a state-run clinic, found that of 80 patients, 32 per cent (n=26) had ever injected methadone, but only five per cent (n=4) had injected in the last month prior to the survey despite the relative leniency of the clinic's TA policy [167].

[9] Defined by Mcbride and colleagues as the repetitive puncturing of the skin with or without injection of psychoactive drugs via intravenous, subcutaneous or intramuscular routes irrespective of the drug or drugs injected or the anticipated effects of the drug' [165].

4.3: Prison history: drug use and associated risk factors

Injecting drugs and increased risk of BBV transmission while incarcerated has been shown to occur quite frequently in Australia and overseas [27, 88, 168-170]. In Australia, not having NSPs or providing bleach for cleaning injecting equipment in prisons may be contributing to risky injecting behaviours and associated BBV transmission [171, 172]. Overseas studies have shown that in prisons with NSPs there is decreased sharing of syringes translating into decreased transmission of BBVs. Dolan and colleagues conducted a review of journal publications and conference presentations on prison-based NSPs overseas in 2003. This review found six evaluations of prison based NSPs, which all showed that syringe sharing decreased dramatically and there were no new cases of HIV, HCV or HBV reported after the introduction of the NSPs. Negative events such as the use of needles as weapons had also decreased [173].

Another study in Germany in 2006 evaluated the impact of prison based NSPs in two prisons in Berlin. Prior to commencement of the programme, 71 per cent of injectors within these two prisons shared syringes. This declined to 11 per cent during the first four months of the programme. After commencement of the programme no HIV seroconversions were noted, and there were just four HCV seroconversions [174].

Table 4.4 summarises prison history and risk behaviours while incarcerated for participants in my study. Overall, 50 per cent (n=58) of participants in my study had been in prison at least once, and this was similar for the two study groups. This is comparable to other studies that have found that between 20-50 per cent of IDUs have been previously imprisoned, mainly due to illegal activities associated with injecting drug use [44]. In an Australian study of prison entrants in 2004, 59 per cent had a history of injecting drug use [175].

Of participants in my study who had been previously incarcerated, 48 per cent (n=28) were on methadone treatment while in prison. Urban clients were much more likely to have been on treatment than rural clients (57% vs. 39%), but this was not statistically significant (p=0.19). Twenty eight per cent (n=16) had injected in prison, and 24 per cent (n=14) were tattooed; these proportions were similar for both study groups. Overall, males were significantly more likely to be incarcerated than females (60% vs. 37%, p=0.02). When adjusted for study groups, the significant gender difference was found to be only amongst rural participants (64% vs. 32%, p=0.02). These results relating to gender differences have not been tabulated.

Table 4.4: Prison history

Characteristic	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
Been in prison							
- Yes (includes remand/police cells)	30	49.2	28	50.9	58	50	0.85
- No	31	50.8	27	49.1	58	50	
- **Total**	**61[a]**	**100**	**55[a]**	**100**	**116[b]**	**100**	
Prison factors (n=58)							
Methadone treatment while in prison							
- Yes	17	56.7	11	39.3	28	48.3	0.19
- No	13	43.3	17	60.7	30	51.7	
- **Total**	**30**	**100**	**28**	**100**	**58**	**100**	
Inject drugs while in prison							
- Yes	9	30.0	7	25.0	16	27.6	0.67
- No	21	70.0	21	75.0	42	72.4	
- **Total**	**30**	**100**	**28**	**100**	**58**	**100**	
Tattooed while in prison							
- Yes	7	23.3	7	25.0	14	24.1	0.88
- No	23	76.7	21	75.0	44	75.9	
- **Total**	**30**	**100**	**28**	**100**	**58**	**100**	

[a] *One missing value,* [b] *two missing values*

4.4: Other treatments sought for opioid dependence

Table 4.5 details all drug treatments[10] other than methadone sought for opioid dependence by the participants prior to their current methadone programme. For the overall sample, the most common other treatment sought (apart from previous methadone treatment) was withdrawal services[11] followed by drug-free counselling. Urban participants were more likely to have accessed withdrawal services and in-patient rehabilitation[12] than their rural counterparts. For rural participants drug-free counselling was the most highly accessed form of other treatment. Approximately one third of the sample had not accessed any other form of drug treatment. Rural participants were marginally more likely to have not accessed other treatments in comparison to their urban counterparts (30% as opposed to 26%). There were no significant differences between the two study groups in terms of other treatments accessed.

Table 4.5: Other drug treatments accessed for opioid dependence

Other drug treatment	ACT N=62*		SNSW N=56*		Total N=118*		p-values (Pearson X^2)
	n	%	n	%	n	%	
Withdrawal service	38	61.3	29	51.8	67	56.8	0.30
Drug free counselling	32	51.6	30	53.6	62	52.5	0.83
In-patient rehabilitation	23	37.1	14	25.0	37	31.4	0.16
Narcotics anonymous	19	30.6	18	32.1	37	31.4	0.86
No previous treatment	16	25.8	17	30.4	33	28.0	0.58
Other (Narcotics Anonymous/ psychotherapy/family support/religion)	11	17.7	5	8.9	16	13.6	0.16

** Total for each treatment does not tally to total sample as participants could pick more than one option*

Although these results were not statistically significant they indicate that a greater proportion of urban clients accessed withdrawal and in-patient rehabilitation services in comparison to their rural counterparts. This could be due to these services mainly being based in urban centres. Rural participants in my study who accessed these services would have accessed them through the ACT AOD programme or through services elsewhere.

[10] These treatments could also have been sought outside the ACT and SNSW.

[11] ACT: 5-7 days on a combination of Valium and Doloxene; could be done as in-patient or out patient.
SNSW: Admission to hospital and symptomatic relief.

[12] ACT: Abstinence and supportive therapy as an in-patient for 3, 6 to 12 months. In-patient rehabilitation could be done after withdrawal.
SNSW: No in-patient rehabilitation, could access ACT or other NSW services.

4.5: Methadone treatment history

Forty seven per cent of the overall sample (n=55) were on their current methadone programme for the first time. There was a slightly higher proportion of rural participants on their programme for the first time as compared to urban participants (50% vs.44%) as seen in Table 4.6. Of the 62 participants who had been on the programme before, the majority (78%) had been on the programme between 1-3 times previously. The rural sample had a higher proportion of participants who had been on the programme in this category (82% and 75% respectively); while there was a higher proportion of urban participants who had been on the programme 3-6 times (25 % and 11% respectively). These findings were not significantly different for the two study groups (possibly due to numbers in the groups being small).

Table 4.6: Methadone treatment history

Characteristic	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
First time on programme							
Yes	27	44.3	28	50	55	47.0	0.53
No	34	55.7	28	50	62	53.0	
Total	**61[a]**	**100**	**56**	**100**	**117[a]**	**100**	
Number of other times on a programme *(ACT n=34, SNSW n=28)*							
1-3 times	24	75.0	23	82.1	47	78.3	0.24
3-6 times	8	25.0	3	10.7	11	18.3	
> 6 times	0	0	2	7.1	2	3.3	
Total	**32[b]**	**100**	**28**	**100**	**60[b]**	**100**	

[a] *One missing value,* [b] *two missing values*

Overall, people who were on the programme for the first time were relatively evenly distributed through the three tiers with no significant difference between tiers (p=0.1). There was also no significant difference between the two study groups in relation to the number of participants who were on the programme for the first time within each tier (Tier 1 p=0.88, Tier 2 p=0.93, Tier 3 p=0.26). These results are not tabulated.

4.5.1: Reasons for leaving previous methadone programmes

Of participants who had been on a previous programme (n=62), it was interesting to note that most (76%, n= 47) had left their previous methadone programme for reasons such as completing or transferring to another programme rather than for issues related to access, financial or confidentiality. Table 4.7 tabulates reasons for leaving previous programmes. There were relatively small numbers who stated that travel distance (10%, n=6), cost associated with the programme (5%, n=3) and confidentiality (3%, n=2) were reasons for leaving previous programmes. Although numbers were small, and the findings were not statistically significant there was a higher proportion of rural participants who left their previous programmes for these reasons. This was to be expected as rural people can have poorer access to services and access can be affected by confidentiality within services as shown in the literature review (Chapter 2). A higher proportion of urban participants had left the previous programme as it was not suited for them as opposed to the rural sample (urban: 24%, n=8; rural:7%, n=2). These differences were, however, not significant, most likely due to the small numbers in each category. Both urban and rural study groups had similar small numbers of people stating that the programme did not fit their schedule as a reason for leaving it (urban 13%, n=4; rural 11%, n=3).

Table 4.7: Reasons for leaving previous methadone programme

Reasons for leaving the last methadone program	ACT N=34*		SNSW N=28*		Total N=62*		p-values (Pearson X^2)
	n	%	n	%	n	%	
Completed/transferred programme	26	76.3	21	75.0	47	75.8	0.74
Did not suit ("was not for me")	8	23.5	2	7.1	10	16.0	0.09+
Did not fit schedule	4	12.5	3	10.7	7	11.3	1.00+
Too far to travel	2	5.9	4	14.3	6	9.7	0.40+
Too expensive	1	2.9	2	7.1	3	4.8	0.59+
Confidentiality	1	2.9	1	3.6	2	3.2	1.00+

** Total for each reason does not tally to actual sample numbers as participants could pick more than one option*
+ Fishers exact test

Studies have shown that retention rates are greater with methadone maintenance rather than withdrawal treatment, and when methadone dose is higher [117, 176-178]. The results from my study suggest that service delivery factors such as programme suitability and time-related issues could affect retention, while issues such as access, cost and confidentiality may not. These results should, however, be interpreted with caution as the numbers are small. A literature search revealed there were no studies conducted to date to examine the association between methadone programme service delivery factors and retention. Further research in this area may be warranted.

4.6: Current methadone programme treatment and management characteristics

This section describes and compares characteristics related to participants in the urban and rural study group that are associated with their current methadone treatment. It includes reasons for accessing the programme, referral source to the programme, dosing, cost associated with the programme and clinical management.

4.6.1: Reasons for accessing the current methadone treatment programme.

Table 4.8 summarises the reasons for study participants accessing their current methadone treatment programme. Overall, the main reasons were, financial (82%), a need to get out of the drug scene (79%), health related issues (76%), to stop drug usage (71%), and general relationship issues (65%). Whilst the five main reasons were the same for both study groups, they differed in priority within each group.

For urban clients the five main reasons in order of highest to lowest priority were:

- health issues,
- financial issues,
- to get out of the drug scene,
- general relationship issues,
- to stop drug usage.

For rural clients the five main reasons in order of highest to lowest priority were:

- getting out of the drug scene
- financial issues,
- to stop drug usage,
- health issues,
- general relationship issues.

Table 4.8: Reasons for accessing the current methadone programme

Reasons for getting on the current programme	ACT N=62*		SNSW N=56*		Total N=118*		p-values (Pearson X^2)
	n	%	n	%	n	%	
To improve financial situation	50	87.7	35	74.5	85	81.7	**0.08**
To get out of the drug scene	43	81.1	37	77.1	80	79.2	0.62
To improve health status	51	87.9	30	61.2	81	75.7	**0.001**
To stop illegal drug usage completely	35	70.0	35	71.4	70	70.7	0.88
To improve general relationships	41	75.9	25	53.2	66	65.3	**0.02**
To improve employment prospects	31	60.8	17	38.6	48	50.5	**0.03**
To decrease injecting	26	49.1	20	47.6	46	48.4	0.89
To decrease criminal activity	23	46.9	19	42.2	42	44.7	0.65

**Total for each reason does not tally to actual sample numbers as participants could pick more than one option*

Urban participants were significantly more likely to have accessed their current programme than rural participants for health reasons (88% vs. 61%, p=0.001), general relationship issues (76% vs. 53%, p=0.02), and to improve employment prospects (61% vs. 39%, p=0.03). A higher proportion of urban participants also accessed the programme for financial reasons, and this was marginally significantly different to rural participants (88% vs. 75%, p=0.08). Overall, less than 50 per cent cited the need to decrease criminal activity as a reason. This was similar for both study groups (p=0.65).

Ward and colleagues note that there has been very little research into the reasons why heroin dependent users decide to access treatment. They suggest that factors such as the increased risk of HIV and HCV amongst IDUs, and the price and purity of heroin related to law enforcement strategies may play a role in accessing treatment [44]. A 12 year follow-up study in the US (1969 onwards) of various aspects of drug dependency examined the reasons for accessing methadone treatment as one of its outcomes. The researchers interviewed 490 people who were opioid dependent over the course of 12 years. The following factors rated highly as reasons for accessing methadone treatment:

- Tired of the 'hustle' involved in maintaining a heroin habit (83%).
- Needed to make a dramatic change in their lives (82%).
- A major personal event, such as a new relationship, childbirth (66%).
- Fear of incarceration (57%).

Rating under 50 per cent were reasons such as high cost of heroin (40%), poor quality of heroin (36%), other financial issues (34%), and fearing a drug overdose (31%) [179].

A more recent study was conducted in Italy between September 1998 and March 2001 amongst 565 heroin users who were on the programme for the first time [180]. The study found the following factors to be associated with accessing methadone treatment:

- age (< 25 years),
- injecting heroin more than twice a day,
- recent imprisonment,
- living with a partner,
- having sex without a condom in the previous six months,
- being HIV positive,
- being enrolled at a National Health Centre where a psychiatrist was available.

4.6.2: Referral source to the current methadone programme

The two study groups were found to be significantly different in relation to referral source to the methadone programme (p=0.04). Referral to the programme for individuals in both study groups was through three sources; self referral, referral by a health care worker and transfer from another programme. Although the majority (70%) had referred themselves to their current programme, urban participants were significantly more likely to have been self-referred than their rural counterparts (79% vs. 61%). Rural participants were significantly more likely to have been referred by a health care worker in comparison to their urban counterparts (30% vs. 11%). These results are presented in Table 4.9.

Table 4.9: Referral sources to the current methadone programme

Referral source	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
Self-referred	49	79.0	34	60.7	83	70.3	
Health care worker referred (GP, D&A worker)	7	11.3	17	30.4	24	20.3	**0.04**
Other (transfer from other programme/ started in jail or hospital)	6	9.7	5	8.9	11	9.3	
Total	**62**	**100**	**56**	**100**	**118**	**100**	

4.6.3: Time and dosage on current programme

Overall, most participants (58%) had been on their current methadone programme between 1-5 years and this was similar for both study groups. Table 4.10 outlines time on the current programme and methadone dosage of participants. Although there were relatively similar proportions of participants in the two study groups who had been on the programme for one year or less, the rural sample had a larger proportion of participants (16%, n=9) who had been on the programme for less than six months as opposed to the urban area (7%, n=4). There was only one participant who had been on the programme for greater than 10 years (results not tabulated).

A larger proportion of rural study participants being on the programme for less than six months could be associated with methadone being free for the first six months of the rural programme regardless of whether it was the client's first time on the programme or not. In the urban programme methadone is also free for the first six months but only for first time clients. A study conducted in 1999 amongst 112 methadone programme clients in Otago, New Zealand found that 86 per cent of clients had a treatment retention rate of six months or more [126].

The range of the daily methadone dose was large and participants received anywhere between one to > 100mgs of methadone as shown in Table 4.10. The majority (65%) had a daily of dose of 21-80mgs.

Table 4.10: Time and dosage on current methadone programme

Characteristic	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
Time on current programme							
12 months and under	13	21.3	11	20.0	24	20.7	
13-24 months	19	31.1	17	30.9	36	31.0	0.96
25-60 months	17	27.9	14	25.5	31	26.7	
>60 months	12	19.7	13	23.6	25	21.6	
Total	**61[a]**	**100**	**55[a]**	**100**	**116[b]**	**100**	
Methadone dose (mgs)							
1-20	9	14.8	10	18.2	19	16.4	
21-40	12	19.7	14	25.5	26	22.4	0.94
41-60	16	26.2	11	20.0	27	23.3	
61-80	12	19.7	10	18.2	22	19.0	
81-100	9	14.8	8	14.5	17	14.7	
>100	3	4.9	2	3.6	5	4.3	
Total	**61[a]**	**100**	**55[a]**	**100**	**116[b]**	**100**	

[a] *One missing value,* [b] *two missing values*

There was no significant difference in methadone dose between study groups by programme tier (Tier 1, p=0.40; Tier 2, p=0.69; Tier 3; p=0.15). There was no significant association between length of time on the programme and methadone dose (p=0.50). There was also no association between length of time on the programme and whether a participant was on the programme for the first time (p=0.38). These results are not tabulated.

4. 6.4: Routine takeaway (TAs) doses

Overall, 56 per cent (n=66) received TAs on a weekly basis with a higher proportion of urban participants having access to TAs than rural participants (61% vs. 50%). These results are summarised in Table 4.11. Comparison of TAs accessed per week by tier found a significant difference between the two study groups for Tier 1, with urban people significantly more likely to get routine TAs as compared to rural people (p=0.001). There was no significant difference for TA doses accessed per week between Tier 2 and Tier 3 clients.

Table 4.11: Routine takeaway doses per week on current methadone programme

Routine takeaway doses per week	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
Routine takeaway doses							
Yes	38	61.3	28	50.0	66	55.9	
No	24	38.7	28	50.0	52	44.1	0.22
Total	**62**	**100**	**56**	**100**	**118**	**100**	
Routine takeaway doses by Tier							
Tier 1: (n=53)							
Yes	9	34.6	0	0.0	9	17.0	
No	17	65.4	27	100.0	44	83.0	**0.001**
Total	**26**	**100**	**27**	**100**	**53**	**100**	
Tier 2: (n=34)							
Yes	15	71.4	12	92.3	27	79.4	
No	6	28.6	1	7.7	7	20.6	0.21[+]
Total	**21**	**100**	**13**	**100**	**34**	**100**	
Tier 3: (n=31)							
Yes	14	93.3	16	100.0	30	96.8	
No	1	6.7	0	0.0	1	3.2	0.48[+]
Total	**15**	**100**	**16**	**100**	**31**	**100**	

[+]*Fishers exact test*

The significant difference between study groups for Tier 1 clients in relation to TAs accessed per week is most likely due to TA policy differing for Tier 1 between programmes. Urban Tier 1 clients had access to TAs once they were eligible[13], whereas rural Tier 1 clients were not allowed TAs at all. This policy is relevant only to the SNSW programme and does not apply to all NSW methadone programmes. This has been done as an incentive to encourage clients to move into Tier 2 and Tier 3 to minimise dosing in the public programme. Rural Tier 3 clients in my study were likely to get more than the prescribed NSW maximum of four TAs per week due to GP prescribers having greater autonomy of treatment.

4.6.5: Costs associated with dosing

The cost of methadone was significantly different for participants in the two study groups ($p<0.001$). The majority of rural clients paid nothing for their methadone or paid more than $15.00 per week. The cost of methadone was significantly different between study groups by tiers (Tier 1, $p<0.001$; Tier 2, $p<0.001$; Tier 3, $p<0.001$). The majority of rural participants in Tiers 2 and 3 paid more than $15.00 per week. These results are presented in Table 4.12.

[13] Four consecutive random urines being drug free after 4 months on programme = 1 TA per week. Same criteria in the next 4 months = 2 TAs per week.

Table 4.12: Cost of methadone per week on the current methadone programme

Cost of methadone/week	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
Overall							
No cost	6	9.7	27	49.1	33	28.2	
Up to $15.00	50	80.6	2	3.6	52	44.4	**<0.001**
> $15.00	6	9.7	26	47.3	32	27.4	
Total	**62**	**100**	**55[a]**	**100**	**117[a]**	**100**	
Tier 1: (n=53)							
Nothing	6	23.1	27	100.0	33	62.3	
Up to $15.00	18	69.2	0	0.0	18	34.0	**<0.001**
> $15.00	2	7.7	0	0.0	2	3.8	
Total	**26**	**100**	**27**	**100**	**53**	**100**	
Tier 2: (n=34)							
Nothing	0	0.0	0	0.0	0	0.0	
Up to $15.00	17	81.0	0	0.0	17	50.0	**<0.001**
> $15.00	4	19.0	13	100.0	17	50.0	
Total	**21**	**100**	**13**	**100**	**34**	**100**	
Tier 3: (n=31)							
Nothing	0	0.0	0	0.0	0	0.0	
Up to $15.00	15	100.0	2	13.3	17	56.7	**<0.001**
> $15.00	0	0.0	13	86.7	13	43.3	
Total	**15**	**100**	**15[1]**	**100**	**30[1]**	**100**	

[a] *One missing value*

The significant difference between costs of methadone between tiers can be attributed to programme policy within the two areas. In the ACT, all clients in Tier 1 paid $15.00 per week for methadone after six months on the treatment and clients in Tiers 2 and 3 were to pay $30.00 per week. However, ACT clients were given a subsidy of $15.00 per week by the programme, which meant they paid only the remaining $15.00 per week. In SNSW, all clients in Tier 1 paid nothing for their weekly methadone, while Tiers 2 and 3 clients paid the full weekly cost of $35.00 with no subsidy from the programme. Why some people (Tier 1: n=2, and Tier 2: n=4) were paying more than $15.00 in the ACT is unclear considering the cost per week for methadone does not exceed $15.00 in any of the tiers. Similarly, how two people in Tier 3 of SNSW were paying only $15.00 for methadone when all others in Tiers 2 and 3 were required to pay $35.00 is unclear. As the numbers are small, one possible explanation could be that clients may have provided an incorrect response. Another reason could be that they had been dosing elsewhere around the time of the study.

4.6.6: Travel-related issues

The majority of participants travelled less than one hour both ways on dosing days, and this was similar for both study groups (p=0.62). However, the financial cost associated with travel to dose was significantly different for the two study groups, with a greater proportion of rural participants paying more than $5.00 per day as compared to their urban counterparts (32% vs. 15% urban, p=0.02). These results are presented in Table 4.13.

Table 4.13: Time and cost to travel for daily dosing

Characteristic	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
Time travelled to dose (both ways)							
< 1 hour to 1 hour	56	90.3	52	92.9	108	91.5	
> 1 hour	6	9.7	4	7.1	10	8.5	0.62
Total	**62**	**100**	**56**	**100**	**118**	**100**	
Cost to travel to dose (both ways)							
< $5.00	53	85.5	38	67.9	91	77.1	
> $5.00	9	14.5	18	32.1	27	22.9	**0.02**
Total	**62**	**100**	**56**	**100**	**118**	**100**	

The cost associated with travel being significantly different for both groups could be due to reasons such as actual distance travelled, transport means used and cost of transport. Unfortunately information regarding transportation used or actual distance travelled was not collected and this may need further investigation.

4.6.7: Clinical assessment and management characteristics

Table 4.14 summarises and compares clinical assessment and management characteristics for the participants within the two study groups. There was a significant difference (p=<0.001) between participants in the study groups for being allocated a case manager. The case manager is separate to the prescriber and manages individual client matters apart from prescribing and certain clinical assessments. This can include support for related health problems, social support and legal matters. Most rural participants (77%, n=43) had a case manager compared to 29 per cent (n=18) of urban participants.

As also shown in Table 4.14, all participants were regularly reviewed by their methadone prescribers. The majority (82%) did not pay to see their prescriber. There was no significant difference between study groups for cost of seeing their prescriber (p=0.13), but a higher proportion of urban individuals were represented in this category compared to rural individuals (89% vs. 75%).

Costs associated with prescriber visits were compared between study groups by tier as the type of prescriber and cost of appointment was based on tier for each study group. There was a marginally significant difference (p=0.06) in cost associated with seeing the prescriber between Tier 3 clients, with the majority of urban clients not paying to see their prescriber (60%, n=9), while the majority of rural clients (81%, n=13) paid $30.00 or more. These results are not tabulated.

All participants saw their prescribers either at monthly, three monthly or six monthly intervals for review. The majority saw their prescriber at three monthly intervals (72%, n=85). Rural study group participants were significantly more likely to see their prescribers more frequently than their urban counterparts (p=0.02). These results are presented in Table 4.14.

When analysed by tiers, the majority of urban Tier 1 participants were significantly more likely (p=0.04) to see their prescribers at three monthly intervals (77%, n=20), while there was an even spread of rural participants seeing their prescribers at monthly or three monthly intervals (monthly: 52%, n=14; three monthly: 48 per cent n=13). Most urban Tier 2 participants (90%, n=19) saw their prescribers at three monthly intervals, while rural Tier 2 participants were once again split between monthly and three monthly appointments (monthly: 31%, n=4; three monthly: 69%, n=9). This difference was not significant (p=0.09) and may be due to small numbers. There were only two participants (one urban and one rural) in Tiers 1 and 2 who saw their prescriber at six monthly intervals. All Tier 3 participants saw their prescribers either at monthly or three monthly intervals only and there was no significant difference between urban and rural study groups. Overall, for both study groups, pregnant clients and new clients were likely to see their prescriber at shorter intervals. These results comparing prescriber appointments by tier are not tabulated.

Table 4.14: Summary of clinical assessment and management characteristics

Characteristic	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
Case Manager							
Yes	18	29.0	43	76.8	61	51.7	
No	44	71.0	13	23.2	57	48.3	**<0.001**
Total	**62**	**100**	**56**	**100**	**118**	**100**	
Cost of prescriber appointments							
No cost	55	88.7	42	75.0	97	82.2	
Up to $30.00	3	4.8	8	14.3	11	9.3	0.13
> $30.00	4	6.5	6	10.7	10	8.5	
Total	**62**	**100**	**56**	**100**	**118**	**100**	
Time in between prescriber appointments							
Once a month or more	10	16.1	21	37.5	31	26.3	
3 monthly	50	80.6	35	62.5	85	72.0	**0.02**
6 monthly	2	3.2	0	0.0	2	1.7	
Total	**62**	**100**	**56**	**100**	**118**	**100**	

Differences between urban and rural study groups and between tiers of study groups in relation to the factors described above can be attributed to differences in policy and service delivery within the programmes (as described in Chapter 2). The significant difference between access to case managers is due to the rural programme policy of allocating a case manager for all Tier 1 and 2 clients, while in the urban programme, case managers are only allocated to people whose management may be complicated.

The significant difference between the two study groups in relation to frequency of seeing their prescriber could be attributed to arrangements within each tier. Rural people in Tier 1 and Tier 2 could access their prescriber monthly if they chose to, as prescriber clinics were run on a monthly basis. In the urban programme, prescriber clinics were not run regularly, but people were reviewed as per their needs. If stable, they saw their prescriber for a methadone prescription on a three monthly basis.

4.7: Current drug usage and associated risk factors

This section describes and compares drug usage, drug injecting practices, and associated risk factors including methadone injecting for urban and rural participants while on their current methadone programme in the month prior to interview.

4.7.1: Drug usage

Table 4.15 summarises drug usage by participants in the month prior to interview. All participants had been on the programme for more than one month at the time of interview; thus all drug use in the last month prior to interview took place while on the programme. Overall, the mean number of other drugs used (apart from methadone) was 3.38 (SD 1.37). The drugs that were used the most frequently in the month prior to interview were tobacco, cannabis, heroin, alcohol and tranquillisers (92%, 65%, 36%, 47% and 47% respectively). Proportions using these drugs in both study groups were similar, apart from tranquillisers which seemed to be used more amongst rural participants as compared to urban participants (55% vs. 39%), but was not significantly different ($p=0.14$). Only a small proportion used cocaine and this was completely restricted to the urban population. There was no significant difference in mean number of drugs used or type of drug used between the two study groups.

These results demonstrate that many people continue to use opioids and other drugs while on methadone treatment in keeping with other studies [44, 166, 181]. Benzodiazepines have been shown to be one of the more common drugs used amongst people on methadone treatment [126, 182]. A recent study showed that benzodiazepine intake on a daily basis was significantly more likely in people on methadone or codeine, than people using heroin [183]. The difference between cocaine and tranquilliser use between urban and rural study groups could be relative to availability of the two drugs within urban and rural areas respectively.

Table 4.15: Drugs used in the month prior to interview

Drugs used in the last month prior to interview	ACT N=62*		SNSW N=56*		Total N=118*		p-values (Pearson X^2)
	n	%	n	%	n	%	
Heroin	23	37.1	19	33.9	42	35.6	0.59
Other opioids	13	21.0	15	26.8	28	23.7	0.50
Alcohol	29	46.8	26	46.4	55	46.6	0.63
Cannabis	38	61.3	39	69.6	77	65.3	0.45
Amphetamines	13	21.0	8	14.3	17.8	21.0	0.39
Cocaine	3	4.8	0	0.0	3	2.5	0.15
Tranquillisers	24	38.7	31	55.4	55	46.6	0.14
Barbiturates	1	1.6	1	1.8	2	1.7	0.63
Hallucinogens	4	6.5	2	3.6	6	5.1	0.49
Inhalants	0	9.0	1	1.8	1	0.8	0.37
Tobacco	57	91.9	51	91.1	108	91.5	0.57
Mean number of other drugs used in the month prior to interview	3.33 ± 1.47 (n = 61)[a]		3.43 ± 1.26 (n = 56)		3.38 ± 1.37 (n = 117)[a]		0.69

**Total for each drug used does not tally to actual sample numbers as participants could pick more than one option*
[a] One missing value

4.7.2: Frequency of injecting drugs

A little over 50 per cent of the total sample had injected drugs in the month prior to interview and this was similar for both study groups (p=0.73). Table 4.16 summarises frequency of injecting amongst study participants in the month prior to interview. Of all the participants who had injected (n=61), 54 per cent (n=33) had done so once a week or less, 36 per cent (n=22) had injected more than once a week but not daily, and 10 per cent (n=6) had injected more than once a day. Although the results suggest that urban people injected more often than rural people (64% injected once a week or less), there was no significant difference between the two study groups in terms of frequency of injecting (p=0.40).

Table 4.16: Frequency of injecting drugs in the month prior to interview

Injecting practices in the month prior to interview	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
Injected drugs							
Yes	33	53.2	28	50.0	61	51.7	
No	29	46.8	28	50.0	57	47.9	0.73
Total	**62**	**100**	**56**	**100**	**118**	**100**	
Frequency of injecting (n=61)							
Once a week or less	15	45.5	18	64.3	33	54.1	
More than once a week but not daily	14	42.4	8	28.6	22	36.1	0.40
Once a day or more	4	12.1	2	7.1	6	9.8	
Total	**33**	**100**	**28**	**100**	**61**	**100**	

4.7.3: Risk factors and protective behaviours associated with injecting drugs

Of the participants who had injected in the month prior to interview (urban n=33, rural n=28), the majority (93%) had not used injecting equipment after someone else. This was similar for both study groups (p=0.13). Table 4.17 summarises risk factors and protective behaviours associated with injecting drugs in the month prior to interview.

Ninety per cent of participants (n=51) who had injected in the month prior to interview had accessed NSPs. A greater proportion of these were urban participants in comparison to rural participants (94% vs. 84%), but this difference was not significant (p=0.39) (Table 4.17). Overall, 53 per cent (n=59) of study participants had accessed NSPs during their injecting careers and this was similar for both study groups (urban: 56%, rural: 49%, p=0.39). These results are not tabulated.

Whether accessing NSPs equates to safer injecting behaviour and using clean equipment for each injecting episode cannot be ascertained. Considering the low proportion of persons who used equipment after someone else, it would be reasonable to assume that most injecting in the month prior to interview was done using clean equipment.

Living with someone who injects drugs has been shown to be a risk factor associated with injecting drugs [184-187]. Of all participants (injectors and non-injectors), 60 per cent (n= 70) stated that they did not live with someone who injected drugs, 20 per cent said they did (n=24), 19 per cent lived by themselves (n=22), and two per cent (n=2) did not know if anyone in their household injected. These results are not tabulated.

Of the persons who had injected in the month prior to interview (n=61), 35 per cent (n=21) lived with someone who injected drugs. This was similar for the study groups (urban: 34%, n=11; rural 36%, n=10; p= 0.91). This analysis included those who lived alone (in the category of injectors who did not live with someone who injects). These results are presented in Table 4.17.

Table 4.17: Injecting risks and NSP access in the month prior to interview

Characteristic	ACT N=33		SNSW N=28		Total N=61		p-values (Pearson X^2)
	n	%	n	%	n	%	
Injectors who shared injecting equipment							
0 times	31	93.9	26	92.9	57	93.4	0.13
1-2 times	2	6.1	0	0.0	2	3.3	
> 2 times	0	0.0	2	7.1	2	3.3	
Total	**33**	**100**	**28**	**100**	**61**	**100**	
Injectors who accessed NSPs							
Yes	30	93.8	21	84.0	51	89.5	
No	2	6.3	4	16.0	6	10.5	0.39[+]
Total	**32[a]**	**100**	**25[b]**	**100**	**57[c]**	**100**	
Injectors who lived with someone who injects							
Yes	11	34.4	10	35.7	21	35.0	
No (includes people who lived alone)	21	65.6	18	64.3	39	65.0	0.91
Total	**32**	**100**	**28**	**100**	**61**	**100**	

[a] One missing value [b] three missing values, [c] four missing values. [+] Fishers exact test

I examined if living with someone who injects drugs and having injected drugs in the month prior to interview were associated. Analysis included those who lived alone (similar to previous analysis). These findings are outlined in Table 4.18. For the overall sample, people who lived with someone who injected were significantly more likely to have injected drugs (p=<0.001). Eighty eight per cent of all participants who were living with someone who injected drugs (21 of 24 people) had injected in the month prior to interview as compared to 42 per cent of participants (39 of 92 people) who did not live with someone who injected. This association was also found to be statistically significant within each study group (urban study group, p=0.009; rural study group p=0.004). When people who lived alone were not included in the analysis, the significant association still remained (total sample, p<0.001; urban p=0.009; rural p=0.004). These results suggest that people who live with someone who injects drugs are more likely to inject drugs and support findings from previous studies.

Table 4.18: Association between living with someone who injects drugs and injecting drugs in the month prior to interview

Injected in the month prior to interview	Living with someone who injects drugs						p-values (Pearson X^2)
	Yes (n=24)		No (n=92)		Total (n=116)[a]		
	n	%	n	%	n	%	
Total sample							
Yes	21	87.5	39	42.4	60[a]	51.7	
No	3	12.5	53	57.6	56	48.3	**<0.001[+]**
Total	**24**	**100**	**92**	**100**	**116**	**100**	
Urban group (ACT)							
Yes	11	84.6	21	43.8	32	52.5	
No	2	15.4	27	56.3	29	47.5	**0.01[+]**
Total	**13**	**100**	**48**	**100**	**61**	**100**	
Rural group (SNSW)							
Yes	10	90.9	18	40.9	28	50.9	
No	1	9.1	26	59.1	55	49.1	**0.005[+]**
Total	**11**	**100**	**44**	**100**	**55**	**100**	

[a] Two missing values=people who did not know if anyone injected in their household or not, [+] Fishers exact test

4.7.4: Frequency of methadone injecting

Overall, 67 per cent of participants (n=78) had injected methadone while on the current programme. This was similar for both study groups (urban=64%, n=39; rural=70%, n=39). These results are not tabulated.

Information was collected in relation to when participants had last injected methadone and the frequency of injecting methadone while on the current programme. These results are presented in Table 4.19. Overall, the majority (71%, n=55) had injected in the last year or previous to the last year. Fifteen per cent (n=12) had injected in the last week prior to interview, and 14 per cent (n=11) in the last month prior to interview but not in the last week. Twenty three per cent of urban participants (n=9) had injected in the last week prior to interview as compared to only eight per cent of rural participants (n=3). These results were not significantly different between the two study groups (p=0.17).

Only 55 of 78 participants (70%) who had injected methadone while on the current programme indicated their frequency of injecting. Of these, the majority (60%, n=33) had injected less than monthly, while 24 per cent (n=13) had injected weekly or more and 16 per cent (n=9) had injected once a month or more, but less than weekly. These proportions were similar for both study groups (p=0.91). These results need to be interpreted with caution as there were several missing responses.

Table 4.19: Frequency of methadone injecting while on the current programme

Characteristic	ACT N=39		SNSW N=39		Total N=78		p-values (Pearson X^2)
	n	%	n		n	%	
Last injected methadone							
In the last week	9	23.1	3	7.7	12	15.4	
In the last month but not in the last week	5	12.8	6	15.4	11	14.1	0.17
In the last year/ Previous to the last year	25	64.1	30	76.9	55	70.5	
Total	**39**	**100**	**39**	**100**	**78**	**100**	
Frequency of injecting methadone							
Weekly or more	8	25.8	5	20.8	13	23.6	
Monthly/few times per month	5	16.1	4	16.7	9	16.4	0.91
Less than monthly	18	58.1	15	62.5	33	60.0	
Total	**31[a]**	**100**	**24[b]**	**100**	**55[c]**	**100**	

[a] Eight missing values, [b] fifteen missing values, [c] twenty three missing values

A recent study found that methadone injecting in Australia was associated with the TA policy of the State or Territory. There was a positive correlation between a more flexible TA policy and methadone injecting (more TAs allowed correlated to increased methadone injecting) [93]. I looked at this association in my study sample, and found that there was no significant association between the number of TAs and methadone injecting (2 or less TAs: p=0.453; 3 TAs: p=0.382). However, there were four participants who got more than four TAs per week and all four injected methadone.

4.8: Serological HIV/HCV status and HBV vaccination status

HIV serology was available for 109 participants. No one in the urban study group was positive for HIV antibodies, while one person in the rural study group returned an indeterminate test. Of 110 participants for whom HCV serology was available, 70 per cent (n=76) were HCV antibody positive. Of these, 63 per cent (n=36) were urban and 75 per cent (n=40) were rural. The two study groups did not differ significantly in relation to HIV and HCV serological status. The percentage of HIV and HCV antibody positive results in my study is consistent with data collected from other studies and current published Australian statistics [33, 80-82]. Serological HIV and HCV status and relationship to self-reported status are discussed in Chapter 7.

Overall 39 per cent (n=46) of those interviewed self-reported having been immunised against HBV. The two study groups differed significantly in relation to self-report of HBV vaccination status (p=0.01). A higher proportion of urban participants reported that they were vaccinated in comparison to rural participants (urban 50%, n=31; rural 27%, n=15) and a higher proportion of rural participants reported that they did not know their vaccination status in comparison to their urban counterparts (urban 8%, n=5; rural 23% n=13). These results are not tabulated.

IDUs have been identified as a group for whom HBV vaccination is recommended by NHMRC Guidelines as discussed in Chapter 1 [39]. Many programmes make an effort to immunise IDUs, but as the vaccine is not routinely funded for adults through the NIP or through methadone programmes, the cost of the vaccine has to be borne by the client. As discussed in Chapter 1, HBV vaccination has been included in the NIP as a routine childhood vaccine as of 2000, but not as a vaccine for adults. For these reasons HBV immunisation rates amongst current IDUs can be expected to be low and results from my study on self-reported status support this observation.

4.9: Perceived client outcomes and satisfaction

Perceived client outcomes were measured and compared for the two study groups against the five main reasons identified by participants for accessing their current methadone programme (financial issues, getting out of the drug scene, health issues, stopping drug usage and general relationship issues). Overall 50-70 per cent of participants perceived that they had achieved outcomes against the reasons for which they had accessed the programme. Table 4.20 outlines these results.

4.9.1: Perceived client outcomes

Of the 82 per cent of participants (n=85) who had stated financial issues as a reason for accessing their current methadone programme, 68 per cent (n=57) perceived that their financial situation had improved. The rural study group had a higher proportion of participants who perceived their financial situation to have improved as compared to urban participants, but this difference was not significant (77% vs. 62%, p=0.16). Seventy nine per cent of participants (n=80) had accessed their programme to get out of the drug scene; of these 60 per cent (n=43) perceived that they had achieved this outcome. Once again a higher proportion of rural participants achieved the outcome than urban participants, and these proportions were not significantly different (67% vs. 54%, p=0.27). Health as a reason for accessing the current programme was stated by 76 per cent of participants (n=81); of these, 61 per cent (n=49) perceived that their health had improved. This time, urban participants had a higher proportion who felt that their health had improved in comparison to rural participants, but were not significantly different to the rural study group (63% vs. 57%, p=0.59).

Of those participants who had stated stopping illegal drug usage completely as a reason for accessing the methadone programme (71%, n=70), 55 per cent (n=37) stated that they had achieved this outcome. Rural participants had a higher proportion who perceived achieving this outcome in comparison to their urban counterparts, but there was no significant difference between the study groups (57% vs. 52%, p=0.64). Of the 65 per cent of participants (n=66) who stated improving general relationships as a reason, 63 per cent (n=39) perceived that their relationships had improved. Urban participants had a higher proportion represented in this group in comparison to rural participants, but were not significantly different to the rural group (65% vs. 59%, p=0.64).

Table 4.20: Perceived client outcomes achieved in relation to reasons for accessing the programme

Reasons for accessing the programme	% who perceived this outcome to be achieved						p-values (Pearson X^2)
	ACT (N=62) +		SNSW (N=56) +		Total (N=118) +		
	n	%	n	%	n	%	
To improve financial situation*	31	62.0	26	76.5	57	67.9	0.16
To get out of the drug scene*	21	53.8	22	66.7	43	59.7	0.27
To improve health status*	32	62.7	17	56.7	49	60.5	0.59
To stop illegal drug usage completely*	17	51.5	20	57.1	37	54.4	0.64
To improve general relationships*	26	65.0	13	59.1	39	62.9	0.64
To improve employment prospects	14	48.3	8	53.3	22	50.0	0.75
To decrease injecting	20	92.5	12	85.7	32	88.9	0.63*
To decreased criminal activity	17	85.0	14	93.3	31	88.6	0.62*

** Five main reasons*
+Total for each reason does not tally to actual sample numbers as participants could pick more than one option
** Fishers exact*

For other reasons cited for accessing the programme (to improve employment prospects, decrease injecting and decrease criminal activity), level of perceived outcomes varied. Employment was not one of the highly ranked reasons for accessing the programme (50%, n=48). Urban participants were significantly more likely to have stated this to be a reason for accessing the programme in comparison to rural participants (61% vs.39%, p=0.03). For those who stated employment as a reason for accessing their current programme, 50 per cent (n=22) perceived that they had achieved this outcome. As an achieved outcome, there was no significant difference between urban and rural study groups (urban=48%, rural=53%, p=0.75). Similar to employment, smaller proportions of individuals stated decreasing injecting (48%) and criminal activity (45%) as reasons for accessing the programme; this was similar for both study groups. Eighty nine per cent (n=32) perceived that they had decreased injecting; a higher proportion of urban participants stated they had achieved this in comparison to rural participants (93%, vs. 86%), but this was not significantly different (p=0.63). The rural study group had a higher proportion of participants who perceived they had decreased their criminal activity, but this was once again not significantly different to the urban study group (93% vs. 85%, p=0.62).

All those interviewed were asked if they had any specific health concerns and if they perceived that they were in better control of their lives (these results have not been tabulate). Most participants stated they were worried about their dental health and the majority (70%) reported that it had worsened since being on methadone treatment. Although there was a higher proportion of rural participants reporting worsened dental health, this difference was not significant (77% vs. 66%, p=0.23) Lack of access to dental care either through the programme and in general was seen as a major issue. This could be worse for rural people and could be contributing to the larger proportion affected. Overall, 72 per cent (n=81) stated that their control over their life had improved; this was similar for the two study groups (p=0.98). There were a small number of people who stated that their control had worsened and this may need to be investigated further.

4.9.2: Client satisfaction with the current methadone programme

Table 4.22 summarises levels of client satisfaction in relation to their programme, perceived confidentiality and relationship with programme staff. These results should be interpreted with caution as this sample only includes users of the programme. Overall, 71 per cent of the participants (n=79) were satisfied with their current methadone programme and 71 per cent stated (n=76) that their confidentiality was maintained. There was no significant difference between the two study groups for these factors. There was a marginally significant difference (p=0.09) between study groups in relation to perceived respect from programme staff, with a higher proportion of urban participants feeling more respected (85% vs. 72%)

Table 4.21: Client satisfaction with current methadone programme

Characteristic	ACT (N=62)		SNSW (N=56)		Total (N=118)		p-values (Pearson X^2)
	n	%	n	%	n	%	
Programme satisfaction							
Satisfied	43	74.1	36	66.7	79	70.5	
Unsatisfied	15	25.9	18	33.3	33	29.5	0.39
Total	**58[a]**	**100**	**54[b]**	**100**	**112[c]**	**100**	
Confidentiality							
Yes	43	76.8	33	64.7	76	71.0	
No	13	23.2	18	35.3	31	29.0	0.17
Total	**56[c]**	**100**	**51[e]**	**100**	**107[d]**	**100**	
Respect from programme staff							
Yes	50	84.7	38	71.7	88	78.6	
No	9	15.3	15	28.3	24	21.4	0.09
Total	**59[e]**	**100**	**56**	**100**	**115[e]**	**100**	

[a] Four missing values, [b] two missing values, [c] six missing values, [d] eleven missing values, [e] three missing values, [e] five missing values

These results suggest that there were no dissimilarities between urban and rural study participants in relation to perceived outcomes achieved and satisfaction with their respective programmes.

4.10: Summary

The two study groups were not significantly different in relation to most socio-demographic characteristics, previous drug history, prison history or methadone treatment history. The two groups were also similar in relation to current drug usage, HIV and HCV serological status and perceptions of outcomes achieved. Although there was no difference between the two study groups in relation to continued drug usage and injecting while on the programme, many participants continued to use heroin and other drugs, and practice some risky behaviour such as injecting methadone.

As the two study groups were similar socio-demographically and in relation to previous and current risk factors, these factors may not influence differences in health and BBV risk outcomes for urban and rural clients in my study. However, as the two recent studies by Day and colleagues [141], and Lawrinson and colleagues [67] comparing characteristics and risk behaviours for urban and rural IDUs did find differences, these factors cannot be discounted. As the study groups were similar in relation to perceived outcomes achieved, issues related to outcomes **not** achieved could be addressed as common programme management issues rather than as urban or rural specific issues. The issue of dental health problems stated by the majority and access for dental health care through the programme should be further reviewed.

Most of the significant differences between the two study groups were related to programme policy and delivery. This included differences in cost of methadone, cost of travel to dose, TA policy, time in between prescriber appointments and access to case managers. These differences can be largely attributed to jurisdictional autonomy of service delivery due to the Australian health structure. The significant differences in reasons for accessing the programme, referral source to the programme, and self-reported HBV vaccination status could be related to differing outcomes that urban and rural clients wanted to achieve from the programme. These differences could potentially affect health and BBV risk outcomes for the two study groups.

The following two Chapters (Chapters 5 and 6) measure and compare health and BBV risk for the urban and rural study groups and identify factors significantly associated with these outcomes within the study groups. Differences identified in this chapter are included in the analysis, and any policy implications that may arise for urban and rural methadone clients are discussed in each chapter and conclusively in Chapter 8.

Chapter 5

Measurement and comparison of health outcomes

In this chapter I report findings from the measurement and comparison of health outcomes (physical and psychological) for urban (ACT) and rural (SNSW) people on methadone treatment, and identify factors associated with health outcomes for the two population groups. As it has been shown that there is a relationship between opioid use and psychopathology, I have included indicators of psychological adjustment as a measure of health status in my study, in addition to physical health symptoms [130, 131, 188].

The literature review in Chapter 2 showed that methadone treatment is effective in improving health status of heroin dependent individuals by decreasing use of heroin and injecting. However, as discussed in Chapter 1, there are issues related to service delivery in rural areas (such as availability, access, cost and confidentiality) that could impact on health outcomes for rural people on methadone treatment in comparison to urban people. Methadone treatment provision and delivery can also vary between jurisdictions due to the Australian health service structure (also discussed in Chapter 1). This was supported by results in Chapter 4, where comparison of factors relating to programme policy and delivery for the two study groups indicated that there were some differences. This could further impact on health outcomes for rural methadone clients.

Improvement in health status is a key reason for individuals accessing the methadone programme (supported by results in Chapter 4). Whilst other researchers have shown that there are differences between urban and rural IDUs in relation to some socio-demographic characteristics, risk behaviours and access to harm reduction services in Australia, no evaluation assessing outcomes for urban and rural IDUs on methadone treatment has been done before [67, 141]. It is therefore unknown whether these differences can influence outcomes of methadone treatment for the two populations. Findings from my study can assist with informing policy and service delivery according to needs for urban and rural IDUs to maximise health outcomes achieved from methadone treatment programmes.

5.1: Explanation of OTI measurement of health outcomes

Measurement of health status was done using two sections of the OTI (Sections VI and VII), incorporated into my questionnaire as Section V and Section VI of the OTI (Appendix 2: Part III). Section V measures physical health status, while Section VI (the GHQ-28) measures psychological adjustment. I explain the process of measurement of health outcomes by the OTI in this section.

5.1.1. Measurement and comparison of physical health status

The OTI measures physical health status by the presence or absence of symptomatology in eight health areas/systems mostly in the month prior to interview. The eight areas/systems covered are general health issues (which includes general well-being symptoms such as fatigue, insomnia, appetite, hearing or vision loss), injection related problems, cardio-respiratory, genito-urinary, gynaecological, musculo-skeletal, neurological and gastro-intestinal systems. Each area/system has a set of symptoms. A person can have a 0 or 1 score for each symptom depending on whether or not they have experienced the symptom in the month prior to interview (apart from gynaecological symptoms which are measured for the last few months). A score can be calculated for each of the areas/systems. A Total Health Score (THS) is calculated by summing the scores for each area/system. There are 52 symptoms in total within the eight areas/systems that can be scored; thus a THS for a person can range from 0-52. Group mean scores can be calculated for the THS as well as for each area/system and can be compared between study groups. A higher THS or area/system score indicates poorer health status [189].

5.1.2: Measurement and comparison of psychological adjustment

The OTI incorporates the GHQ-28 to measure psychological adjustment and any existing psychopathology [151]. The GHQ-28 measures psychopathology in four symptom areas: somatic, anxiety, social dysfunction and depression. Scores range from 0-7 in each area and a total psychological adjustment score is calculated by summing the scores of the four areas. A total score can range from 0-28. Like the THS, group mean scores can be calculated for the total score and within each of the four areas and compared for study groups and higher scores indicate greater levels of psychopathology [189].

5.2: Comparison of health outcomes for urban and rural study groups

Group mean scores were calculated and compared for the two study groups for the THS, the eight individual health areas/systems scores that made up the THS, and total psychological adjustment score (GHQ-28 scores). Gynaecological scores were excluded for the THS comparison, as my study sample included both male and female participants.

5.2.1: Measurement and comparison of physical health status (THS) for urban and rural study groups

Figures 5.1.a and 5.1.b show the distributions of THS for the overall study group and for urban and rural study groups. As the underlying distributions were assumed to be normal (Figure 5.1.a and b) for reasons explained in Chapter 3, two sample t-tests were used to compare mean THS between the two study groups and between programme tiers [157].

Figure 5.1a: Distribution of Total Health Scores for the overall sample[14]

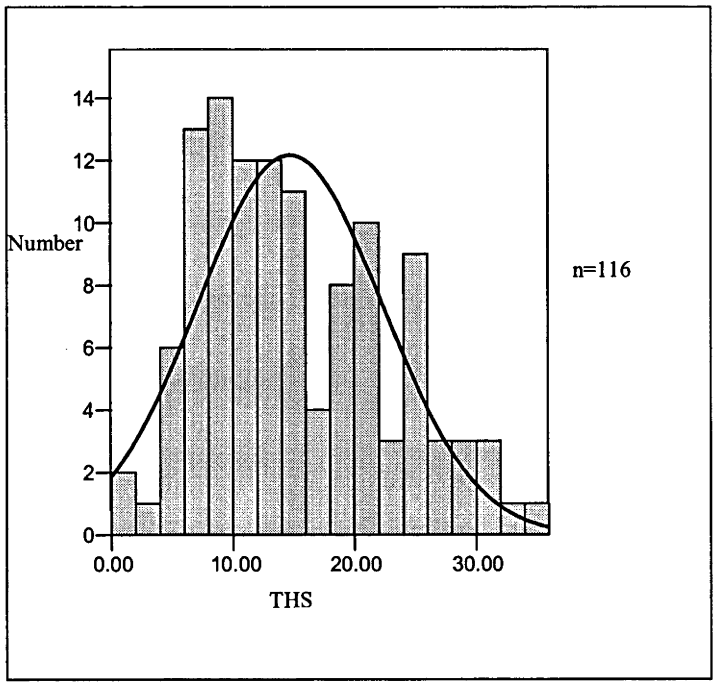
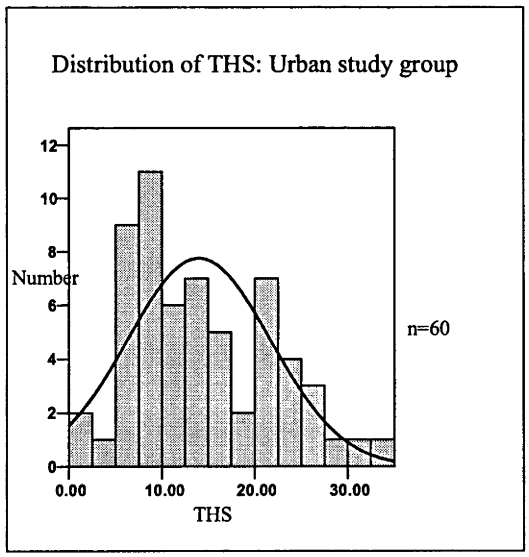
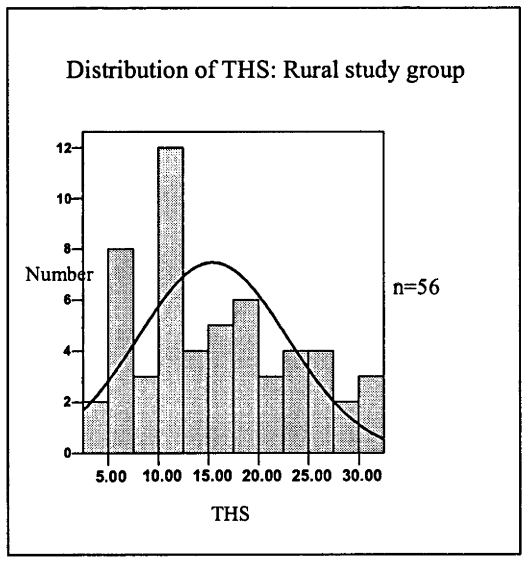


Figure 5.1b: Distribution of Total Health Scores by study group[14]





[14] THS does not include gynaecological scores

Table 5.1 summarises mean THS comparisons for the two study groups overall, and by programme tier. The mean THS for the overall sample was 14.68 (SD 7.61; range 1-35). This score was higher than that of the mean THS from the validation research conducted towards the development of the OTI (mean 12.60, SD 7.60) and the range was slightly narrower (0-42) [189]. The urban study group had a lower mean THS of 13.98 (SD 7.72, range 1-35) compared to the rural study group mean THS of 15.43 (SD 7.48, range 3-32). Mean THS for the three programme tiers were also calculated and compared between the two study groups, as service provision and delivery differed between programme tiers. There was no significant differences in the mean THS between the two study groups (p=0.31) or between programme tiers of the two study groups (Tier1: p=0.27; Tier 2: p=0.96; Tier 3: p=0.66).

Table 5.1: Comparison of mean total health scores by study group and by tier

Characteristics	Overall sample N=118	ACT N=62	SNSW N=56	p-values (Pearson X^2)
Overall sample				
n	116[a]	60[a]	56	
Mean score	14.68	13.98	15.43	0.31
SD	7.61	7.72	7.48	
Range	1-35	1-35	3-32	
Tier 1				
n	52[b]	25[b]	27	
Mean score	14.35	13.08	15.52	0.27
SD	7.91	7.80	7.98	
Range	1-32	1-30	3-32	
Tier 2				
n	33[b]	20[b]	13	
Mean score	14.76	14.70	14.84	0.96
SD	7.49	8.32	6.32	
Range	1-35	1-35	7-29	
Tier 3				
n	31	15	16	
Mean score	15.16	14.53	15.75	0.66
SD	7.42	7.10	7.89	
Range	5-30	5-29	6-30	

[a] *Two missing values,* [b] *one missing value*

5.2.2: Comparison of the eight areas/systems of physical health status for the urban and rural study groups

Mean scores for the eight areas/systems that make up THS (general health issues, injection related problems, cardio-respiratory, genito-urinary, musculo-skeletal, neurological, gastro-intestinal systems and gynaecological) were calculated for the overall sample, compared between the two study groups, and between programme tiers. These results are presented in Appendix 14; Tables 1-8. Once again two sample t-tests were used to compare group mean scores as underlying normal distributions were assumed for reasons explained in Chapter 3. There were no significant differences ($p>0.05$) found in the mean scores for the eight areas/systems between the two study groups and between programme tiers of the two study groups ($p>0.05$).

5.2.3: Comparison of psychological adjustment (GHQ-28) for the urban and rural study groups

The underlying distribution for the mean scores for psychological adjustment for the overall sample and the two study groups were not assumed to be normal. This was because there were many participants who did not have symptomatology and thus had zero scores in each of the four areas that made up the total psychological adjustment score. As seen in Figures 5.2.a (overall sample) and 5.2.b (urban and rural samples), these distributions did not approximate a normal distribution. A non-parametric test (Mann-Whitney test) was used to compare total psychological adjustment mean scores for the two study groups [157].

Figure 5.2a: Distribution of total psychological adjustment scores (GHQ-28 scores) for the overall sample

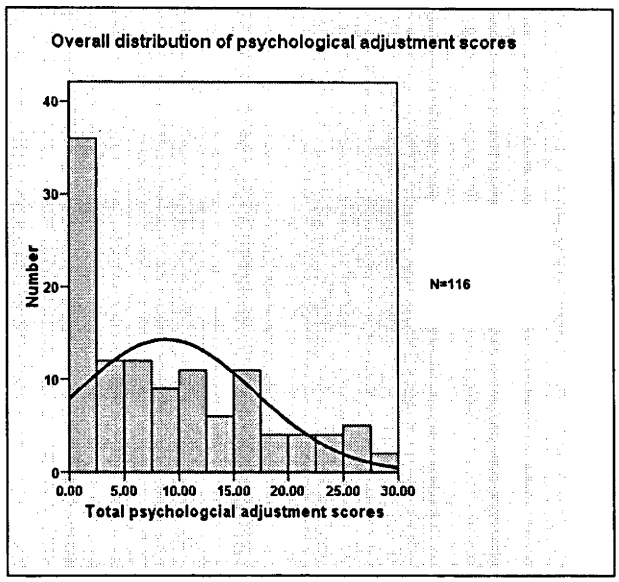
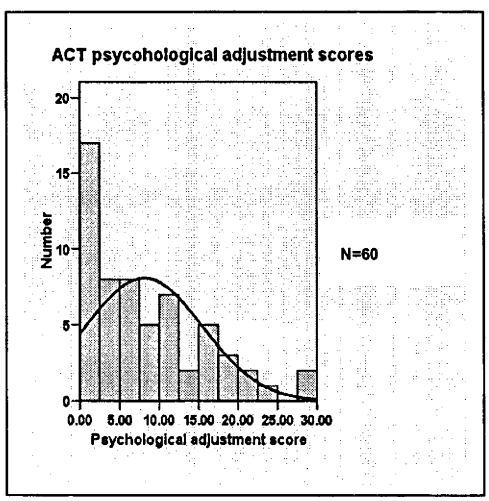


Figure 5.2b: Distributions of total psychological adjustment scores by study group



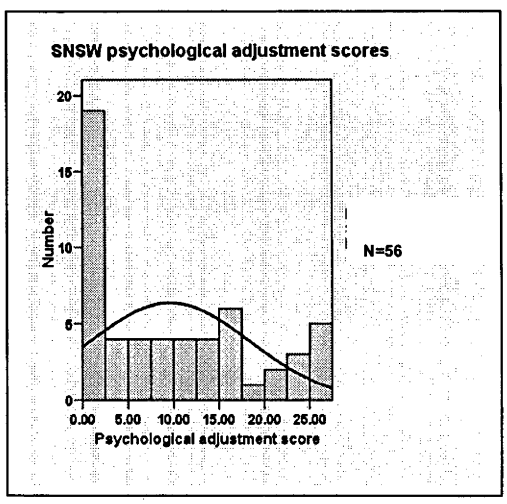


Table 5.2 shows total psychological adjustment scores for the overall sample and for the two study groups. The group mean score for the overall sample was 8.83 (CI 7.34-10.32, range 0-28). This score and range were very similar to the validation research conducted towards the development of the OTI (mean 8.60, SD 7.60, range 0-28) [189]. Group mean scores were calculated and compared between the two study groups and between programme tiers. There were no significant differences found between the psychological total adjustment mean scores for the two study groups (urban: 8.10, SD=7.40, range=0-28; rural: 9.61, SD=8.76, range=0-26; p=0.51) or between programme tiers.

Table 5.2: Psychological adjustment mean scores for the overall sample and the two study groups

Characteristics	Overall sample N=118	ACT N=62	SNSW N=56	p-values (Pearson X^2)
Overall sample				
n	116[a]	60[a]	56	
Mean score	8.83	8.10	9.61	0.51
SD	8.09	7.40	8.76	
Range	0-28	0-28	0-26	
Tier 1				
n	53	26	27	
Mean score	7.55	6.19	8.85	0.31
SD	7.72	6.69	8.52	
Range	0-25	0-21	0-25	
Tier 2				
n	32[a]	19[a]	13	
Mean score	9.97	9.58	10.54	0.80
SD	7.79	7.36	8.65	
Range	0-28	0-28	0-25	
Tier 3				
n	31	15	16	
Mean score	9.84	9.53	10.13	0.92
SD	8.91	8.33	9.69	
Range	0-28	0-28	0-26	

[a] *Two missing values*

As the final sample size was smaller than the required sample size (n=100 in each study group) to elicit a significant difference of 20 per cent between study groups for health outcomes ($p \leq 0.05$, power 0.8), I recalculated the power my study would have to pick up a significant difference between study groups with the sample numbers recruited.

I replaced the standard deviations of mean THS used for initial power calculations (SD from ACT 1993 study) with the SDs of mean THS from my study. With the numbers recruited, my study had a power of 0.53 to detect a 20 per cent difference (at the $p \leq 0.05$ significance level) between mean THS for urban and rural study groups. Any significant differences in urban and rural comparisons with the new power of my study are most likely due to the actual difference being greater than 20 per cent. Some significant differences/associations may also be due to chance. For these reasons results should be interpreted with caution.

The comparison of health outcomes for urban and rural methadone participants in my study indicated that there was no difference between the two study groups in relation to the magnitude of physical and psychological health outcomes (as measured by the THS and GHQ-28). There could be two reasons for this result:
1) There is truly no significant difference between urban and rural study groups in relation to health outcomes,
2) The numbers recruited into the study did not have enough power to elicit a significant difference between the two study groups.

The aim of measuring and comparing health outcomes for urban and rural people on methadone treatment was firstly to examine if health outcomes differed in magnitude for the two populations, and secondly if any differences between the populations (such as socio-demographics, risk behaviours, rural specific issues, programme policy and delivery) could influence health outcomes related to methadone treatment. Whilst there was no significant difference in the magnitude of health outcomes, factors influencing these health outcomes for the two populations could differ as policy and service delivery within the two programmes were shown to be different. In addition to differences found in my study other recent studies have shown that urban and rural IDUs can differ in relation to socio-demographic characteristics and risk behaviours [67, 141]. My analyses reported in the next section of the chapter aims to identify factors that could significantly influence health outcomes related to methadone treatment for urban and rural people. The analyses also examine whether these factors differ for the two populations and whether they have a beneficial or detrimental effect on health outcomes. It is important to identify these factors for appropriate policy development, so that programmes can be tailored according to client needs to ensure maximum benefit.

5.3: Factors contributing to health outcomes within urban and rural study groups

In this analysis all factors identified as potentially being associated with health outcomes related to methadone treatment were included. These were factors identified in my rationale and from other studies (summarised in Chapter 3 Fig 3.1), and differences identified between the study groups in relation to programme policy and delivery in Chapter 4. Factors that were included in this analysis are reiterated below;

1) Sociodemographic characteristics:
   Age, gender, education level, employment status, main income source.
2) Previous risk characteristics associated with incarceration and drug use:
   Prison history, age first injected drugs, age started injecting regularly.
3) Current programme characteristics:
   Programme tier, first time on programme, number of times on programme, length of time on programme, methadone dose, travel time to dose, travel cost to dose.
4) Programme policy and service delivery:
   Access to routine takeaways, cost of methadone per week, cost per prescriber appointment, time in between prescriber appointments, having a case manager.
5) Risk factors while on the programme:
   Total number of other drugs used while on the programme, injected in the month prior to interview, shared injecting equipment in the month prior to interview, living with someone who injects drugs.
6) Client programme satisfaction,

Associations between factors and health outcomes were examined through univariate analyses as explained in Chapter 3. Health outcomes as measured by the OTI THS [15] were used for this analysis. Psychological adjustment (GHQ-28 scores) was not included as GHQ scores cannot be combined with THS scores. Linear regression was used for this purpose as THS were measured on a scale that was approximately continuous. Factors identified as having a significant association at the $p \leq 0.10$ level in the univariate analysis were entered into a stepwise linear regression model to elicit the combination of factors significantly associated ($p \leq 0.05$) with health outcomes in each study group.

[15] Poorer health outcomes = higher mean THS.
Better health outcomes = lower mean THS.

Tables 5.3.a and 5.3.b present the results of the univariate analyses for the factors that were found to have a significant association ($p \leq 0.10$) with health outcome within urban and rural study groups (results of the complete univariate analyses are presented in Appendix 15). There were many factors that had more than two categories and LR tests were used to determine whether these were significantly associated with health outcomes as a whole factor. β coefficients[16] in the model indicate the change in mean score of health outcomes (THS) in relation to the factor and the direction of the association (positive=detrimental, negative=beneficial). R^2 indicates the proportion of the variance of health outcomes within the study groups that can be explained by the factor.

There were six factors in the urban study group and five factors in the rural study group that were significantly associated ($p \leq 0.10$) with health outcomes in the univariate analyses. The one common factor between the two groups was satisfaction level with the programme.

For the urban study group the six factors significantly associated with health outcomes were:

1) employment status,
2) main income in the last six months,
3) cost of methadone per week,
4) having shared injecting equipment in the month prior to interview,
5) having a case manager,
6) satisfaction with the programme.

For the rural study group the six factors significantly associated with health outcomes were:

1) gender,
2) education level,
3) methadone dose,
4) total number of other drugs used in the month prior to interview,
5) satisfaction with the programme.

[16] $THS = \alpha + \beta \times (factor) + random\ error$

Table 5.3a: Factors significantly associated with health outcomes (THS) in the urban (ACT) study group (univariate analysis)

Factors	ACT (N=62)					
	n	β	SE	p-value	LR test (p-value)	R^2
Employment status						
- Unemployed*	16					
- Employed	15	-6.33	2.70	**0.02**	**0.04**	0.13
- Student	2	-5.3	5.56	0.34		
- Other (pension/ home duties)	29	-0.12	2.36	0.96		
- **Total**	**62**					
Main income in the last 6 months						
- Other*	43					
- Through employment	18	-5.75	2.07	**0.008**	NA	0.12
- **Total**	**61**[a]					
Cost of methadone per week						
- no cost*	6					
- up to $15.00	50	3.69	3.23	0.259	**0.05**	0.10
- > $15.00	6	10.33	4.31	**0.02**		
- **Total**	**62**					
Shared injecting equipment in the month prior to interview (n=33)						
- No times*	31					
- 1-2 times	2	12.35	4.99	**0.02**	**0.01**	0.17
- > 2times	0			dropped		
- **Total**	**33**					
Case manager						
- No*	44					
- Yes	18	4.63	2.11	**0.03**	NA	0.08
- **Total**	**62**					
Programme satisfaction						
- Satisfied*	43					
- Unsatisfied	15	5.31	2.27	**0.02**	NA	0.09
- **Total**	**58**[b]					

** Reference category, [a] one missing value, [b] four missing values, NA: Not Applicable*

Table 5.3b: Factors significantly associated with health outcomes (THS) in the rural (SNSW) study group (univariate analysis)

Factors	SNSW (N=56)					
	n	β	SE	p-value	LR test (p-value)	R^2
Gender						
- Male*	34					
- Female	22	4.98	1.95	**0.01**	NA	0.11
- **Total**	**56**					
Education level						
- < Yr 10*	18					
- Completed Yr 10	12	-4.63	2.62	**0.08**	**0.01**	0.19
- Completed Yr 12	7	0.23	3.13	0.94		
- Tertiary	17	4.42	2.38	**0.07**		
- **Total**	**54**[a]					
Methadone dose (mgs)						
- 1-20*	10					
- 21-40	14	-1.04	3.07	0.74	0.27	0.11
- 41-60	11	-2.49	3.24	0.45		
- 61-80	10	-4.90	3.32	0.15		
- 81-100	8	-5.90	3.52	**0.10**		
- >100	2	-9.40	5.75	**0.10**		
- **Total**	**55**[b]					
Total no of other drugs used in the month prior to interview	**56**	1.63	0.77	**0.04**	NA	0.08
Programme satisfaction						
- Satisfied*	36					
- Unsatisfied	18	4.81	2.08	**0.03**	NA	0.09
- **Total**	**54**[a]					

** Reference category, [a] two missing values, [b] one missing value, NA: Not Applicable*

For the urban study group, factors that were shown to be significantly associated with better health outcomes (negative β coefficients) were being employed in the month prior to interview (β=-6.33, SE=2.70, p=0.02), and employment being the main source of income for the last six months prior to interview (β=-5.75, SE=2.07, p=0.008). These two factors could be related to each other, as employment being a factor contributing to better health outcomes, could also be expected to be beneficial as the main source of income. LR tests showed that employment as a whole factor was significantly associated with health outcomes (p=0.04). An LR test was not needed for the main income source as it was a binary variable.

Factors that were found to be significantly associated with poorer health outcomes in the urban study group (positive β coefficients) were methadone cost being greater than $15.00 per week (β=10.33, SE=4.31, p=0.02), sharing injecting equipment 1-2 times in the month prior to interview (β= 12.35, SE=4.99, p=0.02), having a case manager (β=4.63, SE=2.11, p=0.03) and being unsatisfied with the programme (β=5.31, SE=2.27, p=0.002). For the categorical variables, (cost of methadone and sharing injecting equipment), LR tests showed that they were significantly associated with poorer health outcomes as whole factors (cost of methadone per week p= 0.05, sharing injecting equipment p=0.01).

For rural participants, factors that were shown to be significantly associated with better health outcomes (negative β coefficients) were education level and methadone dose. With educational level, only completing Year 10 had a beneficial influence (β=-4.63, SE=2.62, p=0.08) while having a tertiary education had a detrimental influence (β= 4.42, SE=2.38, p=0.07). LR tests indicated that education level remained significantly associated with health outcomes as a whole factor (p=0.01).
Methadone dose had a linear relationship with health outcomes, with higher doses being associated with better health outcomes (increasing negative values of β coefficients as the dose increased). However, only the two highest dose categories were significantly associated with better health outcomes (81-100mgs: β=-5.90, SE=3.52, p=0.10, >100mgs: β=-9.40, SE=5.75, p=0.10). As these categories had very small numbers, I combined dose categories to two categories (<40mgs and > 40mgs) to increase the power of the analysis. Higher methadone doses were still associated with better health outcomes (>40mgs, β=-3.99, SE=1.98, p=0.05). This analysis has not been presented.

Factors that were found to be significantly associated with poorer health outcomes in the rural study group (positive β coefficients) were being female (β=4.98, SE=1.95, p=0.01), having a tertiary education (β=4.42, p=0.07), using a greater number of other drugs in the month prior to interview (β=1.63, SE=0.77, p=0.04) and not being satisfied with the programme (β=4.81, SE=2.08, p=0.03).

Being unsatisfied with the programme was the only common factor for both study groups and was associated with poorer health outcomes. The variance (R^2) in THS scores contributed by each of the factors in the urban study group was between 8-17 per cent, while in the rural study group was between 8-19 per cent.

The factors significantly associated with health outcomes in the univariate analyses for each study group were entered into multiple linear regression models to establish the best combination of factors significantly associated with health outcomes for urban and rural clients. Significance level used for these analyses was $p \leq 0.05$ as these were the final models. Programme tier was entered into the models regardless of whether or not it was significantly associated with health outcomes in the univariate analyses, as programme policy and delivery for the three tiers differed considerably within and between the study groups.

Multivariate analyses showed two factors to be significantly associated with health outcomes related to methadone treatment for urban clients and four factors for rural clients. Tables 5.4.a and 5.4.b outline the results of the multivariate analyses of the two study groups.

Table 5.4a: Factors significantly associated with health outcomes in the urban (ACT) group (multivariate analysis)

Factors	ACT (N=33)				
	n	β	SE	p-value	LR test (p-value)
Cost of methadone per week					
- No cost*	3				
- Up to $15.00	26	12.00	4.33	**0.01**	**0.02**
- > $15.00	4	9.50	4.68	**0.05**	
- **Total**	**33**				
Case manager					
- No*	20				
- Yes	13	10.25	2.85	**0.001**	NA
- **Total**	**33**				

** Reference category, NA: Not Applicable* **Adjusted $R^2 = 0.31$**

Table 5.4b: Factors significantly associated with health outcomes (THS) in the rural (SNSW) group (multivariate analysis)

Factors	SNSW (N=52)[a]				
	n	β	SE	p-value	LR test (p-value)
Total no. of other drugs used in the month prior to interview	**52**	2.47	0.84	**0.001**	NA
Gender					
- Male*	32				
- Female	20	3.78	2.09	**0.008**	NA
- **Total**	**52**				
Programme satisfaction					
- Satisfied*	35				
- Unsatisfied	17	3.96	2.01	**0.04**	NA
- **Total**	**52**				
Education level					
- < Yr 10*	18				
- Completed Yr 10	10	-2.61	2.34	0.27	**0.01**
- Completed Yr 12	7	2.11	2.78	0.45	
- Tertiary	17	4.71	2.14	**0.03**	
- **Total**	**52**				

[a] *Four missing values* Reference category, NA=Not Applicable* **Adjusted $R^2 = 0.38$**

There were only 33 clients in the urban multivariate model as sharing injecting equipment was one of the factors entered into the model. This factor was only directed at injectors in the study, and in the ACT there were 33 participants who had injected in the month prior to interview (Chapter 4, Table 4.16). The two factors significantly associated with health outcomes in the final model; were the cost of methadone per week and having a case manager. Both these factors contributed to poorer health outcomes (β coefficients were positive).

Participants who paid up to $15.00 per week were significantly more likely to have poorer health outcomes than those who did not pay anything (β=12.00, SE=4.33, p=0.01). Those who paid more than $15.00 per week were also more likely to have poorer health outcomes (β=9.50, SE=4.68, p=0.05). All ACT clients were required to pay $15.00 per week regardless of the tier they are in. As new Tier 1 clients received methadone free of charge for the first six months on the programme, this may explain the three participants who paid nothing. The four participants who paid more than $15.00 is harder to explain and as discussed in Chapter 4, this could be due to incorrect responses or the possibility of having dosed at a non-ACT pharmacy that charges more than $15.00 at the time of interview. All in all, having to pay for methadone contributed to significantly poorer health outcomes for urban people in my study.

Having a case manager contributing to poorer health outcomes (β=10.25, SE=2.85, p=0.001) was most likely due to the policy in the ACT, where only clients whose management is complex are allocated case managers. These two factors explained 31 per cent of the total variance of health outcomes (adjusted R^2=0.31). Programme tier did not show any significant association with health outcomes.

For rural participants, those who used a greater number of other drugs in the month prior to interview, were female, and were unsatisfied with their programme, were significantly more likely to have poorer health outcomes as indicated by positive β coefficients (> no. of other drugs used: β=2.47, SE=0.84, p=0.001; female: β=3.78, SE=2.09, p=0.008; unsatisfied with programme: β=3.96, SE=2.01, p=0.04). Education level as a whole factor was still significantly associated with health outcomes (p=0.01). Those with a tertiary education were significantly more likely to have poorer health outcomes, similar to the univariate analysis (β=4.71, SE= 4.71, p=0.03). However, completing Year 10 was no longer significantly associated with better health outcomes.

Methadone dose was also no longer significantly associated with health outcomes. The variance in rural health outcomes explained by this model was 38 per cent (adjusted R^2 =0.38).

The final multivariate models showed that for urban people in my study, the cost of methadone was the main factor that was significantly associated with poorer health outcomes. For rural people in my study, using a greater number of other drugs in the month prior to interview, being female, being unsatisfied with their programme and having a higher level of education as a combination of factors were significantly more likely to contribute to poorer health outcomes. These results suggest that factors significantly associated with health outcomes while on methadone treatment differ for urban and rural clients.

5.4: Summary and discussion

The results from comparing and measuring health outcomes for urban and rural participants in my study indicated that there was no significant difference in the magnitude of outcomes achieved between the two groups while on methadone treatment (as measured by THS and the GHQ-28). However, further analysis found that different factors were significantly associated with health outcomes (as measured by THS) within the two study groups. This could be a reflection of the differences identified between the two study groups in Chapter 4, and the differences identified between urban and rural IDUs and entrants to methadone treatment in other studies [67, 141].

The final multivariate models to identify factors significantly associated with health outcomes within study groups indicated that for urban individuals, having to pay for their methadone dose was associated with poorer health outcomes. The cost of methadone was shown to differ significantly in my study between urban and rural programmes and between tiers of the programmes (Chapter 4), which can be attributed to programme policy within the two study groups. Most urban clients (90%, n=56) paid $15.00 or more for their methadone (regardless of programme tier), while almost half of the rural clients (48%, n=26) paid nothing for their methadone. Rural clients who paid for their methadone were in Tiers 2 and 3 of the programme, were more likely to be stable, and thus may have had better health outcomes.

For this reason, cost of methadone may be a significant contributor to health outcomes for urban clients in my study (particularly in Tier 1), but may not be a significant contributor to health outcomes for rural clients. How generalisable this finding is to other urban and rural people on methadone treatment can only be determined by a larger comparison study, as these policies may be specific to the ACT and SNSW programmes.

The significant association between having a case manager and poorer health outcomes for urban individuals can also be explained by ACT programme policy. Only clients with complex issues were allocated a case manager, and most of these clients were in Tier 1. These individuals could thus be expected to have poorer health outcomes. Having a case manager was possibly not a significant factor associated with health outcomes for rural clients as all were allocated a case manager.

In the rural study group, female participants being significantly more likely to have poorer health outcomes even when gynaecological scores where excluded in the calculation of THS was not a surprising finding. This could be associated with greater risk taking behaviour amongst rural female IDUs as shown by Lawrinson and colleagues [67]. Mondanaro reported findings from several studies that showed that women who use illegal drugs are more likely to have poorer health outcomes than their male counterparts [190]. She also found that women continued to experience poorer health outcomes even while on treatment [191]. This finding should thus be taken into account by rural programmes when female clients are enrolled.

Results from Chapter 4 indicated that rural clients were significantly more likely to pay more for their travel expenses to dose, which may result in missing a dose. This could be a reason for using a greater number of other drugs as a substitute for a missed methadone dose amongst rural individuals. Being unsatisfied with the programme contributing to poorer health outcomes, could be associated with service delivery issues and rapport with staff. This was supported by results in Chapter 4, where (although not significantly different), a higher proportion of rural individuals were not satisfied with their programme as compared to their urban counterparts (33% vs. 26%, p=0.39). A higher proportion also felt they were not respected (28% vs. 15%, p=0.09). Tertiary education being significantly associated with poorer health outcomes for rural individuals was an interesting finding and could be investigated further.

5.5: Conclusion

In conclusion, there was no significant difference between urban and rural individuals in my study in relation to the magnitude of health outcomes while on their current methadone programme. However, factors influencing their health outcomes differed and were mainly associated with policy and service delivery within the urban and rural programmes. These differences should be considered within the respective programmes to inform policy development and service provision to maximise outcomes for individuals.

Chapter 6

Measurement and comparison of BBV Risk

In this chapter I report findings from the comparison of BBV risk between urban and rural methadone clients in my study while on methadone treatment, and the factors associated with risk in each group. I will be concentrating on risk associated with injecting, as methadone is prescribed in Australia for oral administration, and is thus expected to decrease injecting and associated BBV risk. However, studies have shown that methadone programme clients continue to inject other drugs while on treatment, and sometimes inject their methadone takeaways or illegally acquired methadone [126, 163, 166, 181, 182, 192, 193]. These findings were supported in my study (Chapter 4). These injecting episodes while on methadone treatment could contribute to BBV risk. Differences in urban and rural areas in relation to socio-demographic characteristics, risk behaviours and methadone programme policy could also contribute to differences in magnitude and factors influencing BBV risk in the two areas.

Measurement of BBV risk was done by using the BBV TraQ instead of the OTI and the reasons for this are explained in this chapter. A descriptive comparison of the BBV TraQ and the OTI in relation to measurement of BBV risk is also presented.

The chapter is presented in two parts. Part A describes the measurement of BBV risk by the BBV TraQ and the OTI, and includes a descriptive comparison of the two questionnaires. Part B, reports findings of the measurement and comparison of BBV risk for the urban and rural study groups, and the factors associated with risk within the study groups.

Part A: Description and comparison of BBV risk measurement by the BBV TraQ and OTI

6.1: Background

As noted in Chapter 1, a major objective of methadone treatment is to decrease the transmission of BBVs [44]. The BBVs I am interested in for the purpose of my study are HIV, HBV and HCV, as injecting drug use has been shown to be a major risk factor for transmission of these viruses [17]. HIV prevalence in Australia has been kept low amongst IDUs through the introduction of NSPs as a harm minimisation measure when HIV was discovered in the early 1980s [44]. Australia is considered to be a low prevalence zone for HBV, with general population prevalence estimated to be less than two per cent [19]. The Australian prevalence of HBV has been estimated to be four times higher in IDUs as compared to the general population and different studies have showed varying prevalence between 2-30 per cent [19, 84, 194]. HBV transmission can still be a problem for IDUs in Australia even though prevalence is low and there is immunisation against it available, for reasons explained in Chapter 1 [38, 39, 194, 195]. HCV has been prevalent amongst Australian IDUs for many years, is considered to be more infectious and more readily transmitted through blood than HIV, and there is no immunisation against it [17, 24, 44]. People can also be infected more than once as there are several genotypes of the virus [83]. Lack of knowledge of HCV aetiology and transmission until the late 1980s may also be responsible for the higher prevalence. Thus, most methadone clients are already HCV positive when they start on methadone treatment (as discussed in Chapter 2).

For the above reasons methadone treatment has been shown to be effective in preventing new infections of HIV and HBV (where prevalence is low) related to injecting, while it has not been as successful with HCV [24, 44, 55] . For HCV it may be effective in preventing further transmission and minimising re-acquisition of a new genotype.

6.2: Measurement of BBV risk by the BBV TraQ

The BBV TraQ (Appendix 2, Part II) was developed with the primary purpose of having a standardised assessment tool to measure BBV transmission risk for HIV, HBV and HCV. The secondary purpose for its development was to understand and determine risk practices associated with BBV transmission in order to enhance the on-going development of preventive strategies. The BBV TraQ has questions relating to BBV risk alone and needs to be administered with other validated demographic questionnaires. It was developed to be used amongst persons who are considered to be current IDUs (defined as having injected drugs in the month prior to interview) [143].

The BBV TraQ measures risk in three domains: risk associated with injecting drugs, sexual behaviour and other skin penetration (OSP) practices, such as tattooing and body piercing. The BBV TraQ uses a numerical scale to measure risk and there are four scores that can be calculated; risk scores for each of the three domains and a total BBV risk score, measured by combining the scores for the three domains. This can be done as the questionnaire has been shown to have internal validity and reliability for calculation of a score within each domain [196]. Individual and group mean scores can be calculated for the three risk domains and for total BBV risk. Risk is measured through a series of 34 questions: 20 in the injecting risk domain, eight in the sexual risk domain and six in the OSP risk domain. Each question can have a score from 0-5 depending on the frequency of the risk behaviour practiced; a higher score indicating greater frequency. Scores for an individual can range between 0-100 for injecting risk, 0-40 for sexual behaviour risk, 0-30 for OSP practice risk and 0-170 for a total BBV risk score. The higher the score the greater risk of BBV transmission.

The BBV TraQ takes into account protective behaviour that may be practiced to minimise risk related to injecting. There are nine out of the 20 questions in the injecting risk domain that have two parts to it. The first part measures the risk and the second part measures any protective behaviour practiced to minimise the risk. A combined score of these two parts is the score for the risk behaviour, taking into account the protective behaviour practiced. Sexual risk and OSP do not have specific items for protective behaviours.

For the purposes of measuring injecting risk, the BBV TraQ can only be used with people who have injected in the month prior to interview; however this is not a requirement for measurement of sexual and OSP risk scores (C Fry, [Turning Point Drug and Alcohol centre, Fitzroy, Victoria], 1999 pers. comm., 13 November). As BBV risk includes injecting risk, total BBV risk score can only be calculated with a sample of persons who have injected in the month prior to interview. For injecting risk the questionnaire is thus specific to measuring whether or not a BBV risk has occurred while the person is injecting. A score of zero for injecting risk for an individual simply means that although the person has injected in the month prior to interview, there was no BBV risk while injecting.

6.3: Measurement of BBV risk by the OTI

The OTI is a validated questionnaire developed in response to a lack of consistency in the definition, measurement and evaluation of opioid treatment outcomes in the early 1990s. The questionnaire provides a comprehensive and standardised tool for measurement of outcomes and evaluation of opioid treatment, both for clinical assessment and research purposes [120, 189].

The OTI was developed to be multi-dimensional to include the many facets of opioid dependence. It measures outcomes in five domains; Drug use, HIV risk taking behaviour, Social functioning, Criminality and Health. The GHQ is administered with the OTI to measure psychological adjustment [151]. In contrast, the BBV TraQ measures BBV risk only.

The OTI measures BBV risk in two domains; these being injecting risk and sexual risk. A total BBV risk score can be calculated by summing the scores of these two domains. Individual and group mean scores can be calculated for the two risk domains and for total BBV risk. There are six items to measure BBV risk from injecting practice and five items to measure BBV risk from sexual practice. Each item has five responses and is scored from 0-5. For injecting risk a person can have a score ranging from 0-30, for sexual risk from 0-25 and for total BBV risk, a score ranging from 0-55. Each of the risk domains have been validated to provide scores within the domain.

6.4: Comparison of BBV risk measurement by the OTI and the BBV TraQ

Table 6.1 at the end of this section summarises the comparison of the two questionnaires.

6.4.1: Purpose of the two questionnaires

The primary purpose of the OTI BBV risk section is for use as a clinical assessment tool to measure and evaluate opioid treatment in relation to BBV risk behaviour change. A secondary purpose is for use in research for the measurement of BBV risk amongst relevant populations [189]. In comparison, the BBV TraQ is primarily used for measuring and identifying BBV risk for research purposes, and secondarily used to identify common BBV risk behaviours to assist with the development of relevant preventive strategies [143, 196].

Although the two questionnaires have a commonality of purpose, in that they can be used to measure BBV risk for research, the focus of measurement is different. The OTI BBV risk measurement section is termed the HIV risk taking behaviour section as it was specifically designed to measure behaviour of IDUs in relation to HIV transmission. At the time of development of the questionnaire, injecting drug use had emerged as a major BBV risk for HIV and this was used as the basis for BBV risk measurement in the OTI [197]. Emerging data at that time showed that transmission of HIV from IDUs to the general population through unsafe sexual practice was a risk as well. HIV transmission risk through sexual practice was therefore included in determination of total BBV risk [198, 199]. The BBV TraQ in comparison measures BBV risk associated not only with HIV, but also with HBV and HCV.

6.4.2: Comparison of domains and scales of measurement of the two questionnaires

The OTI measures BBV risk in two domains only, while the BBV TraQ measures risk in three domains. The two domains that the OTI measures risk in are injecting and sexual practices; the BBV TraQ measures risk in these two domains as well as with OSP. Apart from the difference in the number of domains within which BBV risk is measured, the two questionnaires are similar in relation to method of measurement.

The time period of measurement of BBV risk for both the OTI and BBV TraQ is the month prior to interview. Both questionnaires use a numerical scale for measuring risk. Risk scores can be calculated within domains and a total risk score combines scores from all domains. A score of zero indicates no risk, while any score above zero indicates risk, and the higher the score the greater the risk. Group mean score can be calculated for the two domains (injecting and sexual risk) and a group mean score for total BBV risk. Thus method of measurement of BBV risk by the OTI is very similar to the BBV TraQ.

6.4.3: Administration and eligible populations for use of the two questionnaires

The OTI and BBV TraQ differ in mode of administration: the BBV TraQ is self-administered with an interviewer present, while the OTI is interviewer administered. The OTI can be administered to two subpopulations to measure BBV risk. The first is those accessing opioid treatment, and the OTI is used to evaluate outcomes of treatment in relation to BBV risk behaviour change. Persons participating do not need to have injected in the month prior to interview. The second set is amongst people with BBV risk practices to measure risk at one point in time for research purposes [189]. In comparison, the BBV TraQ can only be administered to people who are current injectors and have had a history of injecting in the month prior to interview. It is used to research BBV risk behaviours amongst IDUs to assist with developing preventive strategies.

6.4.4: Measurement of BBV risk due to injecting

Measurement of BBV risk due to injecting by the OTI and the BBV TraQ differ. The OTI recognises the act of injecting as a BBV risk whether or not transmission risk has occurred during the process. Both injectors and non-injectors are therefore included in calculation of a BBV risk score due to injecting. A zero score only indicates that a person has not injected. The BBV TraQ measures BBV risk due to injecting only amongst current injectors. A zero score thus indicates that although a person has injected the process was not associated with a BBV risk. BBV TraQ risk scores reflect true BBV risk that may have occurred while injecting. To summarise, a zero OTI injecting risk score indicates that a person has not injected and thus has no BBV risk due to injecting; the BBV TraQ zero injecting score indicates that a person has not had a

BBV risk while injecting. Another major difference between the OTI and the BBV TraQ in relation to the measurement of BBV risk due to injecting is that the BBV TraQ has included the practice of protective behaviours to minimise a BBV risk in its calculation.

The OTI measures BBV risk due to injecting that is specifically related to needle and syringe sharing, re-use and cleaning. The reason for this is that BBV risk measurement by the OTI is specific to HIV. At the time of development of the OTI, HIV contaminated blood had been shown to be transmitted effectively though sharing injecting equipment, and thorough cleaning of injecting equipment with bleach before re-use was being promoted to kill the virus and prevent transmission [197, 200]. The BBV TraQ measures BBV risks that the OTI measures, but also includes risk from other external factors associated with the process of injecting. These include risks associated with indirect blood contamination (such as the act of drawing up of drugs from a common container, sharing of tourniquets, cleaning of the injecting site, assistance from another injector). HBV and HCV have been shown to be effectively transmitted through indirect blood contamination in comparison to HIV [24, 44]. As the BBV TraQ includes measurement of HBV and HCV transmission risk, these other risk factor measurements have been included in the questionnaire.

Measurement of BBV risk due to sexual practice is more similar between the OTI and BBV TraQ. For the BBV TraQ, sexual risk measurement is not dependent on whether a person has had a sexual encounter unlike injecting risk. For both questionnaires a zero score can indicate not having any sexual contact at all. The sexual risk section of the BBV TraQ does not measure protective behaviour practices as is done for injecting risk.

In summary, although the OTI and the BBV TraQ can both be used in research to measure BBV transmission risk, the two questionnaires achieve this differently. The questionnaires differ in terms of purpose, outcomes measures, population groups to which they can be administered to, and measurement of outcomes.
Table 6.1 summarises this comparison of the BBV TraQ and the OTI.

Table 6.1: Comparison of the OTI and BBV TraQ measurement of BBV risk due to injecting

Characteristic	BBV TraQ*	OTI+
Purpose	• Research tool to measure BBV risk • Tool to identify BBV risks to develop strategies for prevention	• Research tool to measure HIV risk • Evaluation tool for opioid treatment to measure HIV risk behaviour change
Outcome measure	• HIV, HBV, HCV risk behaviours	• HIV risk behaviours
Target group	• Current injectors (persons who injected in the month prior to interview)	• Persons on opioid treatment (for clinical assessment) • Persons at risk of HIV transmission
Administration	• Self-administered	• Interviewer administered
Risk measurement period	• Month prior to interview	• Month prior to interview
Measurement Domains	• Injecting practice • Sexual practice • OSP risk	• Injecting practice • Sexual practice
Measurement scores	• Injecting risk score: 0-100 • Sexual risk score: 0-40 • OSP risk score: 0-30 • Total BBV risk score: 0-170 (sum of injecting, sexual and OSP risk scores)	• Injecting risk score: 0-30 • Sexual risk score: 0-25 • Total BBV risk score: 0-55 (sum of injecting and sexual risk scores)
Measurement method	• Numerical rating scale; higher the score greater the risk	• Numerical rating scale; higher the score greater the risk
Measurement of risks	• Risk associated with direct blood contamination (needle sharing, re-use and cleaning) • Risk associated with indirect blood contamination (e.g. drawing up drugs, cleaning injection site)	• Risk associated with direct blood contamination (needle sharing, re-use and cleaning)
Measurement of protective behaviours	• Yes (for injecting risk)	• No

* *The Blood Borne Virus Transmission Risk Assessment Questionnaire*
+*The Opiate Treatment Index*

6.5: Reasons for using the BBV TraQ for measurement of BBV risk

Based on the comparison of the two questionnaires, I chose the BBV TraQ over the OTI to measure and compare BBV risk between urban and rural methadone programmes in my study; specific reasons are detailed below.

- The BBV TraQ measures BBV risk related to HIV, HBV and HCV, while the OTI targets HIV risk specifically. As my study was aimed at measuring and comparing BBV risk due to injecting for HBV and HCV in addition to HIV, the BBV TraQ was the more appropriate instrument.
- The BBV TraQ includes measurement of external risk factors (indirect blood contamination) associated with the process of injecting, which have been shown to be effective in the transmission of HBV and HCV. This is in addition to direct risk factors such as sharing injecting equipment. The OTI only measures BBV risk associated with direct risk factors.
- The BBV TraQ measures actual BBV risk associated with injecting and does not take into account the process of injecting as a BBV risk, while the OTI does.
- The BBV TraQ takes into account protective behaviours that may have been practised while injecting, while the OTI does not. The OTI may therefore be overestimating risk by not accounting for protective behaviours practised.

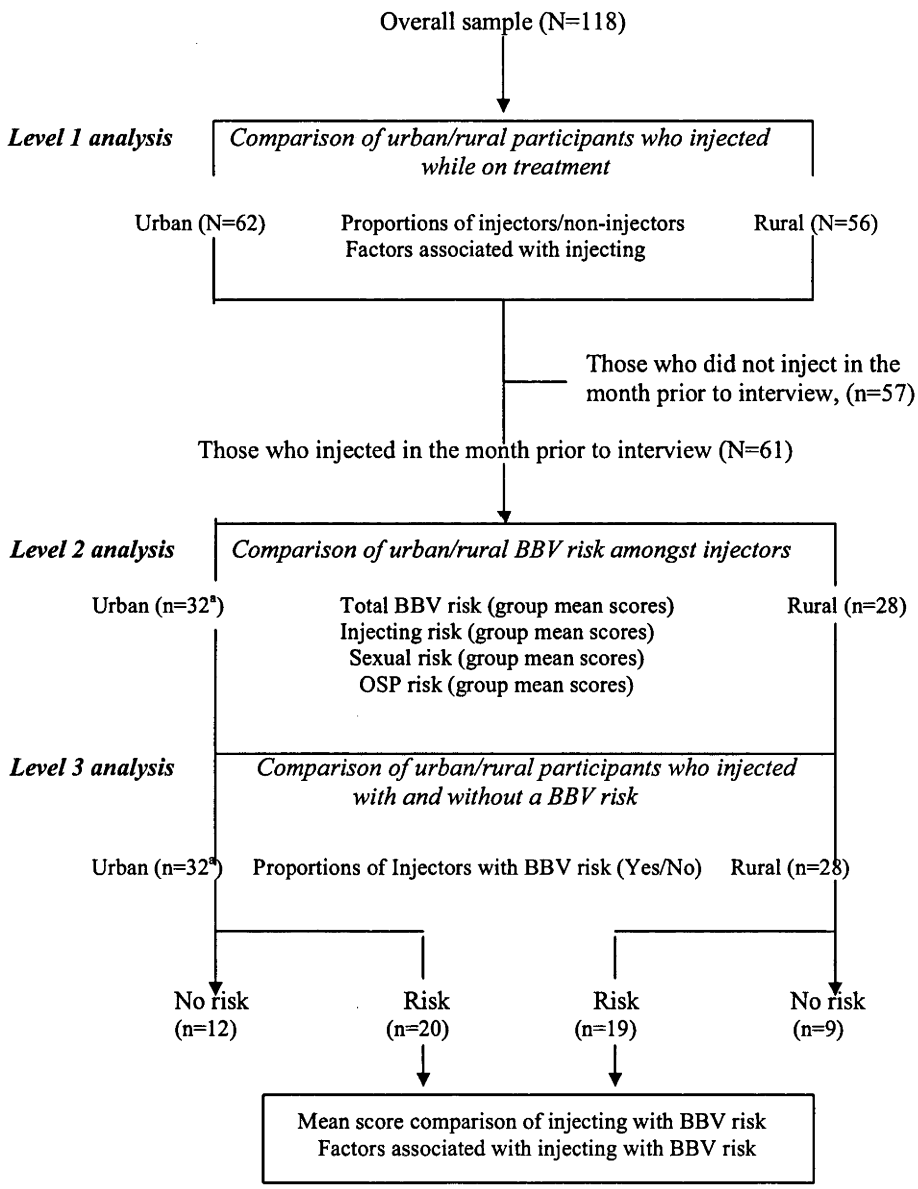
For these reasons I considered the BBV TraQ to be a more specific and robust tool for measuring and comparing BBV risk in my study.

Part B: Measurement and comparison of urban and rural BBV risk

6.6: Analyses outline

Analysis to measure and compare BBV risk between the two study groups was conducted at three levels. Figure 6.1 outlines the analyses plan and structure.

Figure 6.1: Analyses plan and structure



[a] *One missing value*

While methadone treatment aims to minimise risk of BBV transmission through risky injecting behaviour, it also aims to reduce other health problems associated with unhygienic and unsafe injecting practice (e.g. localised infections around the injecting site, collapsed veins and emboli) as described in Chapter 2. For this reason I started my analysis by comparing the risk of the physical act of injecting, amongst injectors and non-injectors in my two study groups in the month prior to interview. This analysis also identified factors significantly associated with injecting within the two study groups and examined if they differed. As the BBV TraQ does not include a question about whether a person had injected in the month prior to interview, the OTI drug use section was used to identify injectors and non-injectors in the study.

My second level of analysis measured and compared total BBV risk and BBV risk from the three domains between the two study groups using the BBV TraQ. This analysis was only amongst injectors and was done using total group mean risk scores, which included zero scores. The main comparison was for injecting risk, however, I also measured and compared risk from sexual practice and OSP and calculated total BBV risk contributed by the three domains. This was done to examine if total BBV risk for urban and rural clients could vary due to risk from exposures other than risky injecting practice. I also compared BBV risk for participants in my study to those of the BBV TraQ validation study.

The third level of analysis was amongst those who injected with a BBV risk (score>0) and had the following aims:

1) To compare proportions of injectors who injected with a BBV risk and without a BBV risk between urban and rural study groups.
2) To measure and compare the magnitude of BBV risk for those who injected with risk behaviour between urban and rural study groups.
3) To identify and compare the factors associated with injecting with a BBV risk between urban and rural study groups.

For the first aim, proportions of individuals who injected with BBV risk (risk score>0) and no risk (risk score= 0) were compared between the two study groups. For aim two, I measured and compared injecting risk mean scores for those who injected with risk behaviour (risk score>0) between the two study groups. For the last aim, I identified factors that were significantly associated with injecting with a BBV risk (risk score>0) within the two study groups and examined if these differed.

By measuring and comparing proportions of injectors, factors significantly associated with injecting and factors significantly associated with BBV risk while injecting within the two study groups, I aim to make a useful contribution towards methadone treatment policy and service delivery within urban and rural areas to decrease BBV risk associated with injecting while on treatment.

6.7: Level 1 Analysis: Factors associated with injecting in urban and rural study groups

Fifty two per cent (n=61) of the total sample had injected in the month prior to interview. There was no significant difference between the proportion of injectors amongst urban and rural study groups (p=0.73), with 53 per cent (n=33) of urban participants and 50 per cent (n=28) of rural participants having injected in the month prior to interview. These results are presented in Table 6.2 and were also presented in Chapter 4, for comparison of current risk factors while on the current programme.

Table 6.2: Comparison of urban and rural proportions of injectors and non-injectors in the month prior to interview

Characteristic	Total (N=118)		ACT (N=62)		SNSW (N=56)		p-value (Pearson X^2)
	n	%	n	%	n	%	
Injectors	61	51.7	33	53.2	28	50.0	0.73
Non-Injectors	57	47.9	29	46.8	28	50.0	

Factors included in the analysis to identify significant associations with injecting in the two study groups were those that were identified in my rationale, through previous studies and differences identified between study groups in Chapter 4 (similar to potential factors associated with health outcomes). These were;

1) Sociodemographic characteristics:
   age, gender, level of education, employment status, main income source in the six months prior to interview, prison history.
2) Current programme characteristics:
   programme tier, length of time on current methadone programme, daily methadone dose, time taken to travel to dose, cost of travel to dose.
3) Programme policy and service delivery:
   cost of methadone per week, access to routine takeaway doses, number of takeaway doses, having a case manager.
4) Risk factors while on the programme:
   total number of other drugs used in the month prior to interview, living with someone who injects drugs.
5) Client programme satisfaction.

Methods used for this analysis were similar to those used to identify factors associated with health outcomes in the urban and rural study group and were explained in detail in the methods chapter (Chapter 3). In summary, univariate analysis was used to test associations of potential significant factors with injecting in each area at the $p \leq 0.10$ level. Significant factors were entered into multivariate regression models (backward stepwise elimination) to identify the combination of factors significantly associated ($p \leq 0.05$) with injecting within each study group. Logistic regression was used for both univariate and multivariate analysis as the outcome was binary (i.e. injected or not).

Tables 6.3.a and 6.3.b present factors that were significantly associated ($p \leq 0.10$) with injecting within the two study groups in this analysis. There were seven factors found to be significantly associated with injecting for urban individuals and four factors for rural individuals in the univariate analyses ($p \leq 0.10$). Appendix 16 presents the complete univariate analyses done to test for associations between all potential factors and injecting within the two study groups.

Table 6.3a: Factors significantly associated with injecting in the urban (ACT) study group (univariate analysis)

Factors	ACT (N=62)					
	n	OR	CI	p-value	LR test (p-value)	Pseudo R^2
Total no. of other drugs used in the month prior to interview	**61**[a]	2.43	1.43-4.12	**0.001**	NA	0.19
Living with someone who injects						
No*	37	1.00				
Yes	13	8.07	1.56-41.73	**0.01**	NA	0.12
Total	**50**[b]					
Main income in the last 6 months						
Other*	43	1.00				
Employment	18	3.28	0.99-10.84	**0.05**	NA	0.05
Total	**61**[a]					
Case manager						
No*	44	1.00				
Yes	18	3.12	0.95-10.25	**0.06**	NA	0.04
Total	**62**					
Time travelled to dose						
< 1hr to 1 hr*	52	1.00				
> 1hr	4	0.15	0.02-1.37	**0.09**	NA	0.04
Total	**56**[c]					
Methadone dose (mgs)						
1-20*	10	1.00				
21-40	14	6.00	0.89-40.31	**0.07**	0.55	0.06
41-60	11	3.33	0.60-18.54	0.17		
61-80	10	2.00	0.33-11.97	0.45		
81-100	8	1.60	0.24-10.81	0.63		
>100	2	1.00	0.06-25.99	1.00		
Total	**55**[d]					

** Reference category, [a] one missing value, [b] 12 people lived alone or did not know if someone in their household injected, [c] six missing values, [d] seven missing values*

In the urban study group (as shown in Table 6.3a), those who used a greater number of drugs in the month prior to interview were almost two and half times more likely to have injected than those who did not (OR=2.43, CI: 1.43-4.12, p=0.001), which could be expected. Individuals living with someone who injected drugs were eight times more likely to have injected than those who did not live with someone who injected drugs (OR=8.07, CI: 1.56-41.73, p=0.01). This correlates with findings from other studies [185, 187, 201]. Those whose main source of income was through employment were a little over three times more likely to have injected than those who had other sources of employment (OR=3.28, CI: 0.99-10.84, p=0.05). This could either be due to not being able to make clinic or pharmacy dosing times or could be associated with having disposable income to spend on other drugs. Individuals with case managers were three times more likely to inject than those who did not have case managers (OR=3.12, CI: 0.95-10.25, p=0.06). This is most likely due to only high risk patients being allocated a case manager in the ACT (similar to contributing to poorer health outcomes). Interestingly the time travelled to dose being greater decreased the chances of injecting (OR=0.15, CI: 0.02-1.37, p=0.09), but was marginally significant. This association is difficult to explain.

Methadone dose showed a linear relationship with injecting. There was a decreased risk of injecting with higher methadone doses (decreasing ORs as methadone dose increased). However, only one category was significantly associated with injecting (methadone dose 21-40mgs: OR= 6.00, CI: 0.89-40.31, p=0.07). An LR test revealed that as a whole factor, methadone dose was not significantly associated (p=0.55) with injecting. This result may be due to the lower power of my study to pick up any significant associations.

The variance in injecting explained by each of these six factors was between 4-19 per cent (as explained by the Pseudo R^2), with number of other drugs used and living with someone who injected contributing the highest percentage.

Table 6.3b: Factors significantly associated with injecting in the rural (SNSW) study group (univariate analysis)

Factors	SNSW (N=56)					
	n	OR	CI	p-value	LR test (p-value)	Pseudo R^2
Total no of other drugs used in the month prior to interview	**56**	2.60	1.47-4.58	**0.001**	NA	0.19
Living with someone who injects						
No*	33	1.00				
Yes	11	15.3	1.75-	**0.01**	NA	0.19
Total	**44[a]**	8	134.87			
Employment status						
Unemployed*	13	1.00				
Employed	10	0.08	0.01-0.56	**0.01**	**0.06**	0.11
Student	3	0.15	0.01-2.29	0.17		
Other (pension, home duties, sick leave)	30	0.30	0.07-1.31	0.11		
Total	**56**					
Programme Tier						
Tier 1*	27	1.00				
Tier 2	13	0.26	0.06-1.07	**0.06**	0.15	0.05
Tier 3	16	0.46	0.12-1.61	0.22		
Total	**56**					

** Reference category, NA: Not Applicable, [a] 12 people lived alone or did not know if someone in their household injected*

For rural participants (as shown in Table 6.3b), of the four factors significantly associated with injecting in the month prior to interview, two were common to the urban study group. These were the total number of drugs used in the month prior to interview and living with someone who injected. Participants who used a greater number of other drugs in the month prior to interview were over two and half times more likely to inject (OR=2.60, CI: 1.47-4.58, p=0.001), while those who lived with someone who injected were a little over 15 times more likely to have injected than those who did not (OR=15.38, CI: 1.75-134.87, p=0.01). Like the urban area these associations could be expected. The other two factors significantly associated were employment status and programme tier, both of which had only one category significantly associated with injecting. Participants who were employed were less likely to inject than those who were unemployed (OR=0.08, CI: 0.01-0.56, p=0.01). Those who were in Tier 2 were also less likely to inject than those in Tier 1 (OR=0.26, CI: 0.06-1.07, p=0.06). LR tests showed that as whole factors employment status was significantly associated with injecting (p=0.06), while programme tier was not (p=0.15). The variance in injecting explained by each of these four factors was between 5-19 per cent.

As there were common factors significantly associated with injecting within the urban and rural study groups in the univariate analysis, I combined the two study groups for the multivariate analysis and included all significant factors in the univariate analysis into one regression model. By doing this I was increasing the power to elicit significant associations that may have otherwise have been missed due to smaller sample size. Programme area (i.e. urban or rural) was included as a factor in the model to establish if being an urban or rural client significantly affected risk of injecting while adjusting for the other factors. Programme tier was entered into the model regardless of its level of significance in the univariate analysis as policy between tiers differed (as was done for health outcomes). Factors included in this multivariate analysis were programme area, programme tier, total number of other drugs used in the month prior to interview, living with someone who injected, main income source in the last six months, having a case manager, the time travelled to dose, and employment status. Significance level was set at p=0.05 as this was the final model.

Table 6.4 summarises the results of the multivariate analysis and the final combination of factors that were significantly associated with injecting in the month prior to interview. There were only 92 clients in this analysis. These were the number of participants who lived with someone who injected and could indicate whether they had injected or not in the month prior to interview.

Table 6.4: Combination of factors significantly associated with injecting in the combined sample (multivariate analysis)

Factor	Total sample (ACT and SNSW: n=92)			
	n	OR	CI	p-value
Total no. of other drugs used in the month prior to interview	**92**	4.29	2.24-8.19	**<0.0001**
Living with someone who injects drugs				
No*	23	1.00		
Yes	69	23.80	4.08-138.91	**<0.0001**
Total	**92**			
Main income in the last 6 months				
Other*	68	1.00		
Employment	14	7.86	1.71-36.24	**0.01**
Total	**92**			

* *Reference category,* **Pseudo $R^2 = 0.43$**

The multivariate analysis determined three factors to be significantly associated with injecting in the month prior to interview (as shown in Table 6.4). These were the total number of other drugs used, living with someone who injected drugs, and main income source being employment. The odds of injecting were a little over four times greater amongst participants who used a greater number of other drugs in the month prior to interview (OR=4.29, CI; 2.24-8.19, $p<0.0001$), almost 24 times greater amongst participants who lived with someone who injected drugs (OR=23.80, CI: 4.08-138.91, $p<0.0001$), and almost eight times greater amongst those whose main income source was employment (OR=7.86, CI: 1.71-36.24, $p=0.01$). The confidence interval was quite wide for the OR associated with living with someone who injects and could either be associated with the small numbers in this group or a large variance in injecting. This combination of factors explained 43 per cent of variance in injecting in the month prior to interview for all participants in my study (pseudo $R^2=0.43$). Interestingly being an urban or rural individual did not influence risk of injecting while on treatment.

I decided to explore if the effect of these three factors on injecting differed between urban and rural individuals, even though programme area was not a factor significantly associated with injecting. To do this, I used statistical methods to create interaction terms [157] between each of these factors and programme area (i.e. programme area and total number of other drugs used, programme area and living with someone who injected, programme area and main income source in the last six months prior to interview). These new interaction factors if significantly associated with injecting would indicate that there was a difference in effect of the factors on injecting for urban and rural individuals. The three factors significantly associated with injecting and the three new interaction factors were entered into the combined model. Programme area was also entered in the model (as this was the factor with which interaction was being determined). None of the interaction factors were significantly associated with injecting ($p\leq0.05$) (these results have not been tabulated). This suggests that there was no difference in the effect of the three factors on injecting between urban and rural individuals. The initial three factors still remained significantly associated with injecting and programme area continued to be not significantly associated.

These results suggest that being an urban or rural client is not significantly associated with injecting while on methadone treatment. Factors that were associated with injecting were mainly influenced by clients' circumstances (i.e. living with someone who injected and having employment as a main source of income). There may be a small influence of programme policy, in that use of greater number of other drugs could be related to not being able to access the dosing centre. This could also be affecting those employed as the dosing time may be inconvenient. Other factors related to policy such as programme tier or having a case manager did not influence risk of injecting.

6.8: Level 2 Analysis: Comparison of urban and rural BBV risk (Total BBV risk, Injecting risk, Sexual risk and OSP risk)

The BBV TraQ was used for the second level of analysis to measure and compare BBV risk between urban and rural study groups. Group means scores (including zero scores) were used to measure total BBV risk, injecting risk, sexual risk and OSP risk for urban and rural study groups, and t-tests were used to compare scores between the two study groups. As the BBV TraQ requires that injecting risk and total BBV risk be calculated only amongst current injectors, this analysis was only amongst participants who had injected in the month prior to interview (urban=33, rural=29). Although measurement of sexual risk and OSP risk does not need to be done only amongst injectors, I chose to measure it amongst injectors in my study, as I compared the results of my study to those of the BBV TraQ validation study which was conducted amongst injectors only. These results are presented in Table 6.5.

Table 6.5: Group-mean scores comparison for BBV risk for urban (ACT) and rural (SNSW) study groups

Characteristics	Overall sample (N=61)	ACT (N=33)	SNSW (N=28)	p-value (Pearson X^2)
Total BBV risk				
n	60[a]	32[a]	28	
Mean score	14.20	12.75	15.85	
SD	13.33	13.62	13.04	0.37
Range	0-65	0-65	0-45	
Injecting risk				
n	60[a]	32[a]	28	
Mean score	6.70	5.78	7.75	0.42
SD	9.26	8.93	9.68	
Range	0-42	0-42	0-38	
Sexual risk				
n	59[b]	32[a]	27[a]	
Mean score	5.22	4.41	6.19	0.36
SD	7.37	6.20	8.58	
Range	0-30	0-22	0-30	
OSP risk				
n	59[b]	32[a]	27[a]	
Mean score	2.42	2.59	2.22	0.65
SD	3.13	3.66	2.41	
Range	0-16	0-16	0-8	

[a] *One missing value,* [b] *two missing values*

The overall total BBV risk score was 14.20 (SD 13.33), with the rural study group having a higher score than the urban study group, but this difference was not significant (rural: 15.85, SD 13.04; urban: 12.75, SD 13.62, p=0.37). The group mean scores for injecting was higher amongst rural participants but not significantly different to urban participants (rural: 7.75, SD 9.68; urban: 5.78, SD 8.93; p=0.42). Sexual risk was also higher for rural participants in comparison to urban participants but once again not significantly different (rural 6.19, SD 8.58; urban: 4.41, SD 6.20; p=0.36). OSP risk was slightly higher in urban participants, but not significantly different to rural participants (urban: 2.59, SD 3.66; rural: 2.22, SD 2.41; p=0.65). The range of scores for all four risk groups for rural participants was narrower than their urban counterparts.

The total BBV risk score for both urban and rural individuals in my study was largely contributed through injecting and sexual risk practices. Injecting risk scores contributed the highest proportion towards total BBV risk scores overall as well as within urban and rural study groups, but was not much higher than the contribution made by sexual risk scores. OSP risk scores contributed to a smaller extent.

Not finding a significant difference between the two study groups in relation to injecting risk and total BBV risk could be due to there actually being no significant difference or a reflection of sample numbers. The study did recruit an adequate sample size to pick up a 20 per cent significant difference between mean scores for total BBV risk (required n=20 per study group) and injecting risk (n=24 per study group). The recruited sample size may, however, have been too small as the SDs used for sample size calculations (ACT 1993 study OTI injecting risk SDs) were quite small. These SDs may not have been truly representative of that expected in methadone clients who inject. SDs in my study for this group were found to be higher. I recalculated power to pick up a 20 per cent significant difference at the $p \leq 0.05$ level using sample numbers and standard deviations from my study. For total BBV risk, the sample numbers recruited had only 40 per cent power to pick up a significant difference of 20 per cent at the $p \leq 0.05$ level. For injecting risk, power to pick up a significant difference of 20 per cent was 25 per cent at the $p \leq 0.05$ level. Thus, sample numbers recruited into my study may have been too low to elicit significant differences between study groups for injecting and total BBV risk.

6.8.1: Comparison of BBV risk scores in my study to BBV TraQ validation study scores

The group mean scores for total BBV risk and the three domains (injecting risk, sexual risk and OSP) in my study in comparison to the risk scores from the BBV TraQ validation study are outlined in Table 6.6 [143]. The mean scores for total BBV risk and injecting risk in the BBV TraQ validation study were much higher than the scores in my study. The scores for sexual risk and OSP were also higher. The higher injecting risk and total BBV risk is most likely due to the sample population of the BBV TraQ validation study being IDUs who were not on methadone treatment. This comparison provides further evidence that methadone treatment decreases the frequency of injecting, thus contributing to lower BBV risk. The lower sexual risk and OSP risk scores in my study population can not be explained.

Table 6.6: Comparison of BBV risk scores from current study to validation study of BBV TraQ

Characteristics	ACT (N=33)	SNSW (N=28)	BBV TRAQ [143]
Total BBV risk			
n	32[a]	28	209
Mean score	12.75	15.85	29.41
SD	13.62	13.04	21.22
Injecting risk			
n	32[a]	28	209
Mean score	5.78	7.75	16.11
SD	8.93	9.68	14.84
Sexual risk			
n	32[a]	27[a]	209
Mean score	4.41	6.19	9.23
SD	6.20	8.58	9.67
OSP risk			
n	32[a]	27[a]	209
Mean score	2.59	2.22	4.16
SD	3.66	2.41	3.88

[a] *One missing value*

6.9: Level 3 Analyses: Comparison of BBV risk due to injecting and identification of factors associated with a risk within the two study groups

Of the 61 participants who had injected in the month prior to interview, one participant in the urban study group did not indicate whether they injected with a BBV risk or not. This made the total sample size for this analysis 60, with 32 individuals in the urban group and 28 in the rural group. A large proportion of these individuals (64%, n=39) had injected with a risk (injecting risk score >0). Fifty one per cent (n=20) were urban and 49 per cent (n=19) were rural. Of the 21 participants who did not have a BBV risk while injecting (injecting risk score=0), 57 per cent (n=12) were urban and 43 per cent (n=9) were rural. These results were presented in Fig 6.1 in the Level 3 analysis section.

6.9.1: Comparison of proportions of urban and rural participants with BBV risk due to injecting.

Amongst participants who injected with a risk (injecting risk score >0), there was a slightly higher proportion of rural participants as compared to urban participants (rural=70%, urban=63%), but these proportions were not significantly different. These results are presented in Table 6.7.

Table 6.7: Proportions of urban and rural participants with and without BBV risk due to injecting

BBV risk due to injecting	Total (n=61)		ACT (n=33)		SNSW (n=28)		p-value (Pearson X^2)
	n	%	n	%	n	%	
Yes	39	65.0	20	62.5	19	67.9	0.66
No	21	35.0	12	37.5	9	32.1	
Total	**60[a]**	**100**	**32[a]**	**100**	**28**	**100**	

[a] *One missing value*

6.9.2: Comparison of urban and rural injecting risk scores for those who had a BBV risk while injecting

Group mean scores for injecting with a BBV risk (injecting risk scores>0) were compared for urban and rural participants using a t-test. These results are presented in Table 6.8. Mean scores were slightly higher for the rural group (rural: 11.42, SD 9.81; urban: 9.25, SD 9.81) but were not significantly different to the urban group (p=0.49). These mean scores were higher than the scores for all participants (injectors with and without risk, Table 6.4) as would be expected.

Table 6.8: Comparison of injecting risk scores for urban (ACT) and rural (SNSW) study groups

Characteristics	Overall sample with BBV risk	ACT injectors with BBV risk	SNSW injectors with BBV risk	p-value (Pearson $X^{2)}$
Injecting risk				
n	39	20	19	0.49
Mean score	10.30	9.25	11.42	
SD	9.74	9.81	9.81	
Range	1-42	2-42	1-42	

These results indicate that there was no significant difference between the two study groups in relation to the proportions of urban and rural injectors who injected with a BBV risk. In addition, there was no difference detected in the magnitude of BBV risk due to injecting between study groups (as measured by the injecting risk score).

6.9.3: Factors associated with BBV risk due to injecting[17] within urban and rural study groups.

Whilst there was no significant difference between urban and rural participants in magnitude of BBV risk due to injecting, due to reasons explained in the rationale for the study and differences identified in Chapter 4, the factors influencing risk could differ (as with health outcomes). My analysis in this section aimed to identify factors that were significantly associated with injecting with a BBV risk for urban and rural individuals and compare them to determine if they differed. Differences identified in Chapter 4, and factors associated with BBV risk due to injecting identified in previous studies and in my rationale, were included in this analysis. These were the same factors used in the analysis to identify significant associations with injecting (Section 6.7). A few additional factors that could potentially influence injecting with a risk were included. These were frequency of injecting in the month prior to interview and participants self-reported HCV status.

The methods used for this analysis were similar to those used for the Level 1 analysis to identify factors associated with injecting and to identify factors associated with health outcomes[18] (described in detail in Chapter 3). Linear regression was used in both the univariate and multivariate analysis as injecting risk was measured as a continuous variable.

Univariate analysis found that there were seven factors that were significantly associated with injecting with a BBV risk ($p \leq 0.10$) for urban participants and three factors for rural participants. These results are tabulated in Tables 6.9a and 6.9b for urban and rural groups respectively. Appendix 17 details the complete univariate analysis.

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[17] BBV risk due to injecting = mean injecting risk scores>0 as measured by the BBV TraQ.
Lower BBV risk due to injecting = lower mean injecting risk scores.
Higher BBV risk due to injecting = higher mean injecting risk scores

[18] Univariate analyses were used to identify a subset of factors significantly associated with BBV risk associated with injecting at the $p \leq 0.10$ level. All factors significantly associated in this analysis were entered into multivariate linear regression models. Backward stepwise elimination was used to determine the final combination of factors that were significantly associated ($p \leq 0.05$) with injecting with a BBV risk within the two study groups.

Table 6.9a: Factors significantly associated with injecting with a BBV risk in the urban (ACT) study group (univariate analysis)

Factors	ACT (n=32)					
	n	β	SE	p-value	LR test (p-values)	R^2
Freq of injecting in the month prior to interview						
- Did not inject*	0					
- Weekly or less	15	-13.65	4.53	**0.005**	**0.01**	0.24
- > weekly but <daily	13	-10.02	4.60	**0.04**		
- Once daily or >	4	dropped				
- **Total**	**32**					
Age (in years)	**32**	-0.37	0.27	**0.04**	NA	0.13
Education level						
- < Yr 10*	5					
- Completed Yr 10	6	-9.70	5.16	**0.07**	**0.10**	0.18
- Completed Yr 12	5	-11.60	5.39	**0.04**		
- Tertiary	16	-9.58	4.37	**0.04**		
- **Total**	**32**					
Programme Tier						
- Tier 1*	13					
- Tier 2	9	6.38	3.65	**0.09**	**0.05**	0.17
- Tier 3	10	-2.74	3.54	0.44		
- **Total**	**32**					
Number of takeaway doses						
- None*	15					
-1-2 doses	7	6.93	3.88	**0.08**	**0.07**	0.16
- > 2 doses	10	-2.57	3.46	0.46		
- **Total**	**32**					
Missed doses						
- None*	7					
- up to 2 doses	12	0.81	4.04	0.84	**0.07**	0.09
- > 2 doses	13	7.49	3.98	**0.07**		
- **Total**	**32**					
HCV self-report						0.06
- Negative*	9					
- Positive	21	5.99	3.48	**0.10**	NA	
- **Total**	**30[a]**					

** Reference category, [a] three missing values. NA: Not Applicable*

Table 6.9b: Factors significantly associated with injecting with a BBV risk in the rural (SNSW) study group (univariate analysis)

Factors	SNSW (n=28)					
	n	β	SE	p-value	LR test (p-value)	R^2
Freq of injecting in the month prior to interview						
- Did not inject*	0					
- Weekly or less	18	-25.61	5.47	**<0.001**	**0.0001**	0.47
- > weekly but <daily	8	-23.75	5.80	**<0.001**		
- Daily or more >daily	2	dropped				
- **Total**	**28**					
Methadone dose (mgs)						
- 1-20*	6					
- 21-40	10	8.30	4.59	**0.08**	**0.05**	0.28
- 41-60	6	-3.17	5.13	0.54		
- 61-80	5	-1.80	5.38	0.74		
- 81-100	1	-6.0	9.59	0.54		
- >100	0	dropped				
- **Total**	**28**					
Number of takeaway doses						0.42
- None*	17					
-1-2 doses	1	29.76	8.02	**0.001**	**0.0006**	
- > 2 doses	9	-4.57	3.21	0.17		
- **Total**	**27[a]**					

** Reference category, [a] one missing value*

For urban participants, frequency of injecting in the month prior to interview, older age and being educated were significantly associated with lower BBV risk due to injecting (as β coefficients were negative and $p<0.01$). Although frequency of injecting as a whole factor was significantly associated with decreased risk (LR test $p=<0.0001$), results showed that those who injected more (> once a week but < daily) had a slightly higher risk than those who injected less (weekly or less) ($\beta=-10.02$, SE=4.60 vs. $\beta=-13.56$, SE=4.53). This result is hard to explain, and it is possible that frequency may be associated with being a regular injector and thus being more prepared to practice safe injecting behaviours. Even though frequency of injecting was associated with lower risk those who injected more frequently had a slightly higher risk than those who injected less. Age had an inversely significant linear association with BBV risk due to injecting. Increasing age significantly contributed to lower risk ($\beta=-0.37$, SE=0.27, $p=0.04$). Level of education as a whole factor also significantly lowered BBV risk due to injecting ($p=0.10$) and any level greater than Year 10 appeared to significantly decrease risk.

Being in programme Tier 2 was significantly associated with increased BBV risk due to injecting for urban clients ($\beta=6.38$, SE=3.65, $p=0.09$). Although not significant, being in Tier 3 appeared to decrease risk ($\beta=-2.74$, SE=3.54, $p=0.44$). As the LR test for programme tier showed that it was significant as a whole factor ($p=0.05$), these results suggest that as clients progressed through the programme tiers their risk decreased. Access to only up to two TAs was also significantly associated with increased BBV risk due to injecting ($\beta=6.93$, SE=3.88, $p=0.08$). Although not significant, having more than two TAs decreased risk ($\beta=-2.57$, SE=3.46, $p=0.46$). An LR test deemed number of TAs as a whole factor to be significantly associated with risk ($p=0.07$). This suggests that as the number of TAs increased the BBV risk due to injecting decreased. These significant associations with programme tier and number of TAs could be related as clients in the ACT have access to a greater number of TAs as they progress through tiers.

Missing a greater number of methadone doses per week also had a linear association with BBV risk due to injecting amongst urban clients. As the number of doses increased (>2), BBV risk significantly increased (β=7.49, SE=3.98, p=0.07). Although missing lower number of doses was not significantly associated in its own right (β=0.81, SE=4.04, p=0.84), LR tests showed that as whole factor the number of doses missed per week was significantly associated with risk (p=0.07). This result suggests that as the number of missed doses increased, individuals experienced significantly higher BBV risk due to injecting. Participants who self-reported a positive HCV status were also just significantly more likely to have a BBV risk while injecting (β=5.99, SE=3.48, p=0.10). The variance in BBV risk due to injecting contributed by each of the seven factors in the urban study group was between 6-24 per cent. Frequency of injecting contributed the highest percentage.

For rural participants the factors significantly associated with BBV risk due to injecting were similar to those for urban participants. Once again frequency of injecting was significantly associated with decreased risk. This association appeared to be stronger than elicited in urban clients as the β coefficients were larger and the p-values smaller. Like the urban study group, greater frequency of injecting was associated with a slightly higher risk (weekly or less: β=-25.61, SE=5.47; >weekly <daily: β=-23.75, SE=5.80). As with urban clients BBV risk due to injecting decreased with access to increased number of TAs per week. The difference in risk between access to up to two doses and greater than two doses was marked (β=29.76, SE=8.02, vs. β=-4.75, SE=3.21). Although only one category of number of TAs (up to 2 doses) was significantly associated, LR tests showed the whole factor to be significantly associated with risk (p=0.0006). This association also appeared to be stronger than that elicited with urban clients. The reasons for these associations are most likely similar to those found in the urban study group. A lower daily methadone dose of 21-40mgs was significantly associated with increased BBV risk due to injecting (β=8.30, SE=4.59, p=0.08). Methadone dose as a whole factor was shown to be significantly associated as a whole factor (LR test; p=0.05). It also had a linear association with risk. As the dose increased BBV risk due to injecting decreased. The variance in BBV risk due to injecting contributed from each of these factors was between 28-47 per cent. Frequency of injecting in the month prior to interview contributed to the highest percentage like the urban study group.

As two of the three factors in the rural study group associated with BBV risk due to injecting (frequency of injecting in the month prior to interview and number of TAs per week) were common to the urban study group, I combined the two study groups into one sample for multivariate analysis. This was similar to the methods used to establish the combination of factors associated with injecting (Level 1 analysis, Section 6.7). All factors that were significantly associated in the univariate analysis in each study group were entered into the model. Programme area was entered into the multivariate model to examine if being urban or rural contributed significantly to risk. Programme tier was also entered into the model (for reasons explained previously).

Factors entered into the multivariate model were thus, programme area, programme tier, frequency of injecting in the month prior to interview, number of TAs per week, methadone dose, age, education level, missed doses, and self-reported HCV status. Linear regression analysis was used as the outcome was a continuous variable (BBV risk due to injecting as measured by mean injecting risk scores). Significance level was set at $p \leq 0.05$ as this was the final model. The final combination of factors significantly associated with injecting with a BBV risk is presented in Table 6.10.

There were six factors that contributed significantly to BBV risk due to injecting in the final model. These were programme area, age, frequency of injecting, number of TAs per week, the number of missed methadone doses per week and methadone dose. Education level, programme tier and HCV self-reported status were no longer significantly associated.

Table 6.10: Combination of factors significantly associated with injecting with a BBV risk for the combined sample (multivariate analysis)

Factor	Total sample (n=56)				
	n	β	SE	p-value	LR test
Programme area					
Urban	30				
Rural	26	5.77	1.81	**0.003**	NA
Total	**56**				
Age (yrs)	**56**	-0.38	0.11	**0.001**	NA
Freq of injecting in the month prior to interview					
Did not inject*	0				
Weekly or less	32	dropped			
> weekly but <daily	18	1.48	1.93	0.45	**<0.0001**
Once daily or >	6	16.94	2.74	**<0.0001**	
Total	**56**				
Number of takeaway doses					
None*	31				
up to 2 doses	7	9.44	2.64	**0.001**	**<0.0001**
> 2 doses	18	-2.95	1.89	0.13	
Total	**56**				
Missed doses					
None*	12				
up to 2 doses	20	2.13	2.43	0.39	**0.02**
> 2 doses	24	5.09	2.17	**0.02**	
Total	**60**				
Methadone dose (mgs)					
1-20*	8				
21-40	17	6.01	2.56	**0.02**	**0.03**
41-60	15	0.001	2.72	1.00	
61-80	10	2.76	2.89	0.35	
81-100	5	5.93	3.87	0.13	
>100	1	0.60	6.51	0.93	
Total	**56**				

** Reference category,* **Adjusted $R^2 = 0.62$**

Rural programme clients were significantly more likely to experience increased BBV risk due to injecting compared to urban programme clients (β=5.77, SE=1.81, p=0.003). Older age continued to be significantly associated with lower risk (β=-.038, SE=0.11, p=0.001). Increasing frequency of injecting in the month prior to interview was now significantly associated with increased risk as a whole factor (LR test, p=<0.0001), (unlike the univariate analysis which showed decreased risk), which could be expected. The number of TAs accessed per week was significantly associated as a whole factor (LR test, p=<0.0001) and increasing number of TAs significantly decreased risk.

Increasing numbers of missed methadone doses per week continued to be significantly associated with increased BBV risk due to injecting (LR test, p=0.02). Methadone dose as a whole factor was significantly associated with increased risk (LR test, p=0.03). The lower (21-40mgs) and the higher spectrum of doses (81-100mgs) appeared to contribute to higher risk compared to doses in between. This combination of factors explained 62 per cent of the variance in injecting with a BBV risk for my overall study sample.

6.10: Summary and discussion

In the descriptive comparison of the BBV TraQ and the OTI, the BBV TraQ was found to be more comprehensive in measuring BBV risk. The BBV TraQ was designed to measure BBV risk in relation to HIV, HBV and HCV, while the OTI only measured risk from HIV. The BBV TraQ also had the advantage of including protective measures practiced during injecting in the measurement of BBV risk. The OTI includes the physical act of injecting as a BBV risk whether risk behaviour has occurred or not. The BBV TraQ measures BBV risk from injecting only when risk behaviour has occurred; Non-injectors are thus not included in risk measurement by the BBV TraQ. The descriptive comparison showed that there were differences between the OTI and BBV TraQ in measurement of risk outcomes, but as done in my study the two questionnaires can be used complementarily.

In the first level of analyses, a little over half of the people in my study (52%) had injected in the month prior to interview. The proportions of injectors in the two study groups were similar (urban=53%, rural=50%, p=0.73). There were two common factors within the study groups that were significantly associated with injecting while on methadone treatment in the univariate analysis (living with someone who injected drugs and number of other drugs used in the month prior to interview). Multivariate analysis combining both urban and rural study groups showed that there were three factors significantly associated with injecting. These were the two common factors from the univariate analysis, and the main source of income in the six months prior to interview being employment. All three factors increased the risk of injecting for individuals while on treatment and all were factors external to the programme and not related to programme policy or service delivery. Interestingly, programme area and programme tier were not associated with injecting and the effect of the three significant factors on injecting did not differ between urban and rural study groups.

In the second level of analyses, the two study groups did not differ in relation to magnitude of total BBV risk, BBV risk due to injecting, sexual or OSP practices. Although BBV risk due to injecting was found to be the main contributor towards total BBV risk in both study groups, risk from sexual behaviour contributed almost as much as injecting risk. It may be useful for methadone programmes to include routine education regarding BBV risk related to sexual practice as a part of the programme. In comparison to the risk scores of the BBV TraQ validation study, participants in my study had lower injecting risk scores. This finding supports the use of methadone treatment to decrease BBV risk from injecting. Risk from sexual practice and OSP were also lower; whether being on methadone assisted with this is uncertain. As the objective of my study was to concentrate on measurement and comparison of BBV risk due to injecting between study groups the rest of the discussion is in relation to injecting risk.

The third level of analyses, found that there was no difference between urban and rural study groups in the proportions of injectors who injected with a BBV risk, even though rural injectors had a higher proportion in this group (urban=63%, rural=68%, p=0.66). Similar to factors associated with injecting within study groups, univariate analysis showed that urban and rural study groups had common factors that were significantly associated with injecting with a BBV risk. Frequency of injecting in the month prior to interview and access to a lower number of TAs per week were found to be common factors associated with increased risk within both study groups. Multivariate analysis combining the two study groups showed that these factors continued to be significantly associated with increased BBV risk due to injecting. Other factors in the model that were significantly associated with increased risk were being a rural programme client, being of younger age, missing a greater number of methadone doses per week and having lower methadone doses.

Rural clients significantly having a higher BBV risk due to injecting in comparison to urban clients is an important finding, particularly as programme area did not influence the risk of injecting in the Level 1 analysis. This finding needs to be taken into account by methadone programme policy makers. Reasons for the increased risk should be determined and addressed within rural programmes. Younger age being associated with increased risk could be associated with younger people being known to practice more risky behaviours in general [201, 202].

Frequency of injecting significantly contributing to increased BBV risk while injecting could be related to factors associated with injecting in the month prior to interview: i.e. living with someone who injected drugs and the number of other drugs used. These were common factors for both urban and rural individuals. Greater number of missed doses being associated with increased risk and a greater number of TAs being associated with decreased risk could be related to dosing access issues. Factors such as the cost of travel and restricted dosing times could influence access to dosing and the number of missed doses. Similarly, having a greater number of TAs per week could be associated with decreased BBV risk, as the number of missed doses would be decreased. These two factors may just be a surrogate of a higher risk group defined by access issues. Studies have shown that there is an association between methadone dose and expected outcomes of methadone treatment including retention [177]. Strain and colleagues studied the effect of low to moderate doses of methadone on opioid use while on treatment. They conducted a randomised, double-blind, placebo-controlled study amongst 247 opioid dependent individuals who were put into three groups and prescribed different stable daily doses (50, 20 or 0 mg per day). Only the 50mg treatment group showed a significantly reduced rate of opioid use (56.4% vs. 67.6% and 73.6% for the 20mg and 0mg groups respectively; $p < 0.05$) [177]. Results in my study were similar and suggested that intermediary methadone doses (21-40 and 61-80mgs) contributed to lowest BBV risk due to injecting while on the programme.

6.11: Conclusion

A large proportion of methadone clients in my study continued to inject while on the programme. The proportions of urban and rural injectors were similar. The factors significantly associated with injecting were also similar for both study groups and the effect of the factors on injecting did not differ between study groups. All significant factors associated with injecting were external to the programme since they were related to client environment and behaviour (living with someone who injected, no. of other drugs used). In contrast, factors related to programme policy were the main factors that significantly influenced injecting with a BBV risk (number of TAs, methadone dose, and missed methadone doses). Rural programme clients were significantly more likely to inject with a BBV risk than urban programme clients. This could be related to access issues and could thus affect client behaviour (such as frequency of injecting).

Chapter 7
Validity of HCV self-reported status

In this chapter I address the second aim of my study. I report findings from my analysis aimed at determining the validity of HCV self-reported status for urban and rural IDUs by comparing self-report to serum antibody status (referred to as serology from here onwards). Validity measures used are explained in this chapter and summarised in Appendix 1. Serology was done at the time of interview through a finger prick blood spot (as described in Methods, Chapter 3) and used as the gold standard to establish true HCV status of participants. HIV self-report validity was used as a comparator. Validity of HCV and HIV self-reported status was measured for the overall sample and compared between urban and rural study groups.

In this chapter I also report findings from analysis conducted to identify factors significantly associated with HCV status as determined by serology. I also examined if significant risk factor associations established with HCV serological status differed to that elicited through serology. These analyses were done for the whole sample combining urban and rural study groups. Reasons for this were explained in the methods chapter; Chapter 3.

7.1: Background

HCV has emerged as a major health issue amongst IDUs as it is mainly transmitted through blood. Research findings published prior to commencement of my study, suggested that the validity of HCV self-reported status is poor [56, 57, 88-90]. Results of the NSW methadone injectors study in 1999 suggested that validity of HCV self-report was also poor among rural IDUs (as described in Chapter 2) [58, 192]. The research opportunity presented through my PhD allowed me to investigate the validity of HCV self-report amongst IDUs further.

As discussed in my rationale and literature review (Chapters 1 and 2), HCV continues to be highly prevalent amongst IDUs [24, 44]. This was supported from results in my study (Chapter 4). Although IDUs should practice safe injecting behaviours to minimise BBV transmission risk and other harms associated with injecting, my results suggest that risky behaviours while injecting continue to occur (Chapter 4). Accurate knowledge of HCV status amongst IDUs may promote safer injecting behaviour and thus decrease the chances of HCV transmission. Accurate knowledge of status may also assist with seeking treatment, support services, and making relevant work choices. In addition, HCV self-report has been used as the indicator of HCV status in research to identify risk factors associated with HCV. It is thus important for self-reported status to be accurate for research integrity.

Many studies have shown that methadone programme clients continue to inject drugs while on treatment [14, 81, 126, 203]. In my study approximately 50 per cent of participants had injected in the month prior to interview (Chapter 4). Of the 64 rural individuals in the NSW methadone injectors study, 73 per cent (n=47) were on methadone treatment [58]. Most people on methadone are also HCV positive from their previous injecting careers when they access treatment (as discussed in Chapter 2). A study in Australia conducted between January 2002 and June 2003, examined HCV sero-prevalence amongst 178 IDUs receiving opioid replacement therapy. HCV prevalence was found to be 75 per cent [45] Another study in 1995 amongst 116 methadone clients in one clinic in New Zealand, found that HCV antibodies were detected in 84 per cent of the sample [14]. A US study in 2001, found 87 per cent of methadone treatment clients to be HCV positive [204]. These rates are similar to those amongst IDUs not in methadone treatment [17, 20].

7.2: Validity measures used to establish accuracy of HCV and HIV self-reported status

Validity measures are used to establish the accuracy of a screening test. Screening tests are used as early detectors of markers of a disease or the disease itself. If a positive screening test has good accuracy, then a person with a positive test has a high likelihood of having the markers of the disease or early stages of the disease itself. Conversely if a negative screening has good accuracy then a person with a negative test will most likely not have the disease [79, 205]. Epidemiological validity measures examine the reliability of a screening test to detect early markers of disease and minimise the need to conduct complicated or invasive diagnostic tests unless indicated. In my study, HCV and HIV self-reported status were demarcated as the screening tests. Their validity was tested against HCV and HIV serological status, which were the gold standards used to indicate true disease.

As was done in Chapter 2, I used sensitivity, specificity, PPVs and NPVs, PLRs and NLRs to measure the validity of HCV self-reported status as an accurate indicator of true HCV status. Sensitivity, PPV and PLR measure the validity of positive self-reports, while specificity, NPV and NLR measure the validity of negative self-reports. PLRs and NLRs are newer validity measures and test the odds of a correct self-report in people with HCV and without HCV, thus combining the effect of sensitivity and specificity [205]. As Likelihood ratios (LRs) combine sensitivity and specificity measurements, they are dependent on the magnitude of these measures. As LRs are ratios, they have an added advantage of not being dependent on disease prevalence in the population.

7.3: HCV and HIV self-reported and serological status

Overall, 91 per cent of the sample provided a self-reported status for HCV. There was a higher proportion of urban participants providing a report, but this difference was not significant (urban=94%, n=58; rural=88%, n=49; p=0.35). The number of participants who provided self-reports for HCV and HIV are presented in Table 7.1. For HIV, 92 per cent of the overall sample provided a self-report. A higher proportion of urban participants provided a report, once again this difference was not significant (urban=95%, n=59; rural=88%, n=49; p=0.19).

7.1: Number of self reports (HCV and HIV) provided for whole sample and the two study groups

Self-report	ACT (N=62)		SNSW (N=56)		Total (N=118)		p-values (Pearson X^2)
	n	%	n	%	n	%	
HCV							
Provided*	58	93.5	49	87.5	107	90.7	0.35
Not provided+	4	6.5	7	12.5	11	9.3	
Total	**62**	**100.0**	**56**	**100.0**	**118**	**100.0**	
HIV							
Provided*	59	95.2	49	87.5	108	91.5	0.19
Not provided+	3	4.8	7	12.5	10	8.5	
Total	**62**	**100.0**	**56**	**100.0**	**118**	**100.0**	

* *Results=positive, negative, don't know*
\+ *Results=missing, no previous test*

As shown in Table 7.2, a large proportion (98%, n=115) of the overall sample agreed to have a finger prick blood test done for HCV and HIV serology. There were similar proportions in the urban and rural study groups (urban=97%, n=60; rural=98%, n=55; p=1.00).

Table 7.2: Serology testing for HCV and HIV in urban and rural study groups

Serology (HCV & HIV)	ACT (N=62)		SNSW (N=56)		Total (N=118)		p-values (Pearson X^2)
	n	%	n	%	n	%	
Yes	60	96.8	55	98.2	115	97.5	1.00
No	2	3.2	1	1.8	3	2.5	
Total	**62**	**100.0**	**56**	**100.0**	**118**	**100.0**	

7.3.1: Previous serological testing for HCV and HIV

Table 7.3 presents the numbers of urban and rural people who stated they were previously tested for HCV and HIV. Overall, 92 per cent (n=108) stated they were previously tested for HCV. Of these, 95 per cent of urban individuals (n=59) said they were previously tested as compared to 88 percent of their rural counterparts (n=49); this difference was not significant (p=0.19). For HIV, 94 per cent (n=111) of the overall sample stated that they were previously tested. Like HCV, urban individuals were more likely to have been tested as opposed to rural individuals (urban 98%, n=61; rural 89%, n=50), but once again this difference was not significant (p=0.10). There was a small proportion of people who did not know whether they had been tested previously for both HCV and HIV. There were more rural than urban people in this category.

Table 7.3: Previous serology testing for HIV/HCV for the overall sample and the two study groups

Previously tested	ACT (N=62)		SNSW (N=56)		Total (N=118)		p-values (Pearson X^2)
	n	%	n	%	n	%	
HCV							
Yes	59	95.2	49	87.5	108	91.5	0.19
No	2	3.2	2	3.6	4	3.4	
Don't know	1	1.6	5	8.9	6	5.1	
Total	**62**	**100.0**	**56**	**100.0**	**118**	**100.0**	
HIV							
Yes	61	98.4	50	89.3	111	94.1	0.10
No	0	0.0	2	3.6	2	1.7	
Don't know	1	1.6	4	7.1	5	4.2	
Total	**62**	**100.0**	**56**	**100.0**	**118**	**100.0**	

7.3.2: HCV and HIV self-report

Although self-reports were collected for HCV, HIV, HBV and Hepatitis A Virus (HAV), only results for HCV and HIV self-report are presented as these were the BBV of interest for this research question. In addition, serology testing was available only for these two viruses. Table 7.4 presents results of self-reported status for HCV and HIV. Overall, of those who provided a self-report for HCV (n=107), 71 per cent (n=76) reported a positive status. There was no significant difference between urban and rural self-reports (p=0.64), even though rural individuals reported a higher percentage of positive self-reports (rural 76%, n=37, urban 67%, n=39). Similar but smaller proportions of participants in both study groups reported not knowing their status.

Overall, 108 participants provided a self-report of HIV status. Of these 98 per cent (n=106) reported their status to be negative. All urban individuals (n=59) reported their status to be negative, while two rural individuals reported their status as unknown.

Table 7.4: HCV and HIV status as per self-report

Self-reported status	ACT (N=62)		SNSW (N=56)		Total (N=118)		p-values (Pearson X^2)
	n	%	n	%	n	%	
HCV							
Positive	39	67.2	37	75.5	76	71.0	0.64
Negative	16	27.6	10	20.4	26	24.3	
Don't know	3	5.2	2	4.1	5	4.7	
Total	**58[a]**	**100.0**	**49[b]**	**100.0**	**107[c]**	**100.0**	
HIV							
Positive	0	0.0	0	0.0	0	0.0	0.12
Negative	59	100.0	47	95.9	106	98.1	
Don't know	0	0.0	2	4.1	2	1.9	
Total	**59[d]**	**100.0**	**49[e]**	**100.0**	**108[f]**	**100.0**	

[a] Three no previous test and one missing value, [b] seven no previous tests, [c] ten no previous tests and one missing value, [d] one no previous test and two missing values, [e] six no previous tests and one missing value, [f] seven no previous tests and three missing values

7.3.3: HCV and HIV serology

Of 115 blood samples collected, there were five (2 urban and 3 rural) that did not yield a result (due to a poor sample). Table 7.5 outlines the results of HCV and HIV serology for the overall sample, and urban and rural study groups. Overall, of 110 individuals for whom serology was available 69 per cent (n=76) tested positive for HCV. A higher proportion of rural people tested positive as opposed to urban (rural=76%, urban=63%), but this was not significantly different (p=0.16).

For those for whom serology was available for HIV (n=110), all urban participants tested negative (n=57). All but one rural individual tested negative. This individual had an indeterminate result. The result was cross-checked with the person's self-report to see if they had reported their status as unknown. The indeterminate result had been reported as a negative self-report. As I did not know the identity of participants it was impossible to contact this person to be retested, and the result was recorded as indeterminate for the purposes of the study.

Table 7.5: HCV and HIV status as per serology

Serology Result	ACT N=62		SNSW N=56		Total N=118		p-values (Pearson X^2)
	n	%	n	%	n	%	
HCV *,+							
Positive	36	63.2	40	75.5	76	69.1	0.16
Negative	21	36.8	13	24.5	34	30.9	
Total	**57**[a]	**100.0**	**53**[b]	**100.0**	**110**[d]	**100.0**	
HIV *,+							
Positive	0	0.0	0	0.0	0	0.0	0.48
Negative	57	100.0	52	98.1	109	99.1	
Total	**57**[a]	**100.0**	**52**[c]	**100.0**	**109**[e]	**100.0**	

** ACT: two not tested, three poor samples, + Rural: one not tested, two poor samples, one indeterminate*
[a] five missing values, [b] three missing values, [c] four missing values, [d] eight missing values [e] nine missing values

7.4: Validity of HCV and HIV self-report

In order to calculate validity of HCV and HIV self-report, only positive and negative self-reports and serological results were used. Self-reports where status was reported as unknown, serology results that were indeterminate and missing (including persons who were not tested and poor blood samples) have been excluded.

7.4.1: Validity of HCV self-report (comparison of HCV self-reported status to serological status)

Table 7.6 represents a two by two table of positive and negative HCV self-reports tabulated against HCV serological results for the overall sample and the two study groups. Overall, there were 94 participants for whom both HCV serological and self-reported status were available (of 102 participants who provided self reports and 110 participants who had serology done). Of these, 50 were urban individuals and 44 were rural individuals. This formed the sample for which validity of HCV self-report was calculated. Of the 94 individuals, 74 (79%) provided a correct self-report (positive and negative). Fifty per cent (n=37) were urban and fifty per cent (n=37) were rural. Table 7.7 presents the results of validity measurement of HCV self-reported status.

Table 7.6: Cross tabulation of HCV positive and negative self-reports and serology

HCV self-reports	ACT (n=50)		SNSW (n=44)		Total (n=94)	
	Sero +ve	Sero -ve	Sero +ve	Sero -ve	Sero +ve	Sero -ve
Self-rep +ve	27	8	31	3	58	11
Self-rep -ve	5	10	4	6	9	16
Total	**32**	**18**	**35**	**9**	**67**	**27**

Table 7.7: Comparison of HCV self-report validity between study groups

Validity measure	Overall sample measure (CI)	Urban (ACT) measure (CI)	Rural (SNSW) measure (CI)	p=value
Sensitivity	0.87 (0.76-0.94)	0.84 (0.67-0.95)	0.89 (0.73-0.97)	0.73
Specificity	0.59 (0.39-0.78)	0.56 (0.31-0.80)	0.67 (0.30-0.93)	0.69
PPV	0.84 (0.73- 0.92)	0.77 (0.60-0.90)	0.91 (0.76-0.98)	0.19
NPV	0.64 (0.43- 0.82)	0.67 (0.38-0.88)	0.60 (0.26-0.89)	1.00
PLR	2.12 (1.34-3.38)	1.90 (1.11-3.25)	2.66 (1.05-6.75)	0.53
NLR	0.23 (0.11-0.45)	0.28 (0.11-0.70)	0.17 (0.06-0.48)	0.48

Sensitivity of self-report for the overall sample indicated that 87 per cent of the participants who actually had HCV had reported a positive status. The rural study group had higher sensitivity than the urban study group, but the difference between the two study groups was not significant (urban=84%; rural= 89%; p=0.73). The PPV for the overall sample indicated that 84 per cent of participants who reported a positive self-report were correct. The rural study group had a higher PPV than urban study groups, but the difference was not significant (urban= 77%; rural=91%; p=0.19). For the overall sample, the PLR indicated that participants with HCV were 2.12 times more likely to report a positive status as opposed to those without HCV. Again the rural study group had a higher PLR, but the difference between the groups was not significant (urban=1.90, rural=2.66; p=0.53). These results measured the validity of HCV positive self-reports and indicate that over 80 per cent of the sample was sure of their HCV positive status. Rural individuals were more likely to report their status correctly.

Specificity of HCV self-report for the whole sample was relatively low at 59 per cent. This indicated that only 59 per cent of the sample who reported their status as negative actually did not have HCV. The specificity for the urban study group was relatively lower than the rural study group, but the difference was not significant (urban=56%; rural=67%; p=0.69). The NPV indicated that only 64 per cent of all participants who reported a negative status were correct. The urban study group had a higher proportion of correct negative self-reports than the rural study group in this instance, but this difference was not significant (urban=67%; rural=60%; p=1.00). The NLR indicated that the likelihood of a negative self-report in persons who were HCV positive in comparison to those who were HCV negative was approximately one in four (0.23). This is quite a high proportion of incorrect negative self-reports. The likelihood was higher for urban participants in comparison to rural, but were not significantly different (0.28 vs. 0.17, p=0.48). These results measured the validity of HCV negative self-reports and indicate that validity was quite poor.

7.4.2: Validity of HIV self-report (comparison of HIV self-reported status with serological status)

For HIV, of 106 individuals who provided positive or negative self reports and of 109 individuals who had positive or negative serology, 97 had both available (54 urban and 43 rural). Of these 97 individuals, all (both urban and rural) reported their negative status correctly. These results indicate that validity of HIV self-reported status was high and accurate amongst participants in my study.

7.5: Duration between last serological test and validity of HCV self-reports

As information regarding the time of last serological test was collected in the study, I conducted further analysis to examine if the duration between last serological tests for study participants affected validity of HCV self-reported status. Duration since last serological test could affect validity of negative self-reports particularly, as a person may have had a risk exposure and seroconverted since the last test. The window period for seroconversion from time of exposure for a HCV serum antibody test (anti-HCV EIA-3) to be positive is between 1-3 months (mean=2.2 months). Lower validity of negative self-reports in my study could thus be related to seroconversion since the last test if it was done more than three months prior to self-report in my study. Duration of time since last test could also affect validity of positive self-reports through bias related to recall of test result. Analysis to examine if duration since last serological test was related to validity of self-report was done for the overall sample and compared for urban and rural study groups. These results are presented in Table 7.8.

Table 7.8: Duration between current self-report and last stated serology

Self-report	N	Mean time since last serology (Yrs)	SD (yrs)	Range (Yrs)
Correct +ve self-report				
Overall	58	6.2	3.9	0.2-14.1
ACT	27	7.2	3.9	0.3-14.1
SNSW	31	5.2	3.6	0.2-12.6
Correct -ve self-report				
Overall	16	1.1	1.3	0.1-3.9
ACT	10	0.9	1.2	0.1-3.9
SNSW	6	1.5	1.4	0.2-3.3
Incorrect +ve self-report				
Overall	11	8.3	5.1	0.5-15.3
ACT	8	8.0	5.9	0.5-15.3
SNSW	3	9.0	3.0	6.5-12.3
Incorrect -ve self-report				
Overall	9	1.0	0.8	0.3-2.1
ACT	5	1.1	0.9	0.3-2.0
SNSW	4	0.8	0.9	0.3-2.1

There was a total of 58 participants who had provided a correct positive self-report. The mean time since their last serological test was just over six years (74 months). The range was large with serological testing having been done from between two months to 14 years prior to self-report in my study. The mean time for last serological test for rural individuals was almost two years less than for urban individuals (urban=7.2 years, rural=5.2 years). This shorter mean time could be associated with greater validity of positive self-reports (sensitivity, PPV and PLR) for rural individuals.

For the 16 participants who had correct negative self-reports, the mean time from last serology was just over one year (13 months) with a range of 1 month to 4 years. This mean time was much less than that related to correct positive self-reports. The mean time since last serology for urban individuals was a little over six months less than their rural counterparts (urban=0.9 years, rural=1.5 years). This could be associated with urban participants having a higher number of correct negative reports reflected in the higher NPV (urban= 67%, rural= 60%).

Although urban participants had a higher NPV, the proportion who reported their status as negative but truly did not have HCV (specificity) was lower than that of rural participants (urban=56%, rural=67%). This is also reflected in the incorrect positive self-reports, where there was a higher number of urban individuals (urban=8, rural=3). Even though urban individuals had poorer specificity, for those who had an incorrect positive self-report their mean time since last serology was a year shorter than that of their rural counterparts (urban=8.0, rural=9.0).

Overall, there were nine participants who provided incorrect negative self-reports. The mean time between the last serological tests and the incorrect negative self-reports provided at the time of my study was one year with a range between three months to two years. Validity of negative self-reports (specificity, NPV and NLR) was quite poor for both urban and rural individuals. This may be associated with seroconversion since their last serological test. For all participants with incorrect negative reports, the time between last serological tests and self-reports in my study was greater than three months. The number of urban and rural individuals who provided incorrect negative self-reports did not differ greatly (urban=5, rural=4). This is reflected in the sensitivity of HCV self-report, where although rural participants had a higher sensitivity, the difference was not great (urban=84%, rural=89%). The mean time between last serological tests and incorrect negative self-reports for urban and rural individuals was also not very different (urban=1.1 years, rural=0.8 years).

These results suggest that the duration between a person's last serological test and providing a correct HCV self-report could potentially influence validity of self-report. Shorter time frames between last serological test and self-report appeared to provide better validity of self-report. Rural individuals had shorter mean time-frames and this may be reflected in them having better validity of HCV self-report (both positive and negative). Other factors influencing validity of self-report could be the knowledge that HCV prevalence is high amongst IDU, which could be associated with the higher validity of positive self-reports, whilst the high HCV incidence in IDU could be related to poor validity of negative self-reports.

7.6: Factors significantly associated with HCV status identified through serology and comparison to those identified through self-reported status

This analysis aimed to identify factors significantly associated with HCV status (as diagnosed through serology) in my study. It also compared significant risk factor associations determined through HCV serology to those elicited through self-report to examine if they differed. Factors tested for their association with HCV serology and HCV self-report were those identified as possible risk factors in the methods chapter (Chapter 3). These factors included sociodemographic characteristics, previous and current risk factors, and relevant current methadone programme characteristics. Urban and rural samples were combined for these analyses as validity of HCV self-reported status was not different between the two study groups, and for reasons explained in the methods chapter (Chapter 3). Only sample results that were positive or negative were included in the analysis.

7.6.1: Factors significantly associated with HCV status as determined through serology

Univariate analyses were conducted to establish a subset of factors significantly associated with HCV serological status at the $p \leq 0.10$ using Pearson's X^2 tests. These were entered into a stepwise (backward elimination) multiple regression model to establish the final combination of factors significantly associated with HCV serological status at the $p \leq 0.05$ level (as this was the final model). Logistic regression analysis was used as the outcome of interest (HCV serological status) was a binary variable

Tables 7.9a and 7.9b present results of the univariate analyses. Table 7.9a presents sociodemographic factor associations with HCV serological status while Table 7.9b presents associations of previous and current risk factors, and relevant current methadone programme characteristics with HCV serological status.

Table 7.9a: Sociodemographic factors associated with HCV serological status (univariate analysis)

Factor	HCV –ve (n=34)		HCV +ve (n=76)		Total (n=110)		p-values (Pearson X^2)
	n	%	n	%	n	%	
Age group							
< 20	0	0.0	1	100.0	1	100.0	**0.02**
20-29 years	12	46.2	14	53.8	26	100.0	
30-39 years	17	37.0	29	63.0	46	100.0	
40 +	4	11.4	31	88.6	35	100.0	
Total	**33[a]**	**30.6**	**75[a]**	**69.4**	**108[b]**	**100.0**	
Gender							
Male	18	28.6	45	71.4	63	100.0	0.54
Female	16	34.0	31	66.0	47	100.0	
Total	**34**	**30.9**	**76**	**69.1**	**110**	**100.0**	
Education level [§]							
< Yr10	3	11.1	24	88.9	27	100.0	**0.03**
Year 10	12	48.0	13	52.0	25	100.0	
Year 12	7	36.8	12	63.2	19	100.0	
Tertiary	10	27.8	26	72.2	36	100.0	
Total	**32[b]**	**29.9**	**75[a]**	**70.1**	**107[c]**	**100.0**	
Employment status							
Unemployed	8	33.3	16	66.7	24	100.0	0.97
Employed	7	28.0	18	72.0	25	100.0	
Student	1	25.0	3	75.0	4	100.0	
Other (pensioners, sick leave, home duties)	18	31.6	39	68.4	57	100.0	
Total	**34**	**30.9**	**76**	**69.1**	**110**	**100.0**	
Main income in the last 6 months							
Paid employed (part time/full-time)	8	33.3	16	66.7	24	100.0	0.80
Other (pension, student, home duties)	26	30.6	59	69.4	85	100.0	
Total	**34**	**31.2**	**75[a]**	**68.8**	**109[a]**	**100.0**	

[§] Mutually exclusive categories, [a] one missing value, [b] two missing values, [c] three missing values

Sociodemographic factors significantly associated with HCV serological status in the univariate analyses were age group of study participants and level of education. HCV prevalence was statistically significantly higher in the 30-39 years and >40 year age groups (p=0.02). Individuals who had only completed year 10 and those who had a tertiary education also had significantly higher HCV prevalence in comparison to other education levels (p=0.03). Gender, current employment status and main source of income in the last six months were not significantly associated with HCV serological status.

Table 7.9b: Previous and current risk factors and relevant current methadone programme characteristics associated with HCV serological status (univariate analysis)

Factor	HCV –ve (n=34)		HCV +ve (n=76)		Total (n=110)		p-values (Pearson X^2)
	n	%	n	%	n	%	
Ever injected methadone							
Yes	17	23.6	55	76.4	72	100.0	**0.04**
No	16	43.2	21	56.8	37	100.0	
Total	**33[a]**	**30.3**	**76**	**69.7**	**109[a]**	**100.0**	
Previous imprisonment							
Yes (n=53)	11	20.8	42	79.2	53	100.0	**0.03**
No	22	40.0	33	60.0	55	100.0	
Total	**33[a]**	**30.6**	**75[a]**	**69.4**	**108[b]**	**100.0**	
MTP in prison (n=53)							
Yes	9	36.0	16	64.0	25	100.0	**0.02***
No	2	7.1	26	92.9	28	100.0	
Total	**11**	**20.8**	**42**	**79.2**	**53**	**100.0**	
Injected in prison (n=53)							
Yes	3	21.4	11	78.6	14	100.0	1.00*
No	8	20.5	31	79.5	39	100.0	
Total	**11**	**20.8**	**42**	**79.2**	**53**	**100.0**	
Tattooed in prison (n=53)							
Yes	1	8.3	11	91.7	12	100.0	0.42*
No	10	24.4	31	75.6	41	100.0	
Total	**11**	**20.8**	**42**	**79.2**	**53**	**100.0**	
Programme area (urban or rural)							
Urban (ACT)	21	36.8	36	63.2	57	100.0	0.16
Rural (SNSW)	13	24.5	40	75.5	53	100.0	
Total	**34**	**30.9**	**76**	**69.1**	**110**	**100.0**	
Living with someone who injects drugs (n=94)							
Yes	7	33.3	14	66.7	21	100.0	0.73
No	20	29.4	48	70.6	68	100.0	
Total	**27**	**100.0**	**62**	**100.0**	**89[c]**	**100.0**	
Routine takeaways							
Yes	22	35.5	40	64.5	62	100.0	0.24
No	12	25.0	36	75.0	48	100.0	
Total	**34**	**30.9**	**76**	**69.1**	**110**	**100.0**	
Case manager							
Yes	16	28.1	41	71.9	57	100.0	0.50
No	18	34.0	35	66.0	53	100.0	
Total	**34**	**100.0**	**76**	**100.0**	**110**	**100.0**	

** Fishers exact test, [a] one missing value, [b] two missing values, [c] five missing values*

Previous and current risk factors, and relevant current methadone treatment programme characteristics established as being significantly associated with HCV serological status in the univariate analyses were; having injected methadone, previous incarceration, and methadone treatment in prison. HCV prevalence was significantly higher amongst individuals who had ever injected methadone and were previously imprisoned (ever injected methadone: p=0.04, previously imprisoned: p=0.03). Methadone treatment in prison was significantly associated with lower HCV prevalence (p=0.02). Interestingly, having injected or being tattooed in prison was not significantly associated with HCV serological status. Programme area, living with someone who injected drugs, access to routine TAs and having a case manager were also not significantly associated with HCV serological status ($p<0.05$).

Factors found to be significantly associated with HCV serological status in the univariate analyses were entered into a multiple regression model. Table 7.9c (next page) presents the results of this analysis and the final combination of factors significantly associated with HCV serological status. This analysis had a sample size of n=53, as it only included people who had been in prison. Of the five factors entered in the multiple regression model, one factor was dropped due to collinearity (previous imprisonment). Of the remaining four factors, being on methadone treatment in prison and education level remained significantly associated with HCV serological status and had a protective effect.

Table 7.9c: Factors significantly associated with HCV serological status (multivariate analysis)

Factors	All participants (N=53^)				
	n	OR	CI	p-value	LR test (p-value)
MTP in prison					
No*	28				
Yes	25	0.11	0.02-0.74	**0.02**	NA
Total	**53**				
Education level §					
< Yr10*	12				
Year 10	15	7.84^{-09}	9.98^{-10}-6.17^{-08}	**<0.001**	**0.03**
Year 12	7	8.82^{-09}	8.06^{-10}-9.64^{-08}	**<0.001**	
Tertiary	19	dropped			
Total	**53**				

*§ Mutually exclusive categories, * Reference category, ^ 5 missing values,* **Pseudo R^2 = 0.39**

Individuals who had methadone treatment in prison were 10 times less likely to be HCV sero-positive compared to those who were not on treatment (OR=0.11, CI=0.02-0.74, p=0.02). Education level as a whole factor remained significantly associated with HCV serological status (LR test: p=0.03).

Having completed Year 10 and Year 12, had a highly significant protective effect with individuals in this group less likely to be HCV sero-positive (Year 10: OR= 7.84^{-09}, CI=9.98^{-10}-6.17^{-08}, p=<0.001; Year 12: OR=8.82^{-09}, CI=8.06^{-10}-9.64^{-08}, p=<0.001).

Having ever injected methadone remained marginally significantly associated with HCV serological status. The odds of being HCV sero-positive for those who had ever injected methadone was five times greater than those who had not injected methadone (OR=5.28, CI=0.91-30.72: p=0.06).

7.6.2: Comparison of factors significantly associated with HCV self-reported status and serological status

Univariate analyses to identify significant associations of possible risk factors with HCV self-reported status were also conducted, to examine if the associations differed to those established with HCV serological status. Tables 7.10a and 7.10b present results of this analysis. Table 7.10a presents sociodemographic factor associations, while Table 7.10b, presents associations of previous and current risk factors, and relevant current methadone programme characteristics with HCV self-reported status.

Table 7.10a: Sociodemographic factors associated with HCV self-reported status (univariate analysis)

Factor	HCV –ve (n=26)		HCV +ve (n=76)		Total (n=102)		p-values (Pearson X^2)
	n	%	n	%	n	%	
Age group							
< 20	0	0.0	1	100.0	1	100.0	**0.004**
20-29 years	12	44.4	15	55.6	27	100.0	
30-39 years	13	29.5	31	70.5	44	100.0	
40 +	1	3.4	28	96.6	29	100.0	
Total	**26**	**25.7**	**75[a]**	**74.3**	**101[a]**	**100.0**	
Gender							
male	13	22.4	45	77.6	58	100.0	0.41
female	13	29.5	31	70.5	44	100.0	
Total	**26**	**25.5**	**76**	**74.5**	**102**	**100.0**	
Education level[§]							
< Yr10	6	21.4	22	78.6	28	100.0	0.69
Year 10	5	25.0	15	75.0	20	100.0	
Year 12	3	17.6	14	82.4	17	100.0	
Tertiary	11	31.4	24	68.6	35	100.0	
Total	**25[a]**	**25.0**	**75[a]**	**75.0**	**100[b]**	**100.0**	
Employment status							
unemployed	4	16.0	21	84.0	25	100.0	0.57
employed	6	33.3	12	66.7	18	100.0	
student	1	20.0	4	80.0	5	100.0	
Other (pensioners, sick leave, home duties)	15	27.8	39	72.2	54	100.0	
Total	**26**	**25.5**	**76**	**74.5**	**102**	**100.0**	
Main income in the last 6 months							
Paid employed (part time/full-time)	9	47.4	10	52.6	19	100.0	**0.02**
Other (pension, student, home duties	17	20.7	65	79.3	82	100.0	
Total	**26**	**100.0**	**75[a]**	**100.0**	**101[a]**	**100.0**	

[§] Mutually exclusive categories, [a] one missing value, [b] two missing values

Table 7.10b: Previous and current risk factors and relevant current methadone programme characteristics associated with HCV self-reported status (univariate analysis)

Factor	HCV –ve (n=26)		HCV +ve (n=76)		Total (n=102)		p-values (Pearson X^2)
	n	%	n	%	n	%	
Routine takeaways							
Yes	20	35.7	36	64.3	56	100.0	**0.009**
No	6	13.0	40	87.0	46	100.0	
Total	**26**	**25.5**	**76**	**74.5**	**102**	**100.0**	
Ever injected methadone							
Yes	16	22.5	54	77.1	70	100.0	0.51
No	9	29.0	22	71.0	31	100.0	
Total	**25[a]**	**24.8**	**76**	**75.2**	**101[a]**	**100.0**	
Previous imprisonment							
Yes (n=53)	9	17.3	43	82.7	52	100.0	0.06
No	16	33.3	32	66.7	48	100.0	
Total	**25[a]**	**25.0**	**75[a]**	**75.0**	**100[b]**	**100.0**	
MTP in prison (n=53)							
Yes	5	20.0	20	80.0	25	100.0	0.72*
No	4	14.8	23	85.2	27	100.0	
Total	**9**	**17.3**	**43**	**82.7**	**52[a]**	**100.0**	
Injected in prison (n=53)							
Yes	2	12.5	14	87.5	16	100.0	0.70*
No	7	19.4	29	80.6	36	100.0	
Total	**9**	**17.3**	**43**	**82.7**	**52[a]**	**100.0**	
Tattooed in prison (n=53)							
Yes	1	7.1	13	92.9	14	100.0	0.09*
No	9	23.1	30	76.9	39	100.0	
Total	**10**	**18.9**	**43**	**81.1**	**53**	**100.0**	
Area (urban or rural)							
Urban (ACT)	16	29.1	39	70.9	55	100.0	0.37
Rural (SNSW)	10	21.3	37	78.7	47	100.0	
Total	**26**	**25.5**	**76**	**74.5**	**102**	**100.0**	
Living with someone who injects drugs (n=94)							
Yes	4	20.0	16	80.0	20	100.0	1.00[a]
No	14	23.7	45	76.3	59	100.0	
Total	**18**	**22.8**	**61**	**77.2**	**79[c]**	**100.0**	
Case manager							
Yes	10	18.9	43	81.1	53	100.0	0.11
No	16	32.7	33	67.3	49	100.0	
Total	**26**	**25.5**	**76**	**74.5**	**102**	**100.0**	

** Fishers exact test, [a] one missing value, [b] two missing values, [c] fifteen missing values*

As can be seem from Table 7.10a the two sociodemographic factors that were significantly associated with HCV self-reported status were age group and main income source in the six months prior to interview (age group=0.0004; main income: p=0.02). Age group was also associated with HCV serological status, but main income source was not. Similar to the association with HCV serological status, HCV self-reported prevalence was statistically significantly higher in the 30-39 years and >40 year age groups (p=0.004). HCV self-reported prevalence was statistically significantly higher amongst those whose main source of income in the last six months was not through paid employment (p=0.02). Education level, although significantly associated with HCV serological status, was not associated with HCV self-reported status. Gender and employment at the time of interview were not significantly associated with HCV self-reported status. This was similar to the association found with HCV serological status.

Of previous and current risk factors, and relevant current methadone programme characteristics, only one factor was significantly associated with HCV self-reported status as presented in Table 7.10b. This factor was whether or not individuals had access to routine TAs (p=0.009). HCV self-reported prevalence was statistically significantly higher amongst those who did not have access to routine TAs. This association did not exist with HCV serological status.

Having injected and being tattooed in prison, programme area, living with someone who injected drugs and having a case manager were factors that were not significantly associated with HCV self-reported status (p>0.05). This is similar to the association found with HCV serological status. There were three other factors significantly associated with HCV serological status: previous imprisonment, having been on methadone treatment in prison and having injected methadone. Previous imprisonment was marginally significantly associated with HCV self-reported status (p=0.06). The other two factors were not.

These results suggest that risk factors associated with HCV serological status and self-reported status vary. This could affect the validity of studies conducted to identify risk factors associated with HCV status.

7.7: Summary and discussion

HCV antibody positivity amongst methadone clients in my study (69%) was within the range of that found in other Australian studies conducted amongst IDUs (65-90%) [20, 81, 82]. It was lower than that found in the Australian study amongst 178 IDUs receiving opioid replacement therapy between January 2002 and June 2003 (75%) [45]. It was also lower than the other two validity studies of HCV self-reported status conducted amongst methadone treatment clients (UK=84% and US=89%) [56, 57]. HCV positivity for rural individuals in my study (76%) was higher than that found amongst rural participants in the NSW methadone injectors study (65%) [58]. In comparison, less than one per cent in both study groups was HIV positive, which suggests that methadone continues to be effective in preventing HIV transmission. All but one participant who had serology done for HIV in my study were negative, but it was disturbing to note that some (even though numbers were small) were unsure whether they had been previously tested for HIV.

There were a few important sociodemographic characteristics, risk factors and programme related characteristics that were significantly associated with being HCV serological status. Individuals with a secondary school education (Year 10 and 12) and individuals who were on methadone treatment in prison were significantly less likely to be HCV sero-positive. Ever having injected methadone being marginally significantly associated with higher HCV sero-prevalence is an important finding for policy makers to consider. The marginality of the results may be due to a small sample size.

Validity measurements for the whole sample and for the two study groups suggested that a correct positive self-report in people with HCV was more likely than a correct negative self-report in people without HCV. This result could be a reflection of knowledge that prevalence of HCV amongst IDUs is high, rather than knowledge of actual positive status. The proportion of incorrect negative self-report was quite high and was more likely than incorrect positive self-report. Validity of self-reported status for rural people being better than for urban people (even if not statistically significant) may be a reflection of some rural programme management characteristics (such as every client being allocated a case manager and having access to their methadone prescriber on a monthly basis if they wished). Validity measurements in my study were compared to those calculated for the studies reviewed in Chapter 2 [56-58, 88, 89]. This comparison is presented in Table 7.11.

Table 7.11: Validity of HCV self-report for the studies reviewed in comparison to my study

Validity Measure	Thornton & Barry (Irish Prisoners)	Butler et al (NSW prisoners)	Loxley et al (Australian IDU)	Best et al (London MMT)	Stein et al (US MMT)	Southgate et al (Rural methadone injectors)	Isaac-Toua (Australian methadone clients)
Year of study	2000	1999	1995	1999	2001	2001	2002
N	304	738	599	74	149	38	94
Method of testing	Salivary antibody	Serum antibody (venous blood)	Serum antibody (venous blood)	Serum antibody (venous blood)	Serum antibody (venous blood)	Serum antibody (capillary blood)	Serum antibody (capillary blood)
Sensitivity (CI)*	89% (84-92)	65% (60-71)	80% (76-84)	80% (77-94)	77% (69-84)	60 % (39-78)	87% (76-94)
Specificity (CI)	81% (68-90)	Not calculable	89% (84-93)	100% (60-100)	88% (62-98)	54% (26-80)	59% (39-78)
Positive Predictive Value (CI)	95% (91-98)	Not calculable	92% (89-95)	100% (92-100)	98% (93-100)	71% (48-88)	84% (73-92)
Negative Predictive Value (CI)	63% (51-73)	Not calculable	74% (68-79)	50% (26-75)	33% (20-49)	41% (19-67)	64% (43-82)
Positive Likelihood Ratio (CI)	4.70 (2.13-7.22)	Not calculable	7.43 (4.60-10.27)	Not calculable	6.57 (-2.18-15.32)	1.30 (0.4-2.19)	2.12 (1.34-3.38)
Negative Likelihood Ratio (CI)	0.13 (0.09-0.19)	Not calculable	0.22 (0.18-0.27)	0.12 (0.04-0.20)	0.26 (0.16-0.35)	0.74 (0.22-1.27)	0.23 (0.11-0.45)

* *Confidence Intervals*

Validity of positive self-report in my study was relatively high and compared well with the first five studies reviewed in general. It was very comparable to the two studies amongst methadone clients in the US and UK, and higher than that of the rural methadone injectors study. Validity of negative self-reports in my study was relatively low and validity results were comparable to the NSW rural methadone injectors study.

The sensitivity and PPVs were greater than 75 per cent in my study and in four of the six studies reviewed [56, 57, 89, 90]. The NSW prisoners and rural methadone injectors' studies had values lower than this. Results from my study and reviewed studies where sensitivity was greater than 75 per cent, suggest that people who were actually HCV positive are more likely to report their status correctly. However, this still leaves 10-40 per cent of a high risk population for HCV unaware of their correct positive status. The low validity of positive self-report in the NSW prison study and rural methadone injectors study also raises some doubt as to the robustness of positive self-report [58, 88]. Whether the low values are just an artefact of those particular studies or whether they are a true reflection of the validity of positive self-report can only be determined by further research. It is difficult to compare the PLRs, as these were not calculable for two of the studies. From results where they were calculable, the PLRs were higher in the studies that had higher sensitivity. This suggested that the likelihood of correctly self-reporting a positive status while actually positive as compared to when actually negative is quite high. The PLR in my study was more comparable to that of the NSW rural methadone injectors study. These results suggest that validity of positive HCV self-reported status is relatively good, but due to lower validity in some studies, it should be investigated further.

There was a small proportion of people in my study who reported their positive status incorrectly (reported positive while serologically negative). It is highly unlikely that a person who was serologically positive could test negative the next time. Serological tests to establish HCV status are conducted through identifying antibodies against the virus. Twenty five per cent of persons exposed may clear the virus, but antibodies still remain in the system [17]. Thus conversion from a positive HCV antibody test to a negative one is highly unlikely. These people, who are actually negative but think they are positive, may face unnecessary stigmatisation and discrimination in society due to inaccurate knowledge of status.

Results from testing validity of negative HCV self-reported status in my study and for the six studies reviewed suggested that it was poor. The NPVs were low for all studies and particularly so for the two methadone treatment programme studies in the US and the UK [56, 57]. These results were comparable to my study. The NLR for four of five the studies where it was calculable were also comparable to my study [56, 57, 89, 90]. The NLR for the rural methadone injectors study was much greater in comparison. It indicated that the likelihood of a negative self-report in persons who were HCV positive in comparison to those who were HCV negative was approximately three in four (0.74) as compared to one in four (0.23) in my study. Although, the specificity for four of five studies reviewed where it was calculable was greater than 80 per cent, the specificity for the rural methadone injectors study and my study were lower than 60 per cent. The low NPVs and the relatively high NLRs in all studies (particularly the rural methadone injectors' study) suggest that negative HCV self-reported status is not a good indicator of a truly negative status. This may relate in part to the high HCV incidence amongst IDU and testing intervals being longer than the window period for seroconversion. The lower specificity in my study and the NSW rural injectors study suggested that validity of negative self-reports in these studies were poorer than the other five studies.

Since the commencement of my PhD in 2000 and data collection in 2002, there were two more studies conducted in the US investigating the accuracy of HCV self-reported status amongst IDUs [206, 207]. The first study by Schlicting and colleagues was conducted in 2003, amongst 653 IDUs who were part of a project designed to evaluate the effectiveness of a needle exchange programme in decreasing BBVs. The researchers used similar methodology to my study and tested the validity of self-reported HCV status, by calculating the sensitivity and specificity of self-report against serology (as the gold standard) [206]. They also calculated the validity of HAV and HBV self-reported status. Of the 653 participants, 558 had serology for HCV. Of these, 74 individuals self-reported as being HCV positive (13%), but serology found 293 individuals to be positive (53%). The sensitivity of HCV self-report was reported as 24 per cent, while specificity was reported at 98 per cent. The sensitivity from this study was much lower than my study and the other six studies reviewed. The specificity was much higher than my study but within the range of that found in the other studies.

The second study was conducted in 2005 by Weaver and colleagues, and assessed prevalence of HCV self-report versus serology amongst 276 methadone treatment clients in a clinic in Richmond, Virginia [207]. A self-administered questionnaire was used to gather information regarding HCV self-reported status, knowledge about risk factors for transmission, treatment options, and interest in receiving more information. Of the 276 clients in the clinic, 200 completed the questionnaire and provided a self-reported status for HCV. The self-reported prevalence of HCV was found to be 34 per cent. When a chart review of serological status was done for all 276 clinic clients at the clinic, it was found that HCV prevalence was 70 per cent. These results need to be interpreted with caution as self-reported status for 76 clients was not available and hence not included in calculation of self-reported HCV prevalence (as they had not participated). They were, however, included in the estimates of HCV serological prevalence. Actual numbers of participants who reported their status correctly (positive or negative) were not presented in published findings. Thus, validity of self-reported status (sensitivity and specificity) could not be calculated. As the findings from this study are not comparable to mine, they will not be considered in my conclusions and recommendations.

Results from my study suggest that validity could be affected by the duration between last serological tests and provision of self-reports in my study. This may particularly have affected validity of negative self-reports as seroconversion may have occurred since the last serological test. The mean time since last serological test to provision of incorrect negative self-reports was greater than the mean time of two months required for seroconversion. This, however, cannot be taken to be the conclusive reason for poor validity of negative HCV self-report. Even if this were the case, it implies that there may not be sufficient knowledge or awareness on the part of the individual to have practiced safe injecting behaviour or to seek another test when a risk exposure occurred.

The validity of rural participants HCV self-report being greater than that of urban (even if not significantly different), may also be associated with mean time since the last serological test. Results suggest that rural participants had shorter mean times than their urban counterparts since their last serological test.

The comparison of significant associations of risk factors related to HCV serological status and self-reported status showed that different risk factors emerged as being significantly associated with HCV status. This is an important issue and needs to be examined further as many studies use self-reported status to identify risk factors associated with HCV.

7.8: Conclusion

My research investigating the validity of HCV self-reported status has indicated that validity of self-report is poor amongst IDUs, who are a high-risk group for HCV transmission. The results supported limited findings from previous studies and need to be investigated more conclusively.

For individuals in my study it appeared that duration between last serological test and provision of self-report may be related to validity of self-reported status. This indicates the need for better testing criteria and education strategies to seek testing when appropriate. It would be useful to investigate reasons for inaccurate knowledge of HCV status to enable development of targeted strategies to improve validity. Very little is also known about whether or not validity of self-reported status influences risk behaviour and further research towards this may be warranted.

It was reassuring that HIV seroprevalence was almost zero and that validity for both positive and negative self-reports was close to 100 per cent. This indicated a very accurate knowledge of status amongst people in my study. The applicability and adaptability of HIV education strategies to improve knowledge about HCV could be reviewed and considered.

Chapter 8

Major findings, policy implications and recommendations

In this chapter I bring together the results of my study to draw out possible policy and service delivery implications for urban and rural methadone treatment programmes and for improving knowledge of HCV status amongst IDUs. A major strength of this study is the use of primary data collected from urban and rural methadone clients.

8.1: Background

Research from overseas and Australia has shown that rural populations can have poorer general health outcomes due to access, cost, and confidentiality issues associated with health service provision and delivery (as discussed in Chapters 1 & 2). There has been limited research comparing outcomes for urban and rural people on methadone treatment and whether differences in urban and rural health service provision can affect the outcomes. Two recent studies have shown that rural IDUs and entrants to methadone treatment have greater injecting risks and poorer access to harm minimisation services [67, 141]. This could impact on outcomes for urban and rural people on methadone treatment. Literature reviewed suggests that there has been limited evaluation of outcomes of methadone treatment policy and service delivery (as opposed to effectiveness of methadone treatment) and basically no research at all to compare urban and rural outcomes.

Reviewing the history, development and the delivery of methadone treatment in Australia revealed that programmes can be subject to jurisdictional differences. Health service structure in Australia comprises of the Commonwealth and State health systems, with policy development being the responsibility of the Commonwealth Government and service delivery being the responsibility of State and Territory Governments. Based on this structure, there are policy structures and guidelines in place to ensure that the philosophy and goals of methadone treatment are met by all programmes; however, level of service provision and delivery can differ between jurisdictions. This has both advantages and disadvantages. As an advantage, methadone treatment provision and delivery can be tailored according to individual and community needs within urban and rural areas. As a disadvantage, methadone programmes may be given lower priority in areas where resources are stretched.

Transmission of HCV amongst IDUs in Australia continues to occur even with availability of harm minimisation services (as discussed in Chapter 1 and 2). Previous available research amongst at-risk groups (such as IDUs, prisoners and methadone treatment clients) suggests that knowledge of HCV status was poor (as discussed in Chapter 2 and 7). This lack of accurate knowledge may affect HCV transmission risk and treatment seeking behaviour amongst IDUs and research that uses HCV self-reported status as an indicator of HCV status.

For these reasons, I aimed to compare health outcomes and BBV risks due to injecting for urban and rural people on methadone treatment to determine if they differed. I also aimed to identify the factors influencing these outcomes and whether they were associated with programme policy and service delivery within the areas. Validity of HCV self-reported status for urban and rural IDUs was also examined.

8.2: Major findings, policy implications and recommendations

Results from my study indicated that there were differences in policy and service delivery of methadone treatment in the ACT and SNSW. These differences may have influenced health outcomes and BBV risk due to injecting for urban and rural individuals in my study. Validity of HCV self-reported status was also found to be poor. Results suggested that it was better for rural IDUs in comparison to their urban counterparts. In the following sections, I summarise the major findings, discuss possible policy implications and put forward some recommendations.

8.2.1: Programme management and service delivery differences between urban and rural study groups and implications for policy

Evaluation and comparison of the urban and rural methadone programmes in my study indicated that the programmes within the two areas reflected the policy and service delivery arrangements of the Australian health structure. Both programmes used the four guiding principles (availability, access, acceptability, and quality of care) outlined in the National Policy on Methadone Treatment as the basis for treatment provision [13]. In terms of availability both programmes had a combination of public and private services. The services included medical assessment on entry to the programme and access to regular reviews. Both programmes catered for treatment of clients on different tiers of the programme, and in general seemed to be acceptable to clients. There appeared to be an accepted level of quality of care in relation to provision of information and ensuring client confidentiality.

Results in Chapter 4 indicated that urban and rural individuals did not differ in relation to individual characteristics such as sociodemographics, previous drug use, BBV risk factors and previous methadone treatment history. Study groups differed, however, in relation to aspects of service provision and delivery. This may have contributed to differing levels of availability and access, and may have influenced acceptability and quality of care within the two programmes. These differences may have also affected health and BBV risk outcomes for individuals in the two areas.

Differences between programme policy and service delivery affecting availability and access for the two study groups were reflected in differences in costs associated with treatment and access to support services within the programmes. For example, provision of private methadone treatment services (Tier 3) for the two programmes differed. Tier 3 rural clients had to negotiate these services directly with GP prescribers rather than being registered through the Area programme, unlike Tier 3 urban clients. This difference had implications for Tier 3 rural clients in relation to cost of GP prescriber appointments and access to support services (such as case managers and counselling), which were organised through the programme for Tier 1 and Tier 2 clients. Tier 1 and Tier 2 rural clients were also bulk-billed through the Medicare system for their medical care and had routine access to case managers.

Programme policy in relation to access to dosing facilities was also different for urban and rural study groups. For urban clients who dosed through the public system (Tier 1) there was only one public dosing centre available in the ACT. Urban clients who had to travel for longer than one hour to dose being significantly more likely to inject was possibly related to this. For rural clients, although there were eight public dosing centres to cater for wider population spread; seven of the eight were based in CHCs. This may have compromised confidentiality of clients which was reflected in smaller proportions of rural participants stating that they perceived their confidentiality was maintained. Poorer availability of services may have been a reason for rural clients being significantly more likely to pay more than $5.00 for travel expenses to dose. The increased cost of travel may also be associated with poorer confidentiality reflected in clients travelling to dosing centres further away where they would be anonymous to the local community. Cost of methadone was also significantly different for urban and rural clients who dosed privately through community pharmacies (Tier 2 and Tier 3). Most rural clients paid greater than $15.00.

Some policy and service delivery differences were in favour of rural clients (e.g. case managers for all Tier 1 and 2 clients), while others were in favour of urban clients (e.g. TA for clients in all Tiers). All Tier 1 and 2 rural clients had access to case managers, whilst only urban clients with complicated treatment needs had access to case managers. Rural clients in Tier 1 and Tier 2 also had the option to see their prescribers at shorter intervals if they wished, as prescriber appointments were available at monthly intervals as opposed to three monthly for urban clients. Even though not statistically significant, these differences may have resulted in a higher proportion of rural clients achieving the outcomes against the reasons for which they had accessed their current programme, and having greater validity of HCV self-reports as compared to urban clients.

A programme policy in favour of urban clients was that clients in all tiers had access to TAs dependent on their stability. In comparison, only rural clients in Tier 2 and 3 had access to TAs; clients in Tier 1 did not have access to any TAs regardless of stability. This may have been associated with rural individuals using a greater number of other drugs and injecting more frequently (in the month prior to interview) being significantly more likely to have poorer health outcomes and increased BBV risk respectively.

The two study groups also differed significantly in relation to reasons for accessing the programme and referral sources. Based on these reasons, urban and rural programmes could identify treatment needs of their IDU populations and tailor their programmes accordingly. Programmes should also be flexible to adapt to changing needs, which should be reviewed periodically. The differences also suggest the need for individual goal setting and case management within programmes to maximise outcomes for the individual client as well as the programme.

Overall, only 39 per cent of individuals in my study stated they were immunised against HBV, with rural people significantly less likely to have been immunised than urban clients ($p=0.01$). This could be a reflection of poorer access to these services in rural areas. The NHMRC has identified IDUs as a high risk group for HBV immunisation, but these results suggest that this service is not being delivered through either programme. Methadone treatment programmes need to consider routine provision of HBV vaccination to clients to minimise transmission and to decrease the risk of co-morbidities with HCV.

Results from my study suggest that programme policy and service delivery differed between the urban and rural study group. This may have impacted on availability access, acceptability and quality of care for urban and rural individuals in these programmes. These differences could influence outcomes of methadone treatment differently for urban and rural individuals. Based on these findings, I put forward my first two recommendations for Australian methadone programme policy makers.

Recommendation 1:
Methadone programmes should regularly evaluate needs of urban and rural clients to assist with relevant policy development and service delivery. This should be done to maximise the outcomes achieved for people on methadone.

Recommendation 2:
HBV immunisation strategies for IDUs should be reviewed (particularly for rural IDUs). Methadone treatment programmes should consider providing HBV vaccination to all clients as part of the treatment programme.

8.2.2: Comparison of health and BBV risk outcomes for urban and rural study groups and implications for programme policy

There was no significant difference between urban and rural study groups in relation to the magnitude of health outcomes while on their current methadone programme as measured by the OTI. However, the factors influencing health outcomes for the two areas differed. For urban clients they were related to programme policy (paying for methadone and having a case manager). For rural clients, factors included a combination of individual characteristics (being female), possible access issues (reflected in the greater number of other drugs used) and service delivery issues (lack of satisfaction with their programme). It would be useful for urban and rural programmes to take these differences into account in planning and policy development to maximise benefits at the individual client level and to enhance overall effectiveness of their respective programmes.

A little over 50 per cent of participants had injected while on the programme in the month prior to interview. The proportions of injectors in the urban and rural study groups were similar. This result supports findings from other studies and is of concern, as one of the main objectives of methadone treatment is to prevent injecting and risks associated with it. Factors significantly associated with injecting while on treatment in the two study groups were similar and included the number of drugs used in the month prior to interview, living with someone who injected drugs and having employment as the main source of income in the six months prior to interview. These factors are external to the programme and mainly related to individual client characteristics and risk practices, and cannot be influenced by programme policy. However, they should be considered as possible risk factors when clients enrol into the programme and taken into account during management and review. As the risk factors were the same for urban and rural individuals they should be considered for all methadone treatment clients.

Overall for those who injected, there was no difference between the proportions of participants who injected with and without a BBV risk; this was similar for urban and rural study groups. The two study groups also did not differ in the magnitude of BBV risk due to injecting (as measured by the BBV TraQ injecting risk score).

Factors influencing injecting with a BBV risk were similar for both study groups and were mainly related to programme policy (lower number of TAs per week, greater number of missed doses per week and lower daily methadone dose). There were a few external factors to the programme and these included frequency of injecting and younger age. Interestingly, rural clients were significantly more likely to inject with a BBV risk, even though being rural was not in itself significantly associated with injecting.

Factors associated with injecting with a BBV risk should be considered specifically within rural programmes as rural clients were significantly more likely to be affected. These factors although associated with policy could also be affected by individual circumstances; for example distance from dosing centre and dosing centre times would affect the number of doses missed and frequency of injecting. As increased risk could be due to a combination of policy and individual circumstances, programmes could consider a multi pronged approach to reduce BBV risk due to injecting for clients. This could include reviewing and adapting policy according to client needs (e.g. tailoring dosing times to miss fewer doses, flexibility with TAs according to immediate circumstances), as well as targeted education to assist individuals in managing risk factors at the time of enrolment and while on treatment. Once again individual case management for all clients could assist in identifying circumstantial needs, which in turn would minimise BBV risk and achieve better outcomes from methadone treatment.

BBV risk associated with sexual practice almost equally contributed to Total BBV risk as risk associated with injecting practice. This finding has implications for methadone programme policy and delivery, particularly for HIV and HBV, where sexual transmission is important. Methadone treatment programmes could consider amore holistic approach to include management of sexual behaviour risk amongst clients. Some sexual and reproductive health components such as education and support for minimising sexually transmitted infections, and information and access to contraception could be incorporated into programmes.

The findings from my study indicate that health and BBV risk outcomes from methadone treatment for urban and rural people can be affected by programme policy and service delivery, as well as individual characteristics and risk behaviours. Programmes may thus need to consider a combination of strategies to improve outcomes. This could include tailoring policy and service delivery according to identified area needs and taking into account individual risk factors.

Based on these findings, I put forward my third, fourth and fifth recommendations for Australian methadone programme policy makers. These recommendations should be considered in conjunction with my first recommendation, which will assist in identifying programme needs to allow for appropriate policy development and service delivery.

Recommendation 3:
As there was a combination of policy-related and external factors associated with health and BBV risk outcomes an holistic approach to managing clients receiving methadone treatment should be considered. Holistic care could be supported by allocating case managers for individual clients to assist with identification of needs and risk factors, and goal setting. Continuing case management will assist in identifying circumstantial needs, reviewing progress against goals, and providing support for reintegration into the general community.

Recommendation 4:
Methadone treatment programmes should consider a more flexible approach to Takeaway Dose policies and dosing times to accommodate for individual clients' circumstantial needs to minimise risk taking behaviour associated with access issues.

Recommendation 5:
Methadone treatment programmes should incorporate education and harm minimisation strategies aimed at decreasing sexual transmission of HIV and HBV.

8.2.3: Validity of HCV self-reported status and policy implications

Validity of HCV self-reported status in comparison to serological status in my study was found to be poor. Overall, the validity of positive HCV self-report was relatively better than the validity of negative self-report. In comparison, HIV validity was close to 100 per cent. This could be an indication of the enormous effort put into education campaigns in the 1980s in Australia, which included promoting harm minimisation strategies and awareness of the serious consequences associated with HIV and AIDS (including the shorter life expectancy and high mortality).

Results from my study in relation to accuracy of HCV self-reported status supported findings from the five studies conducted prior to my study [56, 57, 89, 90, 195], and the more recent study by Schlicting and colleagues [206]. Although the sampling population, sample size and sampling strategy in these studies and my study were different, participants in the studies were all at high-risk for transmission of HCV. A common theme emerging from the findings in these studies and my study was the poor validity of negative HCV self-reported status. Although validity of positive self-reported status appeared to be better, there were between 10-40 per cent of participants in these studies who had an incorrect self-report. These results suggest that IDUs who are at most risk of being infected with HCV are poorly informed of their actual status.

Results suggested that time between last serological test and provision of self-report may be associated with validity of HCV self-report. Longer mean time periods since last serological testing were noted for participants who provided incorrect positive self-reports. The mean time period since last serological test and provision of incorrect negative self-reports was greater than the mean period for seroconversion, suggesting that these participants had seroconverted since their last test. These results support the need for more frequent HCV testing and education about risk exposure.

Validity of self-report amongst rural individuals in my study appeared to be greater than that of urban individuals. This finding may be related to HCV education and testing policies in the rural programme. The mean time between last serological test and provision of self-report in my study was shorter for rural individuals than for their urban counterparts. This finding could be investigated further towards determining reasons for better validity.

With the growing epidemic of HCV and HCV related liver disease amongst injecting drug users, and the lack of success of harm minimisation services such as NSPs in decreasing incidence in Australia it is important for IDUs to have accurate knowledge of their status [24, 53, 54]. As discussed, lack of accurate knowledge of HCV status may affect injecting practices, treatment seeking behaviour and quality of life for IDUs. As validity of HCV self-report was particularly low amongst the two studies conducted in Australian methadone programmes (my study and NSW rural methadone injectors study), it is important for Australian methadone treatment programmes to review their education and testing strategies in relation to HCV.

Hallinan and colleagues have recently suggested an integrated model of care within opioid replacement therapy services to decrease HCV incidence and increase treatment uptake. This model includes the provision of HCV-specific harm reduction strategies, regular HCV testing, clinical assessment and determination of need for HCV treatment referral [47]. Methadone treatment programmes would be well placed to establish this integrated model as clients access the service on a regular basis and there are full-time clinical practitioners on-site who could provide regular education, testing and assessment.

Reasons for inaccurate knowledge of HCV status were not investigated in any of the studies that examined accuracy of HCV self-report. There were some possible reasons cited, and these included:

- people not being informed of their status,
- not knowing the meaning of their result,
- confusion with other hepatitis viruses,
- denial,
- fear of reporting correct status in case they are discriminated against [206, 207].

Further research may be warranted into investigating reasons for levels of HCV status knowledge amongst at-risk groups and whether knowledge of status influences BBV risk behaviour and seeking treatment. It may be useful to conduct this study specifically amongst IDUs not on treatment as they are more likely to practise risk behaviours in comparison to IDUs on treatment. This study amongst methadone treatment clients may actually be overestimating validity as being on a treatment programme may mean better access to information and testing.

It may also be useful to further compare HCV self-report validity and its association with information provision and testing policies between programmes, as results from my study suggest that clients on programmes with better support services have better validity (i.e. rural study groups had better validity which could be related to all participants having case managers). This could be extended to comparison with HCV testing and management policies in other countries. The study amongst US methadone clients reviewed suggests better validity of HCV self-reported status [56], and reasons for this could be explored.

Factors that were significantly associated with being HCV positive for all participants in my study (as measured by serology) were being older, having a tertiary education, having injected methadone, previous incarceration and not being on a prison methadone programme. These findings are relevant for all methadone service treatment programmes to minimise HCV transmission and could be addressed through targeted education for the at-risk populations. A seamless transition for treatment between prison and community programmes may also assist.
Factors significantly associated with HCV self-reported status differed to those associated with HCV serological status. This finding suggests that the use of HCV self-reported status as an indicator of HCV status in research may be inappropriate.

Based on these findings, I put forward my sixth and seventh recommendations. These recommendations are aimed at improving accuracy of knowledge on HCV status and risk exposures to have an impact on HCV transmission and treatment uptake.

Recommendation 6:
The poor validity of HCV self-reported status and the high prevalence of HCV amongst study participants indicate a need for methadone treatment services to promote and support HCV education and prevention strategies and testing processes within programmes. Consideration should also be given to providing support to individuals to enable them to access HCV treatment services.

Recommendation 7:
Further studies should be conducted to determine reasons for poor validity of HCV self-reported status and whether it influences risk taking behaviour. This will assist in developing targeted strategies to improve knowledge, minimise risk behaviours and increase uptake of treatment for HCV.

8.3: Relevance of methods used for future AOD research

I designed a random sampling strategy to minimise selection bias and to ensure representativeness of urban and rural methadone treatment client populations in the study. This was done with the aim of increasing generalisability of results to other urban and rural methadone treatment programmes. Although every effort was made to maintain random selection of participants into the study, due to logistic issues within programmes, unreliability of clients to keep appointments and the design of the sampling strategy to ensure continuing recruitment, proper randomisation was not achieved. This highlights the difficulties in using methods to increase representativeness of samples in AOD research, which are mainly associated with difficulty in accessing clients and unreliability of clients in keeping appointments. Logistic issues that contributed to not being able to randomise and recruit sufficient numbers included the lack of sufficient client numbers on the programmes and the quick turnover of ACT programme co-ordinators.

A major issue in AOD research is that participants are asked about illegal behaviours that may affect outcomes (e.g. use of licit and illicit drugs, crime, and income through illegal sources). Due to anxiety of being identified and repercussions associated with admitting to illegal behaviours, participants may sometimes not provide accurate information. The use of de-identified databases and gaining verbal consent without identification of participants in my study may have assisted with decreasing inaccurate responses and increasing validity of results.

Aspects of the study design also assisted in fulfilling Ethics Committee requirements. Obtaining verbal consent with a witness present rather then signed consent fulfilled the three HRECs requirement of gaining informed consent but not retaining any identifying details of participants. The use of a cross-sectional study design further assisted with accommodating this requirement. Information was collected at one point in time with no client follow-up required and thus there was no need to retain identifying details of clients for future contact.

Cohort studies are the ideal study design to establish causality and a temporal relationship [79]. Most AOD research, however, uses convenience samples due to recruitment and identification issues and difficulty in following up participants for the required time frame. Many people who take part in AOD research are very mobile and change contact details often as seen in my study. Using convenience samples can lead to selection bias and decreased generalisability of research results. A cohort study would be the most effective study design as a follow-up to my study. It would be able to establish causality of significant factors influencing outcomes in urban and rural methadone treatment clients, and reasons for poor validity of HCV self-reported status. However, it may be difficult to conduct for reasons stated.

The instruments (OTI and BBV TraQ) used to measure health and BBV risk outcomes in this study were validated tools designed specifically to measure the outcomes of interest. A descriptive comparison of the two questionnaires found that they defined and measured BBV risk differently and the study population criteria for the questionnaires differed. The comparison suggested that the BBV TraQ is a more robust tool to measure BBV risk due to injecting as it only measures risk when it actually occurs and includes measurement of protective practises to minimise the risk. It does not include the physical act of injecting as a BBV risk, while the OTI does. The two questionnaires can be used in conjunction with each other in relation to investigating harm from injecting drugs as undertaken in my study, as the process should include both the physical act of injecting and associated BBV risk.

8.4: Limitations of the study

The study may not be completely representative of urban and rural methadone clients' health and BBV risk outcomes as random sampling was not achieved to its fullest. However, 13 per cent of the targeted study population was recruited into the study (10% ACT methadone clients and 23% SNSW methadone clients). This proportion should provide a reasonable representation of the overall Australian methadone treatment programme population. Not being able to recruit sufficient numbers into the study may have decreased the power of the study to be able to pick up significant differences in outcomes for study groups.

Although a cross-sectional study design may have assisted with greater validity of results by not having to identify clients, it only assisted with generating hypotheses in relation to differences in urban and rural health and BBV risk outcomes and factors affecting these outcomes. Furthermore, the study design was only able to measure validity of HCV self-reported status at one point in time for a sample population but was unable to establish reasons for poor validity. Validity of HCV self-report in my study may actually be overestimated, as participants being on a treatment programme may have been better informed of their status due to having better access to information and testing.

Another probable limitation is that the data for the study was collected five years ago. Needs of clients within urban and rural programmes and factors affecting outcomes may have changed. There have also been more recent studies conducted in relation to validity of HCV self-reported status; however, findings from these studies are supportive of the findings in my study.

Despite these limitations, results from my study indicate that there are differences in urban and rural methadone treatment client outcomes that need to be considered in programme policy and service delivery. The findings can be used as a baseline to inform programme planning as well as further studies for evaluating outcomes related to urban and rural programmes. The results also support the need to investigate the validity of HCV self-report further and the reasons for it, which may assist with decreasing current rates of HCV transmission.

8.5: Generalisability of study results

Some results from my study in relation to individual client characteristics associated with health and BBV risk outcomes may be generalisable to other urban and rural methadone clients in Australia. This is because the two study groups were socio-demographically similar to clients on other Australian AOD services as seen in the 1998, 2001 and 2004 surveys [4-6]. Other results in relation to policy and service delivery are not generalisable as they are specific to the programme areas in this study.

8.6: Conclusions

In conclusion, there were no significant differences ($p>0.05$) in relation to magnitude of outcomes for health and BBV risk due to injecting for urban and rural clients methadone treatment in my study. The factors that significantly contributed ($p<0.05$) to poorer health outcomes within the urban and rural programmes differed and were related to policy within programmes. These factors should be considered within urban and rural programme policy and service delivery to assist with improving health outcomes. Factors that significantly contributed ($p<0.05$) to increased BBV risk due to injecting were similar for the two study groups and were related to individual client characteristics. These factors would be better addressed on an individual client level within all methadone programmes.

Although the two study groups differed in relation to some outcomes, an interesting finding was that the two study groups were in fact very similar in relation to many socio-demographic characteristics, programme related characteristics and risk taking behaviours. There were several instances where results were not significant but showed trends towards significance and this may have been due to the small sample size. It would be useful to consider a similar study on a larger scale to further help address the question of whether or not outcomes for urban and rural methadone clients are significantly different or in fact very similar.

Validity of HCV self-reported status as elicited in this study suggests that it is poor and more research in specific high-risk populations may be warranted. The findings indicate a need for harm minimisation and treatment programmes to develop better education and testing strategies to improve knowledge of HCV status amongst high risk groups. This may assist with decreasing transmission and enhancing treatment seeking behaviours. It is also important for policy makers and service providers to take into account significant client characteristics and risk factors associated with HCV status in the development of strategies to minimise and prevent HCV transmission.

The findings from my research conducted for this PhD suggests that methadone treatment policy and delivery can affect outcomes for clients. It supports the need for regular evaluation of programmes to assist with development of policy to provide services as needed and as appropriate. By examining the validity of HCV self-reported status, the research has also provided further information about the accuracy of knowledge of HCV status in a high risk population.

By conducting this research, I consider that I have been able to provide valuable input into health and BBV risk outcomes related to urban and rural methadone treatment programmes. The study has generated findings that have important implications for harm minimisation programmes in relation to HCV transmission.

Initial findings have been disseminated to the ACT and SNSW methadone programmes and final recommendations will also be disseminated in the hope of improving outcomes for urban and rural people on methadone treatment.

References

1. Hall, W.D., L.J. Degenhardt, and M.T. Lynskey, *Opioid overdose mortality in Australia, 1964-1997: birth-cohort trends.* Med J Aust, 1999. **171**(1): p. 34-7.
2. Coopers and Lybrand, *Review of Methadone Treatment in Australia.* 1995, Commonwealth Department of Human Services and Health: Canberra.
3. Hall, W.D., et al., *How many dependent heroin users are there in Australia?* Med J Aust, 2000. **173**(10): p. 528-31.
4. Ministerial Council on Drug Strategy, *National Drug Strategic Framework 1998-99 to 2002-03: Building Partnerships.* 1998, Commonwealth of Australia: Canberra.
5. Ministerial Council on Drug Strategy, *The National Drug Strategy: Australia's Integrated Framework 2004-2009.* 2004, Commonwealth of Australia: Canberra.
6. Australian Institute of Health and Welfare, *2004 National Drug Strategy Household Survey: First Results. AIHW cat. no. PHE 57.* 2006: AIHW (Drug Statistics Series No. 13), Canberra.
7. Wodak, A., *Injecting nation: achieving control of hepatitis C in Australia.* Drug Alcohol Rev, 1997. **16**(3): p. 275-84.
8. National Drug and Alcohol Research Centre, *Opioid Overdose Deaths in Australia: 2004 Edition.* 2004, National Drug and Alcohol Research Centre: Sydney.
9. Degenhardt, L., et al., *Effects of a sustained heroin shortage in three Australian States.* Addiction, 2005. **100**(7): p. 908-20.
10. Drucker, E., *AIDS and addiction in New York City.* Am J Drug Alcohol Abuse, 1986. **12**(1-2): p. 165-81.
11. Collins, D. and H. Lapsley, *The Social Costs of Drug Abuse in Australia in 1988 and 1992, Monograph Series No 30.* 1996, Commonwealth Department of Health and Ageing: Canberra.
12. Collins, D. and H. Lapsley, *Counting the cost: estimates of the social costs of drug abuse in Australia in 1998-99, Monograph Series 49.* 2002, Commonwealth Department of Health and Ageing: Canberra.
13. National Drug Strategy, *National Policy on Methadone Treatment.* 1998, Commonwealth Department of Health and Family Services: Canberra.
14. Chetwynd, J., et al., *Hepatitis C seroprevalence amongst injecting drug users attending a methadone programme.* N Z Med J, 1995. **108**(1007): p. 364-6.
15. Fitzgerald, M., et al., *Blood-borne infections in Dublin's opiate users.* Ir J Med Sci, 2001. **170**(1): p. 32-4.
16. Rotily, M., et al., *HIV testing, HIV infection and associated risk factors among inmates in south-eastern French prisons.* Aids, 1994. **8**(9): p. 1341-4.
17. Australian Government, *National Hepatitis C strategy 2005 to 2008.* 2005, Department of Health and Ageing: Canberra.
18. Friedland, G.H. and R.S. Klein, *Transmission of the human immunodeficiency virus: an updated review.* Int Nurs Rev, 1988. **35**(2): p. 44-52, 54.
19. Maddrey, W.C., *Hepatitis B: an important public health issue.* J Med Virol, 2000. **61**(3): p. 362-6.
20. Liddle, C., *Hepatitis C.* Anaesth Intensive Care, 1996. **24**(2): p. 180-3.
21. Rooney, G. and R.J. Gilson, *Sexual transmission of hepatitis C virus infection.* Sex Transm Infect, 1998. **74**(6): p. 399-404.
22. Longshore, D., R.N. Bluthenthal, and M.D. Stein, *Needle exchange program attendance and injection risk in Providence, Rhode Island.* AIDS Educ Prev, 2001. **13**(1): p. 78-90.

23. Shapatava, E., et al., *Risk behaviors and HIV, hepatitis B, and hepatitis C seroprevalence among injection drug users in Georgia.* Drug Alcohol Depend, 2006. **82 Suppl 1**: p. S35-8.
24. Crofts, N., C.K. Aitken, and J.M. Kaldor, *The force of numbers: why hepatitis C is spreading among Australian injecting drug users while HIV is not.* Med J Aust, 1999. **170**(5): p. 220-1.
25. Edeh, J. and P. Spalding, *Screening for HIV, HBV and HCV markers among drug users in treatment in rural south-east England.* J Public Health Med, 2000. **22**(4): p. 531-9.
26. Grogan, L., et al., *Bloodborne virus infections among drug users in Ireland: a retrospective cross-sectional survey of screening, prevalence, incidence and hepatitis B immunisation uptake.* Ir J Med Sci, 2005. **174**(2): p. 14-20.
27. Crofts N, et al., *Hepatitis C virus infection among a cohort of Victorian injecting drug users.* Med J Aust, 1993. **159**(4): p. 237-41.
28. Ramirez-Jonville, A., *Drug addiction: harm reduction policies in France and Spain.* Presse Med, 2006. **35**(7-8): p. 1151-61.
29. Ljungberg, B., et al., *HIV prevention among injecting drug users: three years of experience from a syringe exchange program in Sweden.* J Acquir Immune Defic Syndr, 1991. **4**(9): p. 890-5.
30. Cooper, D.A., *Australia's role in HIV prevention in the developing world.* Aust J Public Health, 1995. **19**(6): p. 639-40.
31. Schwartz, R.H., *Syringe and needle exchange programs worldwide: Part II.* South Med J, 1993. **86**(3): p. 323-7.
32. Wodak, A., *Harm reduction: Australia as a case study.* Bull N Y Acad Med, 1995. **72**(2): p. 339-47.
33. National Centre for HIV Epidemiology and Clinical Research, *HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2006.* 2006, National Centre for HIV Epidemiology and Clinical Research, University of New South Wales, Sydney, NSW; Australian Institute of Health and Welfare, Canberra, ACT.
34. Wright, N.M. and C.N. Tompkins, *A review of the evidence for the effectiveness of primary prevention interventions for Hepatitis C among injecting drug users.* Harm Reduct J, 2006. **3**: p. 27.
35. Rhodes, T., et al., *Prevalence of HIV, hepatitis C and syphilis among injecting drug users in Russia: a multi-city study.* Addiction, 2006. **101**(2): p. 252-66.
36. Platt, L., et al., *The prevalence of injecting drug use in a Russian city: implications for harm reduction and coverage.* Addiction, 2004. **99**(11): p. 1430-8.
37. O'Sullivan, B.G., et al., *Estimates of chronic hepatitis B virus infection in Australia, 2000.* Aust N Z J Public Health, 2004. **28**(3): p. 212-6.
38. Tawk, H.M., et al., *The current pattern of hepatitis B virus infection in Australia.* J Viral Hepat, 2006. **13**(3): p. 206-15.
39. National Health and Medical Research Council, *The Australian Immunisation Handbook* 8th ed. 2003, Canberra: Department of Health and Ageing.
40. Polizzotto, M.N. and G. Whelan, *Hepatitis B immunity in a population of drug and alcohol users.* Drug Alcohol Rev, 2007. **26**(4): p. 417-9.
41. Feng, X., *Hepatitis C infection: a review.* Lippincotts Prim Care Pract, 1999. **3**(3): p. 345-53.
42. Fagan, E.A., et al., *Review of hepatitis non-A, non-B: the potential hazards in dental care.* Oral Surg Oral Med Oral Pathol, 1988. **65**(2): p. 167-71.
43. Dienstag, J.L. and H.J. Alter, *Non-A, non-B hepatitis: evolving epidemiologic and clinical perspective.* Semin Liver Dis, 1986. **6**(1): p. 67-81.

44. Ward J, Mattick RP, and Hall W, *Methadone Maintenance Treatment and Other Opioid Replacement Therapies.* 1998, Amsterdam: Harwood academic publishers.
45. Hallinan, R., et al., *Hepatitis C virus prevalence and outcomes among injecting drug users on opioid replacement therapy.* J Gastroenterol Hepatol, 2005. **20**(7): p. 1082-6.
46. Intergovernmental Committee on Drugs subcommittee on Methadone and Other Treatments, *National pharmocotherapy policy for people dependent on opioids.* 2004, Commonwealth of Australia: Canberra.
47. Hallinan, R., A. Byrne, and G.J. Dore, *Harm reduction, hepatitis C and opioid pharmacotherapy: an opportunity for integrated hepatitis C virus-specific harm reduction.* Drug Alcohol Rev, 2007. **26**(4): p. 437-43.
48. Australian Government, *Better Health/ Better Care/ Better Life.* 2005, Department of Health and Ageing: Canberra.
49. Commonwealth of Australia, *The Australian Health Care System. An Outline.* 2000, Department of Health and Aged Care: Canberra.
50. Carnwath, T., *Prescribing heroin.* Am J Addict, 2005. **14**(4): p. 311-8.
51. Mattick R and Hall W, *A Treatment Outline for Approaches to Opioid Dependence and Quality Assurance in the Treatment of Drug Dependence Project, Monograph series no. 21.* 1993, AGPS: Canberra.
52. Mattick R and Hall W, *Overview of the effectiveness of methadone maintenence treatment.* 1999, National Drug and Alcohol Research Centre: Sydney.
53. Maher, L., et al., *High hepatitis C incidence in new injecting drug users: a policy failure?* Aust N Z J Public Health, 2007. **31**(1): p. 30-5.
54. Dore, G.J., et al., *Epidemiology of hepatitis C virus infection in Australia.* J Clin Virol, 2003. **26**(2): p. 171-84.
55. Maher L, L.J., Jalaludin B, Chant KG and Kaldor JM, *High hepatitis C incidence in new injecting drug users.* Australian and New Zealand Journal of Public Health, 2007. **31**(1): p. 30-5.
56. Stein, M.D., J. Maksad, and J. Clarke, *Hepatitis C disease among injection drug users: knowledge, perceived risk and willingness to receive treatment.* Drug Alcohol Depend, 2001. **61**(3): p. 211-5.
57. Best, D., et al., *Accuracy of perceptions of hepatitis B and C status: cross sectional investigation of opiate addicts in treatment.* BMJ, 1999. **319**(7205): p. 290-1.
58. Southgate E, et al., *Methadone Injection in New South Wales. Monograph 6/2001* 2001, National Centre in HIV Social Research: Sydney.
59. Ward, J., W. Hall, and R.P. Mattick, *Role of maintenance treatment in opioid dependence.* Lancet, 1999. **353**(9148): p. 221-6.
60. Mostafanejad, K., *Reducing the isolation of young adults living with a mental illness in rural Australia.* Int J Ment Health Nurs, 2006. **15**(3): p. 181-8.
61. Iezzoni, L.I., M.B. Killeen, and B.L. O'Day, *Rural residents with disabilities confront substantial barriers to obtaining primary care.* Health Serv Res, 2006. **41**(4 Pt 1): p. 1258-75.
62. Schwarz, E., *Access to oral health care - an Australian perspective.* Community Dent Oral Epidemiol, 2006. **34**(3): p. 225-31.
63. Gilmore, V., *Rural health: different issues, different answers.* Aust Nurs J, 2005. **12**(11): p. 15.
64. Philipp, D.L. and D.L. Wright, *Recruiting healthcare professionals to rural areas.* Radiol Manage, 2005. **27**(6): p. 44-50.
65. Hays, R.B., R.J. Evans, and C. Veitch, *The quality of procedural rural medical practice in Australia.* Rural Remote Health, 2005. **5**(4): p. 474.

66. Australian Bureau of Statistics, *1370.0 - Year Book Australia; Measuring Australia's Progress*. 2002, ABS: Canberra.
67. Lawrinson, P., J. Copeland, and D. Indig, *Regional differences in injecting practices and other substance use-related behaviour among entrants into opioid maintenance pharmacotherapy treatment in New South Wales, Australia.* Drug Alcohol Depend, 2006. **82 Suppl 1**: p. S95-102.
68. Strasser, R., *Rural health around the world: challenges and solutions.* Fam Pract, 2003. **20**(4): p. 457-63.
69. Warner, T.D., et al., *Ethical considerations in rural health care: a pilot study of clinicians in Alaska and New Mexico.* Community Ment Health J, 2005. **41**(1): p. 21-33.
70. Lyckholm, L.J., M.H. Hackney, and T.J. Smith, *Ethics of rural health care.* Crit Rev Oncol Hematol, 2001. **40**(2): p. 131-8.
71. Mainous, A.G., 3rd and S.C. Matheny, *Rural human immunodeficiency virus health service provision. Indications of rural-urban travel for care.* Arch Fam Med, 1996. **5**(8): p. 469-73.
72. Doherty, L., *New approaches to sexual health services in a rural health board area: involving service users and primary care professionals.* Int J STD AIDS, 2000. **11**(9): p. 594-8.
73. Whitson, S., *Treatment issues in rural America.* Posit Aware, 1998. **9**(4): p. 31.
74. Fatmi, Z. and B.I. Avan, *Demographic, socio-economic and environmental determinants of utilisation of antenatal care in a rural setting of Sindh, Pakistan.* J Pak Med Assoc, 2002. **52**(4): p. 138-42.
75. Litaker, D., S.M. Koroukian, and T.E. Love, *Context and healthcare access: looking beyond the individual.* Med Care, 2005. **43**(6): p. 531-40.
76. Richards, D., *Methadone in rural general practice: addiction or rehabilitation.* Aust J Rural Health, 1998. **6**(1): p. 42-5.
77. Edwards, R.W. and J.F. Donnermeyer, *Introduction: substance use in rural communities around the world.* Subst Use Misuse, 2002. **37**(5-7): p. vii-xii.
78. Rothman KJ and Greenland S, *Modern Epidemiology*. second ed, ed. Winters R. 1998, Philadelphia: Lippincott-Raven.
79. Hennekens CH and Buring JE, *Epidemiology in Medicine*. 1987, Boston/Toronto: Little Brown and Company.
80. Fairley CK, et al., *Epidemiology and hepatitis C virus in Victoria.* Med J Aust, 1990. **153**(5): p. 271-3.
81. Selvey, L.A., M. Denton, and A.J. Plant, *Incidence and prevalence of hepatitis C among clients of a Brisbane methadone clinic: factors influencing hepatitis C serostatus.* Aust N Z J Public Health, 1997. **21**(1): p. 102-4.
82. Crofts N, et al., *Epidemiology of hepatitis C virus infection among injecting drug users in Australia.* J Epidemiol Community Health, 1997. **51**(6): p. 692-7.
83. Nolte, F.S., *Hepatitis C virus genotyping: clinical implications and methods.* Mol Diagn, 2001. **6**(4): p. 265-77.
84. Schleicher, S., et al., *Evidence of multiple hepatitis virus infections in autopsied materials of intravenous drug addicts.* Ig Sanita Pubbl, 2005. **61**(5): p. 435-50.
85. Doab, A., C. Treloar, and G.J. Dore, *Knowledge and attitudes about treatment for hepatitis C virus infection and barriers to treatment among current injection drug users in Australia.* Clin Infect Dis, 2005. **40 Suppl 5**: p. S313-20.
86. Kresina, T.F., et al., *Integrating care for hepatitis C virus (HCV) and primary care for HIV for injection drug users coinfected with HIV and HCV.* Clin Infect Dis, 2005. **41 Suppl 1**: p. S83-8.

87. Crofts, N., R. Louie, and B. Loff, *The Next Plague: Stigmatization and Discrimination Related to Hepatitis C Virus Infection in Australia.* Health Hum Rights, 1997. **2**(2): p. 86-97.
88. Butler, T., et al., *Seroprevalence of markers for hepatitis B, C and G in male and female prisoners--NSW, 1996.* Aust N Z J Public Health, 1999. **23**(4): p. 377-84.
89. Loxley W, Carruthers S, and Bevan J, *In the same Vein: First report of the Australian Study of HIV and Injecting Drug Use. ASHIDU.* 1995, National Center for Research into the Prevention of Drug Abuse. Curtin University of Technology Perth.
90. Thornton L, et al., *Comparison between self-reported hepatitis B, hepatitis C, and HIV antibody status and oral fluid assay results in Irish prisoners.* Commun Dis Public Health, 2000. **3**(4): p. 253-5.
91. Australian Bureau of Statistics, *Census Data by Location.* 2001, ABS: Canberra.
92. Bammer G, *Stage 2: Feasibility research into the controlled availability of opioids.* 1995, National Centre for Epidemiology and Population Health: Canberra.
93. Ritter, A. and R. Di Natale, *The relationship between take-away methadone policies and methadone diversion.* Drug Alcohol Rev, 2005. **24**(4): p. 347-52.
94. Collom, A.B., *Tears of the poppy; a review of the history of opium.* J Kans Med Soc, 1957. **58**(9): p. 614.
95. Booth, M., *Opium: A History.* 1996, London: Simon & Schuster.
96. Anderson, S. and V. Berridge, *Opium in 20th-century Britain: pharmacists, regulation and the people.* Addiction, 2000. **95**(1): p. 23-36.
97. Byrne A, *Methadone in the Treatment of Narcotic Addiction.* 1995, Sydney: Tosca Press
98. Herz, A., *Role of endorphins in addiction.* Mod Probl Pharmacopsychiatry, 1981. **17**: p. 175-80.
99. Kreek, M.J., *Effects of opiates, opioid antagonists and cocaine on the endogenous opioid system: clinical and laboratory studies.* NIDA Res Monogr, 1992. **119**: p. 44-8.
100. Griffiths, P., et al., *Transitions in patterns of heroin administration: a study of heroin chasers and heroin injectors.* Addiction, 1994. **89**(3): p. 301-9.
101. Torres-Tortosa, M., et al., *Changes in heroin administration route and frequency of human immunodeficiency virus infection.* Med Clin (Barc), 1995. **104**(7): p. 249-52.
102. Frontline. *Opium throughout history* 2006 [cited 2006 November]; PBS http://www.pbs.org/wgbh/pages/frontline/shows/heroin/etc/history.html:[
103. Baumann, D., *The opium war and its background, one of the darkest chapters of European cultural history.* Pharmazie, 1953. **8**(3): p. 303-5.
104. Dole, V.P. and M.E. Nyswander, *Rehabilitation of the street addict.* Arch Environ Health, 1967. **14**(3): p. 477-80.
105. Inciardi, J.A. and B.R. Russe, *Professional thieves and drugs.* Int J Addict, 1977. **12**(8): p. 1087-95.
106. Mohs, M.E., R.R. Watson, and T. Leonard-Green, *Nutritional effects of marijuana, heroin, cocaine, and nicotine.* J Am Diet Assoc, 1990. **90**(9): p. 1261-7.
107. Abalkhail, B.A., *Social status, health status and therapy response in heroin addicts.* East Mediterr Health J, 2001. **7**(3): p. 465-72.
108. Dole, V.P., *Heroin addiction--an epidemic disease.* Harvey Lect, 1973. **67**: p. 199-211.
109. Ralf, G. *A brief overview on the discovery of methadone INDRO e.V Munster.* 2004 [cited 2006 November]; www.indro-online.de/discovery.pdf:[

110. Dole, V.P. and M.E. Nyswander, *Heroin addiction--a metabolic disease.* Arch Intern Med, 1967. **120**(1): p. 19-24.
111. Dole, V.P., M.E. Nyswander, and M.J. Kreek, *Narcotic blockade--a medical technique for stopping heroin use by addicts.* Trans Assoc Am Physicians, 1966. **79**: p. 122-36.
112. Dole, V.P. and M.E. Nyswander, *The use of methadone for narcotic blockade.* Br J Addict Alcohol Other Drugs, 1968. **63**(1): p. 55-7.
113. Dole, V.P. and M.E. Nyswander, *Rehabilitation of heroin addicts after blockade with methadone.* N Y State J Med, 1966. **66**(15): p. 2011-7.
114. Gerstein DR and Harwood HJ, *Treating drug problems Volume 1: A study of effectiveness and financing of public and private drug treatment systems* 1990, Washington, DC: National Academy Press.
115. Ward, J., et al., *Methadone maintenance and the human immunodeficiency virus: current issues in treatment and research.* Br J Addict, 1992. **87**(3): p. 447-53.
116. Amato L, et al., *An overview of systematic reviews of the effectiveness of opiate maintenance therapies: available evidence to inform clinical practice and research.* J Subst Abuse Treat, 2005. **28**(4): p. 321-9.
117. Amato, L., et al., *Methadone at tapered doses for the management of opioid withdrawal.* Cochrane Database Syst Rev, 2004(4): p. CD003409.
118. Broers, B., et al., *Inpatient opiate detoxification in Geneva: follow-up at 1 and 6 months.* Drug Alcohol Depend, 2000. **58**(1-2): p. 85-92.
119. Mattick, R., et al., *Methadone maintenance treatment.* BMJ, 1995. **310**(6991): p. 1408.
120. Darke S, et al., *The Opiate Treatment Index, Technical Report 11.* 1991, National Drug and Alcohol Research Centre, University of New South Wales: Sydney.
121. Dole, V.P., et al., *Methadone treatment of randomly selected criminal addicts.* N Engl J Med, 1969. **280**(25): p. 1372-5.
122. Gunne, L.M. and L. Gronbladh, *The Swedish methadone maintenance program: a controlled study.* Drug Alcohol Depend, 1981. **7**(3): p. 249-56.
123. Newman, R.G. and W.B. Whitehall, *Double-blind comparison of methadone and placebo maintenance treatments of narcotic addicts in Hong Kong.* Lancet, 1979: p. 485-88.
124. Bell, J., et al., *Methadone maintenance and drug-related crime.* J Subst Abuse, 1997. **9**: p. 15-25.
125. Ward, J., et al., *The effectiveness and safety of methadone maintenance.* Addiction, 1996. **91**(11): p. 1727-9.
126. Dore, G.M., et al., *Methadone maintenance treatment: outcomes from the Otago methadone programme.* N Z Med J, 1999. **112**(1100): p. 442-5.
127. Barnett, P.G., *The cost-effectiveness of methadone maintenance as a health care intervention.* Addiction, 1999. **94**(4): p. 479-88.
128. Ridolfo B and Stevenson C, *The quantification of drug-caused mortality and morbidity in Australia, 1998.* 2001, AIHW cat. no. PHE 29. Australian Institute of Health and Welfare: Canberra.
129. Holman CDJ, Armstrong BK, and Arias LN, *The quantification of drug caused morbidity and mortality in Australia.* 1988, Commonwealth Department of Community Services and Health: Canberra.
130. Corty E, Ball JC, and Myers CP, *Psychological symptoms in methadone maintenance patients: Prevalence and change over treatment.* Journal of Consulting and Clinical Psychology, 1988. **56**: p. 776-77.

131. Darke S and Ross J, *Polydrug dependence and psychiatric comorbidity among heroin injectors.* Drug and Alcohol Dependence, 1997. **48**: p. 135-141.
132. World Health Organisation, *Constitution of the World Health Organization* 1946: Geneva.
133. Gearing, F.R. and M.D. Schweitzer, *An epidemiologic evaluation of long-term methadone maintenance treatment for heroin addiction.* Am J Epidemiol, 1974. **100**(2): p. 101-12.
134. Davoli, M., et al., *Risk factors for overdose mortality: a case-control study within a cohort of intravenous drug users.* Int J Epidemiol, 1993. **22**(2): p. 273-7.
135. Caplehorn, J.R., et al., *Retention in methadone maintenance and heroin addicts' risk of death.* Addiction, 1994. **89**(2): p. 203-9.
136. Ball JC and Ross A, *The effectiveness of methadone maintenance treatment: Patients, programs, services, and outcome.* Vienna:Springer-Verlag, 1991.
137. Baker A, et al., *HIV risk-taking behaviour among injecting drug users currently, previously and never enrolled in methadone treatment.* Addiction, 1995. **90**(4): p. 545-54.
138. Metzger, D.S., et al., *Human immunodeficiency virus seroconversion among intravenous drug users in- and out-of-treatment: an 18-month prospective follow-up.* J Acquir Immune Defic Syndr, 1993. **6**(9): p. 1049-56.
139. Moss, A.R., et al., *HIV seroconversion in intravenous drug users in San Francisco, 1985-1990.* Aids, 1994. **8**(2): p. 223-31.
140. Ernest, D., *Notes from the Drug wars: On the European Front.* The International Journal on Drug Policy, 1990. **2**(1).
141. Day, C., et al., *Patterns of drug use and associated harms among rural injecting drug users: comparisons with metropolitan injecting drug users.* Aust J Rural Health, 2006. **14**(3): p. 120-5.
142. Darke, S., et al., *A scale for estimating the health status of opioid users.* Br J Addict, 1991. **86**(10): p. 1317-22.
143. Fry C, Rombold G, and Lintzeris N, *The Blood Borne Virus Transmission Risk Assessment Questionnaire.* 1998, Turning point alcohol and drug centre: Fitzroy, Victoria
144. The National Committees for Clinical Laboratory Standards, *Blood collection of filter-paper for neonatal screening programmes.* 1988, Centres for Disease Control, the Massachusetts Departments of Public Health, the New York State Department of Public Health, and the National Institutes of Health: New York.
145. Metrebian N, Adelekan ML, and Stimson GV, *A modified version of the Opiate Treatment Index for use in the United Kingdom.* 1995, The Centre for Research on Drugs and Health Behaviour: London.
146. Dean AJ, et al., *Does naltrexone treatment lead to depression? Findings from a randomized controlled trial in subjects with opioid dependence.* J Psychiatry Neurosci, 2006. **31**(1): p. 38-45.
147. Baker, A., et al., *Evaluation of a cognitive-behavioural intervention for HIV prevention among injecting drug users.* Aids, 1993. **7**(2): p. 247-56.
148. Deering, D.E. and J.D. Sellman, *An inter-rater reliability study of the Opiate Treatment Index.* Drug Alcohol Rev, 1996. **15**(1): p. 57-63.
149. Adelekan, M., et al., *Reliability and validity of the Opiate Treatment Index among a sample of opioid users in the United Kingdom.* Drug Alcohol Rev, 1996. **15**(3): p. 261-70.
150. Spooner, C., R.P. Mattick, and W. Noffs, *Outcomes of a comprehensive treatment program for adolescents with a substance-use disorder.* J Subst Abuse Treat, 2001. **20**(3): p. 205-13.

151. Goldberg D and Hillier VF, *A scaled version of the General Health Questionnaire-28.* Psychological Medicine, 1979. **9**: p. 139-145.
152. Commonwealth of Australia, *Privacy Act 1988.* Amended 2006, Act No 119 of 1988.
153. Australian National Council on AIDS, Hepatitis C, and related Diseases, *National Hepatitis C testing policy.* 2003, Commonwealth of Australia: Canberra.
154. Dance P, et al., *"I want to be heard": An analysis of needs of Aboriginal and Torres Strait Islander illegal drug users in the ACT and Region for treatment and other services.* 2004, NCEPH and Winnunga Nimmityjah Aboriginal Health Service: Canberra.
155. Stata Corporation, *Stata Statistical Software: Release 8 [program]. Version 8.* 2003: College Station, Texas.
156. SPSS Inc, *SPSS for Windows [computer program] Version 11.0.1.* 2001.
157. Pagano M and Gauvreau K, *Principles of Biostatistics.* 2nd ed. 2000, Pacific Grove, California: Duxbury Thomson Learning.
158. Webster, P., R.P. Mattick, and A.J. Baillie, *Characteristics of clients receiving treatment in Australian drug and alcohol agencies: a national census.* Drug Alcohol Rev, 1992. **11**(2): p. 111-9.
159. Shand, P. and R. Mattick, *Clients of treatment service agencies:May 2001census findings.* 2001, National drug and Alcohol Research Centre, The University of New South Wales: Sydney, Australia.
160. ACT Commissioner for the Environment, *2003 ACT report: indicator: education.* 2003, ABS: Canberra.
161. Darke S, Topp L, and Ross J, *The injection of methadone and benzodiazepines among Sydney injecting drug users 1996-2000: 5-year monitoring of trends from the Illicit Drug Reporting System.* Drug Alcohol Rev, 2002. **21**(1): p. 27-32.
162. Day, C.A., et al., *Initiation to heroin injecting among heroin users in Sydney, Australia: cross sectional survey.* Harm Reduct J, 2005. **2**(1): p. 2.
163. Darke S, Ros J, and Hall W, *The injection of methadone syrup in Sydney, Australia.* 1995, National Drug and Alcohol Research Centre. Technical report no 23: Sydney.
164. Robinson GM, et al., *Patients in methadone maintenance treatment who inject methadone syrup: a preliminary study.* Drug and Alcohol Review, 2000. **19**: p. 447-50.
165. McBride, A.J., Pates, R. M, Arnold, K, Ball, N., *Needle fixation, the drug user's perspective: a qualitative study.* Addiction, 2001. **96**(7): p. 1049-58.
166. Sunjic, S. and J. Howard, *"Non injectables": methadone syrup and benzodiazepine injection by methadone-maintained clients.* Drug Alcohol Rev, 1996. **15**(3): p. 245-50.
167. Waldvogel, D., B. Figner, and D. Eich, *Illicit methadone injecting during methadone maintenance treatment in a specialised out-patient clinic.* Swiss Med Wkly, 2005. **135**(43-44): p. 644-6.
168. Dolan, K., *Surveillance and prevention of hepatitis C in Australian prisons.* Can HIV AIDS Policy Law Newsl, 2000. **5**(2-3): p. 68-9.
169. Judd, A., et al., *Prevalence of, and risk factors for, hepatitis C virus infection among recent initiates to injecting in London and Glasgow: cross sectional analysis.* J Viral Hepat, 2005. **12**(6): p. 655-62.
170. Champion, J.K., et al., *Incidence of hepatitis C virus infection and associated risk factors among Scottish prison inmates: a cohort study.* Am J Epidemiol, 2004. **159**(5): p. 514-9.

171. Butler, K.A., *The prisoner as patient: when medical care is a constitutional issue.* J Nurs Law, 2003. **9**(2): p. 7-16.
172. Crofts N, et al., *Spread of bloodborne viruses among Australian prison entrants.* BMJ, 1995. **310**(6975): p. 285-8.
173. Dolan, K., S. Rutter, and A.D. Wodak, *Prison-based syringe exchange programmes: a review of international research and development.* Addiction, 2003. **98**(2): p. 153-8.
174. Stark K, et al., *A syringe exchange programme in prison as prevention strategy against HIV infection and hepatitis B and C in Berlin, Germany.* Epidemiol Infect, 2006. **134**(4): p. 814-9.
175. Butler, T., et al., *The 2004 Australian prison entrants' blood-borne virus and risk behaviour survey.* Aust N Z J Public Health, 2007. **31**(1): p. 44-50.
176. Caplehorn, J.R. and J. Bell, *Methadone dosage and retention of patients in maintenance treatment.* Med J Aust, 1991. **154**(3): p. 195-9.
177. Strain, E.C., et al., *Dose-response effects of methadone in the treatment of opioid dependence.* Ann Intern Med, 1993. **119**(1): p. 23-7.
178. Caplehorn, J.R., L. Irwig, and J.B. Saunders, *Physicians' attitudes and retention of patients in their methadone maintenance programs.* Subst Use Misuse, 1996. **31**(6): p. 663-77.
179. Joe GW, Chastain RL, and Simpson BB, *Reasons for addiction stages* in *Opioid addiction and treatment: A 12 year fol/ow-up*, DD Simpson and & SB Sells, Editor. 1990, Robert E Kreiger: Malabar, Florida.
180. Bargagli, A.M., et al., *Determinants of methadone treatment assignment among heroin addicts on first admission to public treatment centres in Italy.* Drug Alcohol Depend, 2005. **79**(2): p. 191-9.
181. Morral, A.R., D. McCaffrey, and M.Y. Iguchi, *Hardcore drug users claim to be occasional users: drug use frequency underreporting.* Drug Alcohol Depend, 2000. **57**(3): p. 193-202.
182. Darke S, Swift W, and Ross M, *Drug Use, HIV risk-taking and psychosocial correlates of benzodiazepine use among methadone maintenence clients.* Drug Alcohol Depend, 1994. **31**: p. 31-36.
183. Backmund, M., et al., *Co-consumption of benzodiazepines in heroin users, methadone-substituted and codeine-substituted patients.* J Addict Dis, 2005. **24**(4): p. 17-29.
184. Crofts, N., et al., *The first hit: circumstances surrounding initiation into injecting.* Addiction, 1996. **91**(8): p. 1187-96.
185. Neaigus, A., et al., *Potential risk factors for the transition to injecting among non-injecting heroin users: a comparison of former injectors and never injectors.* Addiction, 2001. **96**(6): p. 847-60.
186. Ouellet, L.J., A. Rahimian, and W.W. Wiebel, *The onset of drug injection among sex partners of injection drug users.* AIDS Educ Prev, 1998. **10**(4): p. 341-50.
187. Sherman, S.G., C.A. Latkin, and A.C. Gielen, *Social factors related to syringe sharing among injecting partners: a focus on gender.* Subst Use Misuse, 2001. **36**(14): p. 2113-36.
188. Swift, W., et al., *The prevalence of minor psychopathology in opioid users seeking treatment.* Br J Addict, 1990. **85**(5): p. 629-34.
189. Darke S, et al., *The Opiate Treatment Index Manual.* 1991, National Drug and Alcohol Research Centre, University of New South Wales, Technical Report 11: Sydney.

190. Mondanaro J, *Medical services for drug dependent women*, in *Treatment services for drug dependent women, volume 1*, R.B. Beschner G, Mondanaro J, Editor. 1981, National Institute on Drug Abuse: Rockville.
191. Mondanaro, J., *Strategies for AIDS prevention: motivating health behavior in drug dependent women.* J Psychoactive Drugs, 1987. **19**(2): p. 143-9.
192. Hopwood, M., et al., *The injection of methadone syrup in New South Wales: patterns of use and increased harm after partial banning of injecting equipment.* Aust N Z J Public Health, 2003. **27**(5): p. 551-5.
193. Darke, S., et al., *Predictors of injecting and injecting risk-taking behaviour among methadone-maintenance clients.* Addiction, 1994. **89**(3): p. 311-6.
194. Crofts, N., et al., *Blood-borne virus infections among Australian injecting drug users: implications for spread of HIV.* Eur J Epidemiol, 1994. **10**(6): p. 687-94.
195. Butler, T.G., et al., *Hepatitis B and C in New South Wales prisons: prevalence and risk factors.* Med J Aust, 1997. **166**(3): p. 127-30.
196. Fry CL and Lintzeris N, *Psychometric properties of the Blood-borne Virus Transmission Risk Assessment Questionnaire (BBV-TRAQ).* Addiction, 2003. **98**(2): p. 171-8.
197. CDC, *Update: acquired immunodeficiency syndrome associated with intravenous-drug use--United States, 1988.* MMWR Morb Mortal Wkly Rep, 1989. **38**(10): p. 165-70.
198. Feucht TE, S.R., Roman SW, *The sexual behaviour of intravenous drug users: Assessing the risk of sexual transmission of HIV* Journal of Drug Issues, 1990. **20**: p. 195-213.
199. Robertson JR, Skidmore CA, and R. JJK, *HIV infection in intravenous drug users: A follow-up study indicating changes in risk-taking behaviour.* Br J Addict, 1988. **83**(387-391).
200. Shapshak P, M.C., Rivers J, Chitwood DD, Mash DC, Weatherby NL, Inciardi JA, Shah SM, Brown BS, *Letter to the Editor: Inactivation of Human Imunodeficiency Virus-1 at Short Term Intervals Using Undiluted Bleach* Journal of Acquired Immune Deficiency Syndrome, 1993. **6**(2): p. 218-219.
201. Evans, J.L., et al., *Gender differences in sexual and injection risk behavior among active young injection drug users in San Francisco (the UFO Study).* J Urban Health, 2003. **80**(1): p. 137-46.
202. Stark, K. and R. Muller, *HIV prevalence and risk behaviour in injecting drug users in Berlin.* Forensic Sci Int, 1993. **62**(1-2): p. 73-81.
203. Darke, S., S. Kaye, and R. Finlay-Jones, *Drug use and injection risk-taking among prison methadone maintenance patients.* Addiction, 1998. **93**(8): p. 1169-75.
204. McCarthy, J.J. and N. Flynn, *Hepatitis C in methadone maintenance patients: prevalence and public policy implications.* J Addict Dis, 2001. **20**(1): p. 19-31.
205. Sackett LD, et al., *Evidence-Based Medicine; How to Practice and Teach EBM.* second ed, ed. Churchill-Livingston. 2000, London.
206. Schlicting, E.G., et al., *Validity of injecting drug users' self report of hepatitis A, B, and C.* Clin Lab Sci, 2003. **16**(2): p. 99-106.
207. Weaver, M.F., K.L. Cropsey, and S.A. Fox, *HCV prevalence in methadone maintenance: self-report versus serum test.* Am J Health Behav, 2005. **29**(5): p. 387-94.

Abbreviations and Glossary

Abbreviations

ACT	Australian Capital Territory
ACT CBD	ACT Central Business District
AHMC	Australian Health Ministers Council
ANCD	Australian National Council on Drugs
ANU	Australian National University
AOD	Alcohol and Other Drug
AUD	Australian Dollar
BBV	Blood Borne Virus
BBV TraQ	Blood Borne Virus Risk Assessment TraQ
BTOM	Brief Treatment Outcome Measure
CAHMA	Canberra Alliance for Harm Minimisation and Advocacy
CHC	Community Health Centre
CI	Confidence Interval
GHQ-28	General Health Questionnaire-28
GP	General Practitioner
HAV	Hepatitis A Virus
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HREC	Human Research Ethics Committee
IGCD	Intergovernmental Committee on Drugs
IDU	Injecting Drug User
LR	Likelihood Ratio
LR test	Likelihood Ratio test
MCDS	Ministerial Council on Drug Strategy
MTP	Methadone Treatment Programme
NCEPH	National Centre for Epidemiology and Population Health
NCHECR	National Centre for HIV Epidemiology and Clinical Research
NDARC	National Drug and Alcohol Research Centre
NDS	National Drug Strategy
NHMRC	National Health and Medical Research Council
NIP	National Immunisation Programme

NLR	Negative Likelihood Ratio
NPV	Negative Predictive Value
NSP	Needle and Syringe Programme
NSW	New South Wales
OR	Odds Ratio
OSP	Other Skin Penetration
OTI	Opiate Treatment Index
P/W	Per Week
PHU	Public Health Unit
PLR	Positive Likelihood Ratio
PPV	Positive Predictive Value
RCT	Randomised Control Trial
SD	Standard Deviation
Sero	Serology
SNSW	Southern New South Wales
TAs	Takeaway Doses
TCH	The Canberra Hospital
TAFE	Technical and Further Education
THS	Total Health Score
UNSW	University of New South Wales
UK	United Kingdom
US	United States
WHO	World Health Organisation
WONCA	World Organisation of Family Doctors
+ve	Positive
-ve	Negative

Glossary

BBV risk	BBV risk taking behaviour for transmission of BBVs
GP Prescriber	General Practitioner managing private methadone clients; abbreviated to GP prescriber/GP in the text
Overall sample	All participants
Methadone clinic	Clinic where clients were dosed in the public system
Study groups	Urban (ACT) and Rural (SNSW) comparison groups

Appendices

Appendix 1: Explanation of validity measures used in the study

Two by two table for calculation of validity measures

Reports (self-report /serology)	**Disease**[19] **+ve** (serology +ve)	**Disease -ve** (serology -ve)	**Totals**
Screening test +ve (self-report +ve)	a	b	a+b
Screening test –ve (self report –ve)	c	d	c+d
Totals	a+c	b+d	a+b+c+d

a=no. of true positive self-reports, b=no. of false positive self-reports, c=no. of false negative self-reports, d=no. of true negative self-reports

Validity measures used and what it measures in my study[20,21]

Validity measures used	**What it measures in my study**
Sensitivity=a/(a+c) Proportion of people who have a positive screening test amongst those who truly have disease.	The proportion of participants who provided a positive self-report amongst those who were serologically positive.
Specificity=d/(b+d) Proportion of people who have a negative screening test amongst those truly do not have disease.	The proportion of participants who provided a negative self-report amongst those who were serologically negative.
PPV=a/(a+b) The proportion of those who truly have disease with a positive screening test.	The proportion of participants whose positive self-report was correct.
NPV=d/(c+d) The proportion of those who did not have disease with a negative screening test	The proportion of participants whose negative self-report was correct.
PLR=(a/[a+c])/(b/[b+d]) The likelihood of a positive test in someone with the disease compared to someone without the disease	The proportion of participants who were serologically positive and had a positive self-report, compared to the proportion of participants who were serologically negative and had a positive self report.
NLR=(c/[a+c])/(d/[b+d]) The likelihood of a negative test in someone with the disease compared to someone without the disease.	The proportion of participants who were serologically positive and had a negative self-report, compared to the proportion of participants who were serologically negative and had a negative self-report.

[19] The word disease is used as per definitions in Epidemiology textbooks (below) to explain validity measures used for screening.

[20] 79. Hennekens CH and Buring JE, *Epidemiology in Medicine*. 1987, Boston/Toronto: Little Brown and Company.

[21] 205. Sackett LD, et al., *Evidence-Based Medicine; How to Practice and Teach EBM*. second ed, ed. Churchill-Livingston. 2000, London.

Appendix 2: Questionnaire

Comparison of Outcomes for Methadone Treatment Program Clients

Questionnaire

2002

The National Centre for Epidemiology and Population Health

Australian National University

Record number:	_____
Date:	____/____/____
Area code: (ACT = 1) (SNSW = 2)	_____
Interviewer:	_____

PART I

GENERAL QUESTIONS

The National Centre for Epidemiology and Population Health

Australian National University

Please write responses if space is provided or highlight options or place a tick in boxes. Pick only one response unless otherwise specified.

Section 1: General Questions

Q1. How many months have you been on this program?_____ Months

Q2. How did you get on the program?

GP referral $_1$ court order $_2$ drug worker $_3$ self-referred $_4$

Other $_{80}$ (please specify) _____

Q3. Why did you go onto this methadone program? (For each statement tick one box)

	No	Yes	Don't Know	Not Applicable
Because of my relationships	☐ 0	☐ 1	☐ 90	☐ 00
Because of my children	☐ 0	☐ 1	☐ 90	☐ 00
Because of money	☐ 0	☐ 1	☐ 90	☐ 00
Because of employment	☐ 0	☐ 1	☐ 90	☐ 00
Because of study	☐ 0	☐ 1	☐ 90	☐ 00
Because of my health	☐ 0	☐ 1	☐ 90	☐ 00
Had a court appearance	☐ 0	☐ 1	☐ 90	☐ 00
Ordered by court	☐ 0	☐ 1	☐ 90	☐ 00
To cut down/stop criminal activity	☐ 0	☐ 1	☐ 90	☐ 00
To get out of the illegal drug scene	☐ 0	☐ 1	☐ 90	☐ 00
To manage tolerance	☐ 0	☐ 1	☐ 90	☐ 00
To get off illegal drugs completely	☐ 0	☐ 1	☐ 90	☐ 00
To cut down use of illegal drugs	☐ 0	☐ 1	☐ 90	☐ 00
To stop using for a while	☐ 0	☐ 1	☐ 90	☐ 00
To cut down the number of times I inject	☐ 0	☐ 1	☐ 90	☐ 00

Other$_{80}$ (please specify)

_____

_____

Q4. How many doses per week do you get at your dosing center? _____

If more than 7 times, please specify reason _____

_____

Q5. Do you get routine takeaways?

No $_0$ *Yes* $_1$

↓

(Go to Q 7)

Q6. How many takeaway doses do you get per week?

1_1 2_2 3_3 4_4 more than 4_5

Q7. What is your current methadone dose?

1-20 mgs$_1$ 21-40 mgs$_2$ 41-60mgs$_3$ 61-80mgs$_4$ 81-100mgs$_5$ >100mgs$_6$

Q8. Do you give random urines?

No $_0$ Yes $_1$

Q9. Thinking of all the times you were on methadone, what is the most number of days you have missed dosing in a week?

0_0 1_1 2_2 3_3 4_4 5_5 6_6 7_7

Q10. How long do you have to travel to get dosed?

Less than ½ an hour $_1$ ½ an hour to 1 hour $_2$ 1 to 1½ half hours

1½ hours to 2 hours $_4$ > 2 hours $_5$

Q11. How much does it cost per day for travel expenses to get dosed?

Nothing$_0$ $1 –$5_1$ $6 – 10_2 $11 – 15_3 $15 – 20_4 > $ 20 $_5$

Q12. How often do you see your methadone prescriber?

Weekly $_1$ Fortnightly $_2$ monthly $_3$ 3monthly $_4$ 6monthly $_5$ > 6monthly $_6$

Q13. How far do you have to travel to see your methadone prescriber?

Less than ½ an hour $_1$ ½ an hour to 1 hour $_2$ 1 to 1½ half hours $_3$

1½ hours to 2 hours $_4$ more than 2 hours $_5$

Q14. How much do you have to pay for each consultation with your prescriber?

Nothing $_0$ $1.00 – 30.00 $_1$ $31.00 – 60.00 $_2$ more than $60.00 $_3$

Q15. How far do you have to travel to see your case manager?

< ½ an hour$_1$ ½ an hour to 1 hour$_2$ 1 to ½ half hours$_3$

1½ hours to 2hours$_4$ > 2hours $_5$ Not applicable $_{00}$ (if no case manager)

Q16. Which of the following categories does the person who doses you fit into? (Can highlight more than one option)

Unknown prior to program$_1$ Relative $_2$ Family friend $_3$ Work mate $_4$

Acquaintance $_5$ Other $_{80}$ (please specify) _____

Q17. How much does methadone cost you per week?

Nothing $_0$ $1.00 – 15.00$_1$ $16.00 – 30.00$_2$ $30.00 – 45.00 $_3$ > $45.00 $_4$

Q18. How long do you expect to be on methadone?

< 1yr$_1$ 1yr$_2$ 2yrs$_3$ 3yrs$_4$ 4yrs$_5$ 5yrs$_6$ > than 5yrs $_7$

Don't Know$_{90}$

Q19. Is this the first time you have been on a methadone program?

No $_0$ Yes $_1$

↓

(Go to Q 23)

Q20. How many other times have you been on a methadone program?

_____

Q21. When was the last time you were on a methadone program before this one?

_____ Year

Q22. Why did you leave the last program? (Can highlight more than one option)

Too far to travel $_1$ Too expensive$_2$ Confidentiality $_3$ Did not suit me $_4$

Did not fit my schedule $_5$ Other $_{80}$ (Please specify)

_____

_____

_____

_____

Q23. Which of the following would best describe your program? (Ask interviewer for definition)

Public $_1$ Partly public/partly private $_2$ Private $_3$ Don't know $_{90}$

Q24. Where do you get dosed?

Clinic $_1$ Pharmacy $_2$ hospital $_3$ GP surgery$_4$

Other $_{80}$ _____

Q25. How satisfied are you with this program?

Very satisfied $_1$ Satisfied $_2$ Unsatisfied $_3$ Very unsatisfied $_4$Don't know $_{90}$

Q26. Since being on methadone (For each statement tick one box)

	Improved	Stayed the same	Worsened	Don't Know	Not Applicable
My health has	☐ 1	☐ 2	☐ 3	☐ 90	☐ 00
The state of my teeth has	☐ 1	☐ 2	☐ 3	☐ 90	☐ 00
My relationships have	☐ 1	☐ 2	☐ 3	☐ 90	☐ 00
My relationships with my children have	☐ 1	☐ 2	☐ 3	☐ 90	☐ 00
My financial situation has	☐ 1	☐ 2	☐ 3	☐ 90	☐ 00
My employment situation has	☐ 1	☐ 2	☐ 3	☐ 90	☐ 00
My options for study have	☐ 1	☐ 2	☐ 3	☐ 90	☐ 00
My control over my life has	☐ 1	☐ 2	☐ 3	☐ 90	☐ 00
My management of tolerance has	☐ 1	☐ 2	☐ 3	☐ 90	☐ 00
My ability to think clearly has	☐ 1	☐ 2	☐ 3	☐ 90	☐ 00

Q27. Since being on methadone I have found that (For each statement tick one box)

	Agree	Disagree	Don't know	NA
The staff treat me with respect	☐ 1	☐ 2	☐ 90	☐ 00
My confidentiality is respected	☐ 1	☐ 2	☐ 90	☐ 00
I can get away from other users if I want to	☐ 1	☐ 2	☐ 90	☐ 00
I am off illegal drugs completely	☐ 1	☐ 2	☐ 90	☐ 00
I have cut down my illegal drug use	☐ 1	☐ 2	☐ 90	☐ 00
I stopped using for a while	☐ 1	☐ 2	☐ 90	☐ 00
My court case was helped	☐ 1	☐ 2	☐ 90	☐ 00
I didn't have to go to jail	☐ 1	☐ 2	☐ 90	☐ 00
I cut down/ stopped criminal activity	☐ 1	☐ 2	☐ 90	☐ 00
I have less problems with the police	☐ 1	☐ 2	☐ 90	☐ 00
I have stopped injecting completely	☐ 1	☐ 2	☐ 90	☐ 00
I have cut down the number of times I inject	☐ 1	☐ 2	☐ 90	☐ 00
I am out of the illegal drug scene	☐ 1	☐ 2	☐ 90	☐ 00
I use more pills	☐ 1	☐ 2	☐ 90	☐ 00
I drink more alcohol	☐ 1	☐ 2	☐ 90	☐ 00

Other$_{80}$ (please specify)

_____

_____

Q28. What other types of drug treatment have you had in the past? (You can tick more than one box)

None ever ☐ 0

Detoxification ☐ 1

Narcotics anonymous ☐ 2

Drug counseling ☐ 3

In-patient rehabilitation ☐ 4

Other $_{80}$ (please specify)_____

Q29. The methadone program would work better for me if there were.
(For each statement tick one box)

	No	Yes	Don't know	NA
Longer opening hours	☐ 0	☐ 1	☐ 90	☐ 00
More counselling	☐ 0	☐ 1	☐ 90	☐ 00
Crisis counselling available	☐ 0	☐ 1	☐ 90	☐ 00
Easier transfers to other clinics	☐ 0	☐ 1	☐ 90	☐ 00
More take-aways	☐ 0	☐ 1	☐ 90	☐ 00
Emergency take-aways	☐ 0	☐ 1	☐ 90	☐ 00
A needle and syringe exchange	☐ 0	☐ 1	☐ 90	☐ 00
A disposal bin for fits	☐ 0	☐ 1	☐ 90	☐ 00
Support groups for coming off methadone	☐ 0	☐ 1	☐ 90	☐ 00
Injectable methadone	☐ 0	☐ 1	☐ 90	☐ 00
Less urinalysis	☐ 0	☐ 1	☐ 90	☐ 00
More urinalysis	☐ 0	☐ 1	☐ 90	☐ 00
Ways to appeal against decisions made about me	☐ 0	☐ 1	☐ 90	☐ 00
Reward for abstinence	☐ 0	☐ 1	☐ 90	☐ 00
Help in developing my long term goals	☐ 0	☐ 1	☐ 90	☐ 00
More notice taken of my personal goals	☐ 0	☐ 1	☐ 90	☐ 00
A dispensing site closer to home	☐ 0	☐ 1	☐ 90	☐ 00
More information about drugs and pregnancy	☐ 0	☐ 1	☐ 90	☐ 00
More information about the effects of methadone	☐ 0	☐ 1	☐ 90	☐ 00
More information about the effects of illegal drugs	☐ 0	☐ 1	☐ 90	☐ 00
More information about prescription drugs	☐ 0	☐ 1	☐ 90	☐ 00
Help in dealing with my childhood abuse	☐ 0	☐ 1	☐ 90	☐ 00
Help for domestic violence	☐ 0	☐ 1	☐ 90	☐ 00

Other ☐ 80 (please specify)

_____

_____

_____

Q 30. Do you access Needle and Syringe Outlets?

No $_0$ ↓ (*Go to question 33)*

Yes $_1$

Q31. How often do you access the needle and syringe outlets?

Every day$_1$ 2-3 times a week $_2$ Once a week $_3$ Once a month $_4$
> once a month$_5$

Q32. What do you get from the needle and syringe outlets? (Can highlight more than one option)

Injecting equipment $_1$ sterile water $_2$ condoms $_3$ information $_4$
Other $_{80}$ (please specify) _____

Q33. What sex are you?

Male$_1$ Female$_2$ Transexual$_3$

Q34. How old are you? _____ Years

Q35. What is the highest level of education you have completed? (Tick one box)

Postgraduate qualification	☐ 1
Bachelor degree	☐ 2
TAFE certificate (eg. trade)	☐ 3
High school certificate (year 12)	☐ 4
Leaving/school certificate (year 10)	☐ 5
Left high school before leaving certificate (before year 10)	☐ 6
Did not attend high school	☐ 7
Completed primary school	☐ 8
Attended primary school	☐ 9

Q36. How are you employed at the moment?

Unemployed $_1$ Full-time$_2$ Part-time/casual$_3$ Student$_4$ Home duties$_5$
Other$_{80}$ (please specify) _____

Q37. During the last 6 months what were your sources of income? (Can highlight more than one option)

Paid employment $_1$ Self-employed $_2$ Government benefits $_3$
Illegal sources $_4$ Other $_{80}$ (please specify)

_____

_____

Q38. Which was your *main* source of income in the last 6 months?

Paid employment$_1$ Self-employment $_2$ Government benefits$_3$
Illegal sources $_4$ Other $_{80}$ (please specify)

_____

_____

Q39. In what country were you born? _____

Q40. Do you identify as an Aboriginal or Torres Strait Islander?

No $_0$ Yes $_1$

Q41. How many children are financially dependent on you

a) Living with you _____

b) Not living with you _____

c) Not applicable$_{00}$

Q42. What is your current marital status?

Never married$_1$ Married/Defacto$_2$ Separated$_3$ Divorced$_4$ Widowed$_5$

Other $_{80}$ (please specify)_____

Q43. Where do you live?

ACT $_1$ NSW $_2$

Q44. What is your residential postcode? _____

Q45. What is your accommodation type at the moment?

Own accommodation$_1$ Rented accommodation $_2$ Boarding house$_3$
Homeless $_4$ Other $_{80}$ (please specify)_____

Q46. Who do you live with at the moment? (Can highlight more than one option)

Live alone$_1$ Live with parents$_2$ Live with partner$_3$ Share with others $_4$
Other$_{80}$ (please specify) _____

Q47. Do any of the people you currently live with inject illegal drugs?

No $_0$ Yes $_1$ Don't know $_{90}$

Section 2: Prison History

Q48. Have you ever been in prison? (Including remand/police cells)

No$_0$ Yes$_1$

↓

(Go to next section)

Q49. If yes, when was the last time you were in prison?_____ Year

Q50. How many times have you been in prison? _____

Q51. How long were you in prison the last time? _____ Months

Q52. Did you inject drugs while in prison?

No$_0$ Yes $_1$

Q53. Did you get tattooed while in prison?

No $_0$ Yes $_1$

Q54. Were you on a methadone program whilst in prison?

No $_0$ Yes $_1$

Section 3: Drug History

Q55. At what age did you first inject drugs? _____ Years

Q56. What drug did you first inject? (Tick one box only)

Heroin	☐ 1
Methadone	☐ 2
Other opioids (eg; codeine, morphine, opium)	☐ 3
Amphetamines (eg; speed, MDMA)	☐ 4
Cocaine	☐ 5
Hallucinogens (LSD)	☐ 6
Ecstasy	☐ 7
Benzodiazepines (normison, footies, rohypnol, mogadon, temazepam, valium, serapax)	☐ 8
Steroids	☐ 9

Other 80 (please specify) _____

Q57. At what age did you first start to inject regularly? _____ Years
(Regular = at least once a week)

Q58. What drug(s) were you injecting at that time?
(You can tick more than one box)

Heroin	☐ 1
Methadone	☐ 2
Other opioids (eg; codeine, morphine, opium)	☐ 3
Amphetamines (speed, MDMA)	☐ 4
Cocaine	☐ 5
Hallucinogens (LSD)	☐ 6
Ecstasy	☐ 7
Benzodiazepines (normison, footies, rohypnol, mogadon, temazepam, valium, serapax)	☐ 8
Steroids	☐ 9

Other 80 (please specify) _____

Q59. Who have you been injected by in the last month? (Can highlight more than one option)

Self$_1$ Partner$_2$ Friend$_3$ Stranger$_4$ Dealer$_5$

Not applicable 00 Other 80 (please specify)_____

Q60. Who has prepared/mixed the drugs you injected in the last month?
(Can highlight more than one option)

Self$_1$ Partner $_2$ Friend $_3$ Stranger $_4$ Dealer $_5$

Not applicable 00 Other 80 (please specify) _____

Q 61. Who injects/injected you most often? (Circle one option only)

Self$_1$ Partner $_2$ Friend $_3$ Stranger$_4$ Dealer$_5$

Other $_{80}$ (please specify) _____

Q62. Who mostly prepared/mixed the drugs you inject? (Circle one option only)

Self$_1$ Partner $_2$ Friend $_3$ Stranger $_4$ Dealer $_5$

Other $_{80}$ (please specify) _____

Q63. Have you ever injected methadone?

No $_0$ ↓ Yes $_1$

(*Go to next section*)

Q64. If yes, when

In the last week $_1$ In the last month $_2$ In the last year $_3$

Previous to the last year $_4$

Q65. How often do you inject methadone?

Daily $_1$ Weekly $_2$ monthly $_3$ Other$_{80}$ _____

Q66. How many times per week would you inject methadone?

1_1 2_2 3_3 4_4 5_5 6_6 7_7 > 7 times$_8$

Other$_{80}$ _____

Q67. Which of the following methadone did/do you inject?
(Can highlight more than one option)

Regular dose$_1$ Takeaways$_2$ Friends/partners takeaways$_3$ Buy it $_4$

Section 4: Serostatus:

Q68. Have you ever been tested for HIV?

No $_0$ Don't know $_{90}$ Yes $_1$

(Go to question 72)

Q69. What was the result of that test?

Negative $_0$ Positive $_1$ Don't know $_{90}$

Q70. If positive, when were you told this result?_____ Month

_____ Year

Q71. If negative, when was your last test? _____ Month

_____ Year

Q72. Have you ever been tested for the *hepatitis C* virus?

No $_0$ Don't know $_{90}$ Yes $_1$

(Go to question 76)

Q73. What was the result of that test?

Negative $_0$ Positive $_1$ Don't know $_{90}$

Q74. If positive, when were you told this result?_____ Month

_____ Year

Q75. If negative, when was your last test? _____ Month

_____ Year

Q76. Have you ever been tested for the *hepatitis B* virus?

No $_0$ Don't know $_{90}$ Yes $_1$

(Go to question 80)

Q77. What was the result of that test?

Negative $_0$ Positive $_1$ Don't know $_{90}$

Q78. If positive, when were you told this result?_____ Month

_____ Year

Q79. If negative, when was your last test? _____ Month

_____ Year

Q80. Have you ever been vaccinated for the *hepatitis B* virus?

No $_0$ Don't know $_{90}$ Yes $_1$

(Go to Q 81)

If yes

First injection: _____ Month_____ Year

Second injection_____ Month_____ Year

Third injection _____ Month_____ Year

Q81. Have you ever been tested for the *hepatitis A* virus?

No $_0$ Don't know $_{90}$ Yes $_1$

(Go to question 85)

Q82. What was the result of that test?

Negative $_0$ Positive $_1$ Don't know $_{90}$

Q83. If positive, did you have the illness, if so when? _____ Month

_____ Year

Q84. If negative when was your last test? _____ Month

_____ Year

Q85. Have you ever been vaccinated for the *hepatitis A* virus?

No $_0$ Don't know $_{90}$ Yes $_1$

If yes

First injection: _____ Month_____ Year

Second injection: _____ Month_____ Year

Third injection _____ Month_____ Year

End of Part I
Please continue with Part II

PART II

BBV-TRAQ

Blood Borne Virus

Transmission Risk Assessment

Questionnaire

Turning Point Alcohol and Drug Centre Inc. 1998

Instructions to participants

- Please consider the following questions carefully and answer each one as accurately and truthfully as you can. All questions refer to your behaviour in the past MONTH / 4 week period.
- Try and remember that the only correct answer is an accurate and honest answer.
- Remember that the information you provide will remain completely confidential.

SECTION 1 - INJECTING PRACTICES

Record your responses to each of the following questions by highlighting/circling the answer option that you think is most relevant to you.

86. In the last month, how many times have you handled another person's used needle/syringe (eg. to dispose, to break-off needle) at a time when you had cuts, sores or lesions on your fingers and hands?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

87. In the last month, how many times have you sucked or licked left-over drugs from a spoon or other mixing container which had been used by another person?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

88. In the last month, how many times have you sucked or licked a filter which had been used by another person?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

89. In the last month, how many times have you sucked or licked a plunger after using it in a mix which has been used by another person?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

90. In the last month, how many times have you injected a drug that was filtered through another person's filter?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

91a. In the last month, how many times have you injected a drug that was prepared in another person's used spoon or mixing container?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

↓

(Go to Question 92)

91b. On those occasions how often did you clean the spoon or mixing container before using it?

Never $_0$ Rarely $_1$ Sometimes $_2$ Often $_3$ Every time $_4$

92. In the last month, how many times have you injected a drug prepared with water, which had been used by another person?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

93. In the last month, how many times have you injected a drug, which had come into contact with another person's used needle/syringe?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

94a. In the last month, how many times have you injected a drug that you prepared immediately after 'assisting' another person with their injection (eg. injecting them, holding their arm, handling their used needle/syringe; touching their injection site to feel for a vein, to wipe away blood, or to stop bleeding)?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

↓

(Go to Question 95a)

94b. On those occasions, how often did you wash your hands before preparing your mix?

Never $_0$ Rarely $_1$ Sometimes $_2$ Often $_3$ Every time $_4$

95a. In the last month, how many times have you injected a drug that was prepared by another person who had already injected or assisted in someone else's injection?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

↓

(Go to Question 96a)

95b. On those occasions, how often did the person preparing the mix wash their hands before preparing the mix?

Never $_0$ Rarely $_1$ Sometimes $_2$ Often $_3$ Every time $_4$

96a. In the last month, how many times have you been injected by another person who had already injected or assisted in someone else's injection?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

↓

(Go to Question 97a)

96b. On those occasions, how often did the person injecting you wash their hands before injecting you?

Never $_0$ Rarely $_1$ Sometimes $_2$ Often $_3$ Every time $_4$

97a. In the last month, how many times have you injected with a needle/syringe which had been handled or touched by another person who had already injected?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

↓

(Go to Question 98a)

97b. On those occasions, how often did they wash their hands prior to handling the needle/syringe that you used?

Never $_0$ Rarely $_1$ Sometimes $_2$ Often $_3$ Every time $_4$

98a. In the last month, how many times have you injected with another person's used needle/ syringe?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

↓

(Go to Question 99)

98b. On those occasions, how often did you rinse it with a combination of full-strength bleach and water (ie. the '2x2x2' method) before you used it?

Never $_0$ Rarely $_1$ Sometimes $_2$ Often $_3$ Every time $_4$

99. **In the last month, how many times have you injected with a needle/syringe after another person has already injected some of its contents?**
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

100a. **In the last month, how many times have you touched your own injection site (eg. to feel for a vein, to wipe away blood, or to stop bleeding) soon after 'assisting' another person with their injection (eg. injecting them, holding their arm, handling their used needle/syringe; touching their injection site to feel for a vein, to wipe away blood, or to stop bleeding)?**
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$
↓
(Go to Question 101a)

100b. **On those occasions, how often did you wash your hands before touching your own injection site?**
Never $_0$ Rarely $_1$ Sometimes $_2$ Often $_3$ Every time $_4$

101a. **In the last month, how many times has another person touched your injection site (eg. to feel for a vein, to wipe away blood, or to stop bleeding)?**
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ - 10 times $_4$ >10 times $_5$
↓
(Go to Question 102)

101b. **On those occasions, how often did the person wash their hands before they touched your injection site?**
Never $_0$ Rarely $_1$ Sometimes $_2$ Often $_3$ Every time $_4$

102. **In the last month, how many times have you wiped your own injection site with an object (eg. swab, tissue, hanky, towel, etc) which had been used by another person**
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

103. **In the last month, how many times have you used a tourniquet (eg. medical tourniquet, belt, rope, tie, cord, etc), which had been used by another person?**
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

104. **In the last month, how many times have you received an accidental needle-stick/prick from another person's used needle/syringe?**
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

105a. **In the last month, how many times have you re-used a needle/syringe taken out of a shared disposal/sharps container?**
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$
↓
(Go to SECTION 2)

105b. **On those occasions, how often did you rinse it with full-strength bleach before you re-used it?**
Never $_0$ Rarely $_1$ Sometimes $_2$ Often $_3$ Every time $_4$

SECTION 2 - SEXUAL PRACTICES

Record your responses to each of the following questions by circling the answer option that you think is most relevant to you.

106. In the last month, how many times have you engaged in unprotected vaginal sex with another person (ie. penetration of the vagina with the penis)?
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

107. In the last month, how many times have you engaged in unprotected vaginal sex with another person (ie. penetration of the vagina with the penis) during menstruation?
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

108. In the last month, how many times have you engaged in unprotected vaginal sex with another person (ie. penetration of the vagina with the penis) without lubrication?
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

109. In the last month, how many times have you engaged in unprotected anal sex with another person (i.e. penetration of the anus with the penis)?
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

110. In the last month, how many times have you engaged in unprotected oral sex with another person (i.e. lips and tongue come into contact with the vagina, penis and/or anus)?
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

111. In the last month, how many times have you engaged in unprotected manual sex with another person (i.e. fingers and hands come into contact with the vagina, penis and/or anus) during menstruation?
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

112. In the last month, how many times have you engaged in unprotected manual sex with another person (fingers and hands come into contact with the vagina, penis and/or anus) after injecting?
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

113. In the last month, how many times have you engaged in unprotected manual sex with another person (fingers and hands come into contact with the vagina, penis and/or anus) without lubrication?
No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

SECTION 3 - OTHER SKIN PENETRATION PRACTICES

Record your responses to each of the following questions by circling the answer option that you think is most relevant to you.

114. In the last month, how many times have you come into contact with another person's blood (eg. through fights, slash-ups, self-mutilation, accidents, blood-sports, occupational, pimples, blood nose, etc)?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

115. In the last month, how many times have you been tattooed by someone who was not a professional tattooist?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

116. In the last month, how many times have you been pierced (eg. ear or body) by someone who was not a professional piercer?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

117. In the last month, how many times have you used another person's used razor (eg. disposable razors, razor-blades)?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

118. In the last month, how many times have you used another person's toothbrush?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

119. In the last month, how many times have you used another person's personal hygiene equipment (eg. nail file, nail scissors, nail clippers, tweezers, comb, brush)?

No times $_0$ Once $_1$ Twice $_2$ 3 - 5 times $_3$ 6 - 10 times $_4$ >10 times $_5$

End of Part II

The next part is to be filled in by the interviewer

PART III

THE OPIATE TREATMENT INDEX

National Drug and Alcohol
Research Centre

The University of New South Wales

SECTION I: DRUG USE

First, I'm going to ask you some questions on your use of drugs. I'll emphasise again that the information you give me is completely confidential.

NB: *For all categories, if the subject responds that their last use of the drug was more than a month ago, score zero for that category. Do not include use on day of interview.*

Heroin

Now I'm going to ask you some questions about heroin (smack, hammer, horse, scag).

1. On what day did you last use heroin?_____

2. How many hits/smokes/snorts did you have on that day?_____

3. On which day before that did you use heroin?_____

4. And how many hits/smokes did you have on that day?_____

5. And when was the day before that?_____
   (ql= ,q2= ,tl= ,t2=)

Other opiates

These questions are about your use of opiates other than heroin (e.g. street methadone/done, morphine, pethidine, codeine).

6. On what day did you last use opiates other than heroin? (do not include legally obtained methadone)_____

7. How many pills, doses etc. did you have on that day?_____

8. On which day before that did you use opiates other than heroin?_____

9. And how many pills, doses etc. did you have on that day?_____

10. And when was the day before that?_____
    (ql= ,q2= ,tl= ,t2=)

Alcohol

These questions are about your use of alcohol.

11. On what day did you last drink alcohol?_____

12. How much alcohol did you drink on that day?_____

	Wine	Spirits	Beer	Fortified Wine
	Wine Gl.	Nips (30ml)	Middies (285ml)	Port Gl.
	Bottles (750ml)	Doubles	Schooners (425ml)	Bottles
	Flagons	Bottles (750ml)	Cans/Stubbies (375ml)	Flagons
	Casks - lit.		Bottles (750ml)	
NO. STAND DRINKS				

TOTAL STANDARD DRINKS _____

13. On which day before that did you drink alcohol? _____

14. And how much did you drink on that day? _____

	Wine	Spirits	Beer	Fortified Wine
	Wine Gl. (120ml)	Nips (30ml)	Middies (285ml)	Port Gl. (60ml)
	Bottles (750ml)	Doubles	Schooners (425ml)	Bottles (750ml)
	Flagons (1.5lit.)	Bottles (750ml)	Cans/Stubbies (375ml)	Flagons (1.51it.)
	Casks (__ lit.)		Bottles (750ml)	
NO. STAND DRINKS				

TOTAL STANDARD DRINKS _____

15. And when was the day before that?_____
(ql= ,q2= ,tl= ,t2=) Q

Cannabis

These questions are about your use of marijuana (dope, grass, hash, pot).

16. On what day did you last use marijuana ?_____

17. How many joints, bongs, etc. did you have on that day?_____

18. On which day before that did you use marijuana?_____

19. And how many joints, bongs, etc. did you have on that day?_____

20. And when was the day before that?_____

(ql= ,q2= ,tl= ,t2=) Q

Amphetamines

These questions are about your use of amphetamines (speed).

21. On what day did you last use amphetamines?_____

22. How many tablets, snorts, hits etc. did you have on that day?_____

23. On which day before that did you use amphetamines?_____

24. And how many tablets, snorts, hits, etc., did you have on that day?_____

25. And when was the day before that?_____

(ql= ,q2= ,tl= ,t2=) Q

Cocaine

These questions are about your use of cocaine (coke, snow, crack).

26. On what day did you last use cocaine?_____

27. How many snorts, hits, smokes etc. did you have on that day?_____

28. On which day before that did you use cocaine?_____

29. And how many snorts, hits, smokes etc. did you have on that day?_____

30. And when was the day before that?_____

(ql= ,q2= ,tl= ,t2=) Q

Tranquillisers

These questions are about your use of tranquillisers (e.g. Serepax, Rohypnol, Mogadon, Valium).

31. On what day did you last use tranquillisers?_____

32. How many pills did you have on that day?_____

33. On which day before that did you use tranquillisers?_____

34. And how many pills did you have on that day?_____

35. And when was the day before that?_____

(ql= ,q2= ,tl= ,t2=) Q

Barbiturates

These questions are about your use of barbiturates (e.g. Nembutal, Seconal).

36. On what day did you last use barbiturates?_____

37. How many pills did you have on that day?_____

38. On which day before that did you use barbiturates?_____

39. And how many pills did you have on that day?_____

40. And when was the day before that?_____

(ql= ~q2= ,tl= ,t2=) Q

Hallucinogens

These questions are about your use of hallucinogens (e.g. LSD/acid, ecstasy, magic magic mushrooms).

41. On what day did you last use hallucinogens?_____

42. How many tabs, pills, etc. did you have on that day?_____

43. On which day before that did you use hallucinogens?_____

44. And how many tabs, pills, etc. did you have on that day?_____

45. And when was the day before that?_____

(ql= ,q2= ,tl= ,t2=) Q

Inhalants

These questions are about your use of inhalants (e.g. amyl nitrite/rush, glue, laughing gas, aerosols, petrol).

46. On what day did you last use inhalants? (do not include asthma sprays)_____

47. How many sniffs did you have on that day?_____

48. On which day before that did you use inhalants?_____

49. And how many sniffs did you have on that day?_____

50. And when was the day before that?_____
(ql= ,q2= ,tl= ,t2=) Q

Tobacco

Finally, these questions are about your use of cigarettes.

51. On what day did you last use tobacco?_____

52. How many cigarettes did you have on that day?_____

53. On which day before that did you use tobacco?_____

54. And how many cigarettes did you have on that day?_____

55. And when was the day before that?_____
(ql= ,q2= ,tl= ,t2=) Q

General Comments On Drug Use

_____

_____

_____

_____

_____

_____

_____

DRUG USE SUMMARY

Heroin Use Total	
Poly-drug Use Total	

POLY-DRUG USE

Other Opiates		Tranquillisers	
Alcohol		Barbiturates	
Cannabis		Hallucinogens	
Amphetamines		Inhalants	
Cocaine		Tobacco	

SECTION II: INJECTING AND SEXUAL PRACTICES

These questions are about the way you use drugs, and your recent sexual behaviour.
I emphasise again that any information that you give me is completely confidential.

DRUG USE

1. How many times have you hit up (i.e. injected any drugs) in the last month?

Hasn't hit up 0
Once a week or less.....1
More than once a week.....2
(but less than once a day)
Once a day.....3
2-3 times a day.....4
More than 3 times a day.....5

If subject hasn't injected in the last month, score zero for the Drug Use section, and go to question 7.

2. How many times in the last month have you used a needle after someone else had already used it?

No times.....0
One time.....1
Two times.....2
3-5 times.....3
6-10 times.....4
More than 10 times.....5

3. How many different people have used a needle before you in the last month?

None 0
One person.....1
Two people.....2
3-5 people 3
6-10 people.....4
More than 10 people 5

4. How many times in the last month has someone used a needle after you have used it?

No times 0
One time 1
Two times.....2
3-5 times 3
6-10 times 4
More than 10 times 5

5. How often, in the last month, have you cleaned needles before re-using them ?
Doesn't re-use.....0
Every time.....1
Often.....2
Sometimes.....3
Rarely 4
Never 5

6. Before using needles again, how often in the last month did you use bleach to clean them?
Doesn't re-use.....0
Every time 1
Often 2
Sometimes.....3
Rarely 4
Never 5
Drug Use Sub-total
SEXUAL BEHAVIOUR

7,How many people, including clients, have you had sex with in the last month?
None 0
One person.....1
Two people.....2
3-5 people.....3
6-10 people 4
More than 10 people.....5

If no sex in the last month, score zero for Sexual Behaviour section, and go to Section IV.

8. How often have you used condoms when having sex with your regular partners) in the last month?
No reg. partner/No penetrative sex 0
Every time 1
Often 2
Sometimes.....3
Rarely.....4
Never 5

9. How often did you use condoms when you had sex with casual partners in the last month?

No cas. partners/No penetrative sex 0
Every time 1
Often 2
Sometimes 3
Rarely 4
Never.....5

10. How often have you used condoms when you have been paid for sex in the last month?
No paid sex/No penetrative sex..... 0

Every time 1
Often 2
Sometimes 3
Rarely 4
Never 5

11. How many times did you have anal sex in the last month?

No times.....0
One time.....1
Two times 2
3-5 times.....3
6-10 times.....4
More than 10 times.....5

Sexual Behaviour Sub-total=

TOTAL SCORE=

(Drug Use Sub-total + Sexual Behaviour Sub-total)=

General Comments on HIV Risk-taking Behaviour

_____
_____
_____
_____
_____

SECTION III: SOCIAL FUNCTIONING

These next few questions concern the social aspects of your life (things like jobs, friends, etc).

1. How many different places have you lived in over the last six months?

One 0
Two.....1
Three.....2
Four.....3
Five or more.....4

2. How much of the last six months have you been unemployed?

All of the time 4
Most of the time 3
Half of the time 2
Some of the time 1
None of the time 0

3. How many different full-time jobs have you had in the last six months?

One 0
Two.....1
Three.....2
Four.....3
Five or more.....4

4. How often in the last six months have you had conflict with your relatives?

Very often 4
Often.....3
Sometimes.....2
Rarely.....1
Never.....0
N/A.....0

5. How often in the last six months have you had conflict with your partner(s)?

Very often 4
Often.....3
Sometimes.....2
Rarely.....1
Never.....0
N/A.....0

6 How often in the last six months have you had conflict with your friends?

Very often 4

Often 3

Sometimes.....2

Rarely 1

Never 0

N/A.....4

7. About how many close friends would you estimate that you have? (INCLUDE PARTNER)

None 4

One 3

Two.....2

Three.....1

Four or more 0

8. When you are having problems, are you satisfied with the support you get from your friends?

Very satisfied 0

Satisfied 1

Reasonably OK 2

Not satisfied 3

Very unsatisfied 4

N/A.....0

9. About how often do you see your friends?

Very Often.....0

Often 1

Sometimes 2

Rarely.....3

Never.....4

N/A.....4

10. How many of the people you hang around with now have you known for more than six months?

None 4

Less than half 3

About a half 2

More than half 1

All of them 0

N/A.....4

11. How much of the last six months have you been living with anyone who uses heroin?

All of the time 4

Most of the time 3

Half of the time 2

Some of the time 1

None of the time 0

12. How many of the people you hang around with now are users? (INCLUDE PARTNER)

None 0

Less than half.....1

About a half 2

More than half.....3

All of them 4

SOCIAL TOTAL=

General Comments on Social Functioning

SECTION IV: CRIME

In this section I am interested in any crimes that you may have committed. Any information that you give here is completely confidential.

Property Crime

First, I am going to ask you some questions on property crime. By property crime I mean things such as break and enter, robbery without violence, shoplifting, stealing a prescription pad, stealing a car, or receiving stolen goods. I am interested in the number of times that you committed a property crime, not the number of times you've been caught.

1. How often, on average, during the last month have you committed a property crime? (READ OPTIONS)
   No property crime 0
   Less than once a week 1
   Once a week 2
   More than once a week 3
   (but less than daily)
   Daily.....4

Dealing

Now I am going to ask you some questions about dealing. By dealing I mean selling drugs to someone. I am interested in the number of times that you've dealt drugs, not the number of times you've been caught.

2. How often, on average, during the last month have you sold drugs to someone?
No drug dealing.....0
Less than once a week 1
Once a week 2
More than once a week 3
(but less than daily)
Daily 4

Fraud

Now I am going to ask you some questions about fraud scams. By fraud I mean things such as forging cheques, forging prescriptions, social security scams, or using someone else's credit card. I am interested in the number of times that you've committed fraud, not the number of times that you've been caught.

3. How often, on average, during the last month have you committed a fraud?

No fraud 0
Less than once a week.....1
Once a week 2
More than once a week 3
(but less than daily)
Daily.....4

Crimes Involving Violence

Finally, I am going to ask you some questions about crimes involving violence. By crimes involving violence I mean things such as using violence in a robbery, armed robbery, assault, rape, etc. I am interested in the number of times that you've committed a crime involving violence, not the number of times that you've been caught.

4. How often, on average, during the last month have you committed a crime involving violence?

No violent crime 0
Less than once a week.....1
Once a week.....2
More than once a week
(but less than daily).....3
Daily.....4

CRIME TOTAL=

General Comments on Crime

_____

_____

_____

_____

_____

_____

SECTION V: HEALTH

These questions are about your health. I am going to read out a list of health problems. Please answer 'Yes' if you have had any of these problems over the last month.

General

fatigue/energy loss	
poor appetite	
weight loss/underweight	
trouble sleeping	
fever	
night sweats	
swollen glands	
jaundice	
bleeding easily	
teeth problems	
eye/vision problems	
ear/hearing problems	
cuts needing stitches	
TOTAL	

Injection Related Problems

overdose	
abscesses/infections from injecting	
dirty hit (made feel sick)	
prominent scarring/bruising	
difficulty injecting	
TOTAL	

Cardio/Respiratory

persistent cough	
coughing up phlegm	
coughing up blood	
wheezing	
sore throat	
shortness of breath	
chest pains	
heart flutters/racing	
swollen ankles	
TOTAL	

Genito-urinary

painful urination	
loss of sex urge	
discharge from penis/vagina	
rash on/around penis/vagina	
TOTAL	

Gynaecological

(WOMEN ONLY) (in the last few Months;

irregular period	
miscarriage	
TOTAL	

Musculo-skeletal

Joint pains/stiffness	
Broken bones	
muscle pain	
TOTAL	

Neurogical

headaches	
blackouts	
tremors (shakes)	
numbness/tingling	
dizziness	
fits/seizures	
difficult walking	
head injury	
forgetting things	
TOTAL	

Gastro-intestinal

nausea	
vomiting	
stomach pains	
constipation	
diarrhoea	
TOTAL	

HEALTH TOTAL

General Comments on Health

SECTION VI: PSYCHOLOGICAL ADJUSTMENT

GENERAL HEALTH QUESTIONNAIRE

Please read this carefully:

I should like to know if you have had any medical complaints, and how your health has been in general over the past few weeks. Please answer ALL the questions on the following pages simply by circling the answer that you think most nearly applies to you. Remember that we want to know about present and recent complaints, not those that you had in the past.

HAVE YOU RECENTLY:

1. Been feeling well and in good health?	Better than usual	Same as usual	Worse than usual	Much worse than usual
2. Been feeling in need of a pick me up?	Not at all	No more than usual	Rather more than usual	Much more than usual
3. Been feeling run down and out of sorts?	Not at all	No more than usual	Rather more than usual	Much more than usual
4. Felt that you are ill?	Not at all	No more than usual	Rather more than usual	Much more than usual
5. Been getting any pains in your head?	Not at all	No more than usual	Rather more than usual	Much more than usual
6. Been getting a feeling of tightness or pressure in your head?	Not at all	No more than usual	Rather more than usual	Much more than usual
7. Been having hot or cold spells?	Not at all	No more than usual	Rather more than usual	Much more than usual
8. Lost much sleep over worry?	Not at all	No more than usual	Rather more than usual	Much more than usual
9. Had difficulty in staying asleep once you are off?	Not at all	No more than usual	Rather more than usual	Much more than usual
10. Felt constantly under strain?	Not at all	No more than usual	Rather more than usual	Much more than usual
11. Been getting edgy and bad tempered?	Not at all	No more than usual	Rather more than usual	Much more than usual
12. Been getting scared or panicky for no good reason?	Not at all	No more than usual	Rather more than usual	Much more than usual

13. Found everything getting on top of you?	Not at all	No more than usual	Rather more than usual	Much more than usual
14. Been feeling nervous and strung up all the time?	Not at all	No more than usual	Rather more than usual	Much more than usual
15. Been managing to keep busy and occupied?	More so than usual	Same as usual	Rather less than usual	Much less than usual
16. Been taking longer over the things you do?	Quicker than usual	Same as usual	Longer than usual	Much longer than usual
17. Felt on the whole you were doing things well?	Better than usual	About the same	Less well than usual	Much less well
18. Been satisfied with the way you've carried out your task?	More satisfied	About the same	Less than usual	Much less satisfied
19. Felt that you are playing a useful part in things?	More so than usual	Same as usual	Less useful than usual	Much less useful
20. Felt capable of making decisions about things?	More so than usual	Same as usual	Less so than usual	Much less capable
21. Been able to enjoy your normal day to day activities?	More so than usual	Same as usual	Less so than usual	Much less than usual
22. Been thinking of yourself as a worthless person?	Not at all	No more than usual	Rather more than usual	Much more than usual
23. Felt that life is entirely hopeless?	Not at all	No more than usual	Rather more than usual	Much more than usual
24. Felt that life is not worth living?	Not at all	No more than usual	Rather more than usual	Much more than usual
25. Thought of the possibility that you might do away with yourself?	Definitely not	I don't think so	Has crossed my mind	Definitely have

26. Found at times that you couldn't do anything because your nerves were so bad?	Not at all	No more than usual	Rather more than usual	Much more than usual
27. Found yourself wishing you were dead and away from it all?	Not at all	No more than usual	Rather more than usual	Much more than usual
28. Found that the idea of taking your own life kept coming into your mind?	Definitely not	I don't think so	Has crossed my mind	Definitely has

GHQ SUMMARY DATA

A	B	C	D	TOTAL

General Comments on Health

OPIATE TREATMENT INDEX SCORE SHEET

SCALES

	Drug use (Poly)	HIV risk	Social	Crime	Health	GHQ
Initial						
F/up 1						
F/up 2						

DRUG USE SCORES

	Initial	F/up 1	F/up 2
Heroin			
Other opiates			
Alcohol			
Cannabis			
Amphetamines			
Cocaine			
Tranquillizers			
Barbiturates			
Hallucinogens			
Inhalants			
Tobacco			

Appendix 3: Description of the OTI domains

- Section I: Demographics and drug treatment history

This section is not used for the purposes of this study as socio-demographic characteristics and drug treatment histories are covered as a separate section in Part 1 of the questionnaire, for which specific questions were developed.

- Section II: Drug Use

This domain measures the use of illegal and legal drugs by an individual in eleven drug classes: heroin, other opioids, alcohol, cannabis, amphetamines, cocaine, tranquillisers, barbiturates, hallucinogens, inhalants and tobacco. For each drug used, episodes of use are measured rather than the quantity used, due to the difficulty associated with measuring the actual amount of drug used in any given instance. A score for each category of drug used is calculated through a simple formula (*the total number of use episodes in the two most recent days of use, divided by the total time interval between the days of use, within the month prior to interview).* There are two main scores that can be calculated from this section, the first being a poly drug use total, which is a total of the number of drugs used in the month prior to the interview and the second being the drug use risk score, which totals the scores for each drug used in the month prior to the interview. The poly drug use total score is the one used in the OTI total score. A higher score in either of the sections indicates greater risk.

- Section III: Injecting and Sexual Practices

This section measures risk for an individual associated with injecting and sexual risk behaviour, in the last month prior to interview through a series of 11 questions. Each question has a rating from 0-5, zero indicates no risk from that particular behaviour, while any score above zero indicates risk, and the higher the score the greater the risk. This section measures an injecting risk score and a sexual risk score, and the total of these two produce a total BBV risk score, which can range from 0-55.

- Section IV: Social Functioning

This section has 12 questions that measure social adjustment in the last six months prior to interview, under the broad headings of employment, accommodation and personal relationships. Each question is scored from 0-4, with zero indicating no dysfunction in that particular section. The question scores are summed to elicit a total social function score that can range from 0-48.

- Section V: Crime

This section measures criminal activity of an individual in the month prior to interview in four classes of crime; property crime, drug dealing, fraud and crimes involving violence. Each class is scored from 0-4, zero indicating no crime committed in that class. Score for the four classes are summed to elicit a total score that can range from 0-16.

- Section VI: Health

In this section health status of an individual is measured by the presence or absence of symptomatology in eight health areas mostly in the month prior to interview. The eight areas covered are general health, injection related problems, cardio/respiratory, genito-urinary, gynaecological, musculo-skeletal, neurological and gastro-intestinal systems. Gynaecological symptoms are measured for a few months prior to interview. There are 52 symptoms scored in total over the eight areas. A person can have a 0 or 1 score for each of these symptoms depending on whether or not they have experienced the symptom generally in the month prior to interview. Scores for each system are summed to provide a total health score that can range from 0-52. The greater the section score or total health score, the poorer the health outcomes.

- Section VII: Psychological adjustment as measured by the General Health Questionnaire

This section incorporates the General Health Questionnaire-28 (GHQ-28) and measures psychopathology through four classes: somatic symptoms, anxiety, social dysfunction and depression. Scores range from 0-7 in each class and total scores from the four classes can range from 0-28. A higher score indicates greater dysfunction.

Appendix 4: Information sheet and consent form for participants

THE AUSTRALIAN NATIONAL UNIVERSITY
ACT COMMUNITY CARE
SOUTHERN AREA HEALTH SERVICE

MEASURING OUTCOMES FOR METHADONE PROGRAM CLIENTS

Information Sheet & Consent Form

About the study

The purpose of this study is to look at outcomes such as general health, other drug use, risk of contracting HIV, hepatitis B (HBV) and hepatitis C (HCV) and integration into the community for people on the methadone program. By speaking with people on the methadone program directly, it is hoped that outcomes based on your perception will be gathered. The researchers envisage that the results will be used to inform the future planning and delivery of services for methadone program clients.

There are three components to the study, the first will compare outcomes between urban and rural clients, the second will compare outcomes over time for clients in the Australian Capital Territory (ACT) and the third will compare self-report of HIV, HBV and HCV with blood test results.

How the study will be conducted

You will be asked to fill in a questionnaire after which a trained interviewer will ask you a few more questions and the same person will collect a finger prick blood sample. The interview will take approximately one hour including the finger prick blood test, which is a minor procedure, with very little discomfort, and there are no recorded adverse effects.

Confidentiality and anonymity

The questionnaire will be completely anonymous. There will be no identifying details put on the questionnaire. The questionnaire will have a record number, which will be linked to the blood spot. We cannot provide individual test results because finger prick testing in Australia is used only for research and cannot be used for clinical or diagnostic purposes. If you wish to know your HIV, hepatitis B or hepatitis C status, the interviewer administering the questionnaire can organize this for you. Only the research team will have access to the information collected. No publications from this research will identify any individuals.

Storing of Information

All the information from this research will be kept under lock and key, and only the principal investigator will have direct access to it.

Feedback
You can access results of this study, once completed through a report that will be made available at methadone clinics and dosing centres. You can also contact the National Centre for Epidemiology and Population Health (details listed below) and arrangements will be made to forward a report to you directly.

Inquiries
Any inquiries can be directed to the principal investigator Geetha Isaac-Toua on (02) 6125 5602, at the National Centre of Epidemiology and Population Health, the Australian National University.
Further inquiries may be directed to Mrs. Sylvia Deutsch, Human Ethics Officer, Research Services Office, Australian National University on (02) 6125 2900 or e-mail, Human.Ethics.Officer@anu.edu.au.

Your consent to participate in this research is by verbal consent, witnessed by an agency staff member and the researcher. This is to protect your confidentiality and provide anonymity to the information you provide. If you do agree to the interview, you are free to discontinue the discussion at any time. You will be given $15.00 at the completion of the interview to reimburse you for your time and any out of pocket expenses.

The record number below is the number recorded on your questionnaire and blood sample. If you wish to withdraw from the study please contact Geetha Isaac-Toua or Sylvia Deutsche and mention the record number and any information relating to this record number will be destroyed. You can withdraw from the study at any time without giving a reason and without penalty. You will be given a copy of this information sheet with your record number for your records.

Although all possible precautions will be taken to protect the confidentiality of the information you give, there is no legal protection of this information. No information about you will be given to anyone else unless you decide that you are in need of assistance.

Your participation would be extremely helpful, but there is no pressure on you to take part and your access to services will not be affected if you decline. If you have any questions relating to this research or participation in the research study please contact Geetha Isaac-Toua or Sylvia Deutsche.

Record number: _____

Appendix 5: Non-respondent questionnaire

Comparison of Outcomes for Methadone Treatment Program Clients

Non respondent Questionnaire

Record number:	_____
Date:	____/____/____
Area code: (ACT = 1) (SNSW = 2)	_____
Interviewer:	_____

2002

The National Centre for Epidemiology and Population Health

Australian National University

Q1. How old are you? _____ Years

Q1. What sex are you?

Male$_1$ Female$_2$ Transexual$_3$

Q3. What is the highest level of education you have completed? (Tick one box)

Postgraduate qualification	☐ 1
Bachelor degree	☐ 2
TAFE certificate (eg. trade)	☐ 3
High school certificate (year 12)	☐ 4
Leaving/school certificate (year 10)	☐ 5
Left high school before leaving certificate (before year 10)	☐ 6
Did not attend high school	☐ 7
Completed primary school	☐ 8
Attended primary school	☐ 9

Q4. How are you employed at the moment?

Unemployed $_1$ Full-time $_2$ Part-time/casual $_3$ Student $_4$

Home duties $_5$ Other $_{80}$ (please specify) _____

Q5. What is your current marital status?

Never married $_1$ Married/Defacto $_2$ Separated $_3$ Divorced $_4$

Widowed $_5$ Other $_{80}$ (please specify) _____

Q6. Have you ever been in prison? (Including remand/police cells)

No$_0$ Yes$_1$

Q7. Do you identify as an Aboriginal or Torres Strait Islander?

No $_0$ Yes $_1$

Q8. How many months have you been on this program?_____ Months

Q9. Is this the first time you have been on a methadone program?

No $_0$ Yes $_1$

Q10. Which of the following would best describe your program?

Public $_1$ Partly public/partly private $_2$ Private $_3$ Don't know $_{90}$

Q11. How satisfied are you with this program?

Very satisfied $_1$ Satisfied $_2$ Unsatisfied $_3$ Very unsatisfied $_4$

Don't know $_{90}$

Q12. What is your residential Post-code? _____

Q13. Why don't you want to take part in the study?

_____

_____

_____

_____

_____

_____

Appendix 6: Poster advertising study

April/May 2002

ATTENTION ALL METHADONE TREATMENT PROGRAM CLIENTS

STUDY ON

Methadone Program Treatment Outcomes

You maybe approached by your methadone program coordinator in the next month or so, to participate in a study looking at outcomes for people on the program. This study is being carried out to find out how well the program works from your perspective. It will look at expenses associated with the program, service provided, convenience relating to clinic times, travel distances, and whether the program has helped you to achieve outcomes to improve your quality of life. The study will also compare the ACT Program with the Southern New South Wales program to look at differences.

The study is completely independent of the Health Service and is being carried out by qualified researchers from the Australian National University. It is completely anonymous and confidential and interviews will be conducted outside the clinic. There will be no information kept that will link your true identity to information provided by you for the study.

By participating in this study, you will be available to provide valuable information regarding whether the program suits you or not, and how it could be better improved to assist with your life.

Appendix 7: Recruitment sheet for methadone coordinators

Tier 1

Number from database	Sample number	Yes/No

Appendix 8: Appointment schedule

APPOINTMENT SCHEDULE: INTERVIEWER NAME (eg: GEETHA)

Methadone Treatment Program Study 2002

WEEK 1 (18th March to 24th March)

Time/day	Monday 18th Mar	Tuesday 19th Mar	Wednesday 20th Mar	Thursday 21st Mar	Friday 22nd Mar	Saturday 23rd Mar	Sunday 24th Mar
10.00 am – 12.00 pm							
12.30 pm – 2.30 pm							
3.00pm – 5.00pm							

Notes:

Appendix 9: Recruitment Sheet: Tiers 2 and 3

Number on database	Sample Number	Pharmacy

Appendix 10: Recruitment sheet by pharmacy

Pharmacy: ***(eg: Devlins' City Pharmacy)***

Number from database	Name of client	Sample number	Yes/No

Appendix 11: Information sheet for ACT participants recruited through community pharmacies

THE AUSTRALIAN NATIONAL UNIVERSITY
ACT COMMUNITY CARE
SOUTHERN AREA HEALTH SERVICE

NATIONAL CENTRE FOR EPIDEMIOLOGY AND POPULATION HEALTH

MEASURING OUTCOMES FOR METHADONE PROGRAM CLIENTS

(Information sheet for ACT participants recruited through pharmacies)

You have been randomly selected to participate in the methadone program outcomes study and you may have already been asked if you wish to participate. The interview will take about an hour and you will be re-imbursed $15.00 for your time and out of pocket expenses.

If you wish to participate please contact Angie Creed on 6205 1000 or Geetha on 0414 695 840 to make a time for the interview. You can meet the interviewer either at the Griffin Center at Civic or at the Drug and Alcohol Clinic at Woden.

You need to make an appointment by the 28th of June 2002 to be eligible to participate. All information regarding the study has been outlined on the attached information sheet. Please mention your sample number ....., and not your name, when you make your appointment.

Your participation is much appreciated and the information provided will be used towards trying to improve the programme as per your needs.

Appendix 12: Information sheet for SNSW participants recruited through community pharmacies

THE AUSTRALIAN NATIONAL UNIVERSITY
ACT COMMUNITY CARE
SOUTHERN AREA HEALTH SERVICE

NATIONAL CENTRE FOR EPIDEMIOLOGY AND POPULATION HEALTH

MEASURING OUTCOMES FOR METHADONE PROGRAM CLIENTS

(Information sheet for SNSW participants recruited through pharmacies)

You have been randomly selected to participate in the methadone program outcomes study. The interview will take about an hour and you will be re-imbursed $15.00 for your time and out of pocket expenses.

If you wish to participate please contact Geetha on 0414 695 840 to make a time and place for the interview. You have also been given a phone card to enable you to make the phone call without any out of pocket expenses. We are also available on weekends, to enable to fit into your work or other commitments.

You need to make an appointment by the 27th October 2002 to be eligible to participate. All information regarding the study has been outlined on the attached information sheet. Please mention your sample number ....., and not your name, when you make your appointment.

Your participation is much appreciated and the information provided will be used towards trying to improve the programme as per your needs.

Appendix 13: Information and interview schedule for selected rural Tier 3 clients

THE AUSTRALIAN NATIONAL UNIVERSITY
ACT COMMUNITY CARE
SOUTHERN AREA HEALTH SERVICE

NATIONAL CENTRE FOR EPIDEMIOLOGY AND POPULATION HEALTH

MEASURING OUTCOMES FOR METHADONE PROGRAM CLIENTS (Interview details)

(Information and interview schedule for selected rural Tier 3 clients, given at GP practices)

Thank you for agreeing to participate in the methadone program outcomes study. The interview will take about an hour and you will be re-imbursed $15.00 for your time and out of pocket expenses.

Your interview date is: .....

Your interview time is: .....

Your interview venue: ..... Community Health Center

Your study sample number: .....

All information regarding the study has been outlined on the attached information sheet. Please mention your sample number only and not your name, when you come for your interview.

If you need to change times or are unable to attend for unforeseen reasons please contact Geetha on 0414 695 840

Your participation is much appreciated and the information provided will be used towards trying to improve the programme as per your needs.

Appendix 14: Tables comparing mean score for eight areas/systems of physical health status

Table 1: Comparison of general health issue mean scores: Overall sample & by tier

Characteristics	Overall sample N=118	ACT N=62	SNSW N=56	p-values (Pearson X^2)
Total sample				
n	116[a]	60[a]	56	
Mean score	5.06	4.92	5.21	0.52
SD	2.48	2.48	2.50	
Range	0-11	0-11	0-11	
Tier 1				
n	52[b]	25[b]	27	
Mean score	5.15	4.84	5.44	0.44
SD	2.80	2.41	3.13	
Range	0-11	1-10	0-11	
Tier 2				
n	33[b]	20[b]	13	
Mean score	5.09	5.00	5.23	0.79
SD	2.40	2.87	1.54	
Range	0-11	0-11	3-8	
Tier 3				
n	31	15	16	
Mean score	4.87	4.93	4.81	0.87
SD	2.03	2.19	1.94	
Range	1-9	1-8	2-9	

[a] *Two missing values,* [b] *one missing value*

Table 2: Comparison of injecting problems mean scores: Overall sample & by tier

Characteristics	Overall sample N=118	ACT N=62	SNSW N=56	p-values (Pearson X^2)
Total sample	116[a]	60[a]	56	
n	0.43	0.43	0.43	0.97
Mean score	0.83	0.85	0.81	
SD	0-3	0-3	0-3	
Range				
Tier 1				
n	52[b]	25[b]	27	
Mean score	0.40	0.36	0.44	0.46
SD	0.80	0.86	0.75	
Range	0-3	0-3	0-2	
Tier 2				
n	33[b]	20[b]	13	
Mean score	0.36	0.40	0.31	0.74
SD	0.90	0.94	0.85	
Range	0-3	0-3	0-3	
Tier 3				
n	31	15	16	
Mean score	0.55	0.60	0.50	0.48
SD	0.81	0.74	0.89	
Range	0-3	0-2	0-3	

[a] *Two missing values,* [b] *one missing value*

Table 3: Comparison of cardio-respiratory problem mean scores: Overall sample & by tier

Characteristics	Overall sample N=118	ACT N=62	SNSW N=56	p-values (Pearson X^2)
Total sample				
n	116[a]	60[a]	56	
Mean score	2.90	2.78	3.02	0.45
SD	2.33	2.44	2.22	
Range	0-9	0-9	0-8	
Tier 1				
n	52[b]	25[b]	27	
Mean score	2.87	2.48	3.22	0.22
SD	2.16	2.18	2.12	
Range	0-7	0-6	0-7	
Tier 2				
n	33[b]	20[b]	13	
Mean score	2.79	3.10	2.31	0.52
SD	2.45	2.81	1.75	
Range	0-9	0-9	0-5	
Tier 3				
n	31	15	16	
Mean score	3.06	2.87	3.25	0.75
SD	2.54	2.45	2.70	
Range	0-8	0-7	0-8	

[a] *Two missing values,* [b] *one missing value*

Table 4: Comparison of genito-urinary problems mean scores: Overall sample & by tier

Characteristics	Overall sample N=118	ACT N=62	SNSW N=56	p-values (Pearson X^2)
Total sample				
n	116[a]	60[a]	56	
Mean score	0.70	0.68	0.71	0.93
SD	0.76	0.72	0.80	
Range	0-4	0-3	0-4	
Tier 1				
n	52[a]	25[a]	27	
Mean score	0.62	0.76	0.48	0.21
SD	0.75	0.83	0.64	
Range	0-3	0-3	0-2 0	
Tier 2				
n	33[a]	20[a]	13	
Mean score	0.64	0.60	0.69	0.94
SD	0.70	0.60	0.85	
Range	0-2	0-2	0-2	
Tier 3				
n	31	15	16	
Mean score	0.90	0.67	1.13	0.11
SD	0.83	0.72	0.89	
Range	0-4	0-2	0-4	

[a] *Two missing values,* [b] *one missing value*

Table 5: Comparison of musculo-skeletal problems mean scores: Overall sample & by tier

Characteristics	Overall sample N=118	ACT N=62	SNSW N=56	p-values (Pearson X^2)
Total sample				
n	116[a]	60[a]	56	
Mean score	1.17	1.03	1.32	0.07
SD	0.87	0.90	0.81	
Range	0-3	0-3	0-2	
Tier 1				
n	52[b]	25[b]	27	
Mean score	1.19	1.08	1.30	0.36
SD	0.91	0.95	0.87	
Range	0-3	0-3	0-2	
Tier 2				
n	33[b]	20[b]	13	
Mean score	1.09	0.95	1.31	0.25
SD	0.84	0.89	0.75	
Range	0-2	0-2	0-2	
Tier 3				
n	31	15	16	
Mean score	1.23	1.07	1.38	0.32
SD	0.84	0.88	0.81	
Range	0-2	0-2	0-2	

[a] *Two missing values,* [b] *one missing value*

Table 6: Comparison of neurological problems mean scores: Overall sample & by tier

Characteristics	Overall sample N=118	ACT N=62	SNSW N=56	p-values (Pearson X^2)
Total sample				
n	116[a]	60[a]	56	
Mean score	2.53	2.35	2.73	0.31
SD	1.94	1.91	1.98	
Range	0-7	0-7	0-7	
Tier 1				
n	52[b]	25[b]	27	
Mean score	2.50	2.20	2.78	0.25
SD	1.96	1.91	1.99	
Range	0-7	0-6	0-7	
Tier 2				
n	33[b]	20[b]	13	
Mean score	2.73	2.55	3.00	0.49
SD	1.88	1.96	1.78	
Range	0-6	0-6	1-6	
Tier 3				
n	31	15	16	
Mean score	2.39	2.33	2.44	0.97
SD	2.04	1.95	2.19	
Range	0-7	0-7	0-7	

[a] *Two missing values,* [b] *one missing value*

Table 7: Comparison of gastro-intestinal problems mean scores: Overall sample & by tier

Characteristics	Overall sample N=118	ACT N=62	SNSW N=56	p-values (Pearson X^2)
Total sample				
n	116[a]	60[a]	56	
Mean score	1.89	1.78	2.00	0.50
SD	1.58	1.55	1.62	
Range	0-5	0-5	0-5	
Tier 1				
n	52[a]	25[a]	27	
Mean score	1.62	1.36	1.85	0.30
SD	1.55	1.50	1.59	
Range	0-5	0-5	0-5	
Tier 2				
n	33[a]	20[a]	13	
Mean score	2.06	2.10	2.00	0.76
SD	1.69	1.62	1.87	
Range	0-5	0-5	0-5	
Tier 3				
n	31	15	16	
Mean score	2.16	2.07	2.25	0.75
SD	1.49	1.49	1.53	
Range	0-5	0-5	0-5	

[a] *Two missing values,* [b] *one missing value*

Table 8: Comparison of gynaecological problems mean scores: Overall sample & by tier (females only)

Characteristics	Overall sample N=49	ACT N=27	SNSW N=22	p-values (Pearson X^2)
Total sample				
n	49	27	22	
Mean score	0.63	0.67	0.59	0.61
SD	0.57	0.55	0.59	
Range	0-2	0-2	0-2	
Tier 1				
n	23	13	10	
Mean score	0.52	0.62	0.40	0.32
SD	0.51	0.51	0.52	
Range	0-1	0-1	0-1	
Tier 2				
n	10	7	3	
Mean score	0.80	0.86	0.67	0.70
SD	0.63	0.69	0.58	
Range	0-2	0-2	0.70	
Tier 3				
n	16	7	9	
Mean score	0.69	0.57	0.78	0.55
SD	0.60	0.53	0.67	
Range	0-2	0-1	0-2	

Appendix 15: Univariate analysis identifying factors significantly associated with THS within urban and rural study groups

Factors	ACT (n=62)					SNSW (n=56)				
	n	β	SE	p-value	R^2	n	β	SE	p-value	R^2
Age	61	-0.08	0.09	0.37	0.01	55	-0.04	0.09	0.62	0.001
Gender *(Male)**	35					34				
Female	27	-1.25	2.01	0.54	0.01	22	4.98	1.94	**0.01**	0.11
Education level *(< Yr 10)**	11					18				
Completed Yr 10	14	1.55	3.25	0.64	0.02	12	-4.63	2.62	**0.08**	0.19
Completed Yr 12	13	2.67	3.31	0.42		7	0.23	3.13	0.94	
Tertiary	23	0.57	2.91	0.85		17	4.42	2.38	**0.07**	
Employment status *(Unemployed)**	16					13				
Employed	5	-6.33	2.70	**0.02**	0.13	10	-0.01	3.21	1.00	0.02
Student	2	-5.3	5.56	0.34		3	3.03	4.88	0.54	
Other (pension, home duties, sick leave)	29	-0.12	2.36	0.96		30	1.79	2.53	0.48	
Main income source in the last 6 months *(Other)**	43					50				
Employment sources	18	-5.75	2.07	**0.008**	0.12	6	-1.41	3.25	0.67	0.003
Prison history *(No)**	31					27				
Yes	30	2.99	1.94	0.13	0.04	28	1.62	2.04	0.43	0.01
Age first injected drugs	61	0.09	0.08	0.31	0.02	54	-0.04	0.07	0.59	0.001
Age started injecting regularly	58	0.04	0.05	0.49	01	54	-0.02	0.07	0.72	0.002
Program Tier *(Tier 1)**	26					27				
Tier 2	21	1.62	2.34	0.49	0.01	13	-0.67	2.57	0.79	0.002
Tier 3	15	1.45	2.55	0.57		16	0.23	2.40	0.92	
First time on programme *(No)**	34					28				
Yes	27	2.41	1.23	0.22	0.03	28	0.14	2.02	0.94	0.0001

Factors	ACT(n=62)					SNSW (n=56)				
	n	β	SE	p-value	R^2	n	β	SE	p-value	R^2
No of other times on programme *(First time)**	30					28				
1-3 times	24	-2.10	2.14	0.17	0.04	23	-0.89	2.14	0.68	0.02
3-6 times	8	-0.16	3.04	0.96		3	3.50	4.61	0.45	
>6 times	0			dropped		2	3.00	5.56	0.59	
Length of time on programme *(Months)**	61	-0.01	0.03	0.68	0.003	55	-0.01	0.03	0.84	0.0007
Methadone dose mgs *(1-20mgs)**	9					10				
21-40	12	-1.92	3.62	0.60	0.06	14	-1.04	3.07	0.74	0.11
41-60	16	-4.38	3.37	0.20		11	-2.49	3.24	0.45	
61-80	12	-0.96	3.55	0.79		10	-4.90	3.32	0.15	
81-100	9	-5.04	3.78	0.19		8	-5.90	3.52	0.10	
>100	3	-1.04	5.27	0.84		2	-9.4-	5.75	0.10	
Cost of methadone per week *(No cost)**	6					27				0.05
Up to $15.00	50	3.69	1.14	0.26	0.10	2	6.98	5.30	0.19	
> $15.00	6	10.33	2.40	**0.02**		26	-1.29	1.99	0.52	
Access to routine takeaways *(No)**	24					28				
Yes	38	3.05	2.05	0.14	0.02	28	0.07	2.02	0.97	0.000
Travel time to dose *(Up to 1 hour)**	56					52				
> 1 hour	6	4.16	3.60	0.25	0.02	4	0.35	3.91	0.93	0.0001
Travel cost to dose *(<$5.00)**	53					38				
> $5.00	9	0.67	2.81	0.81	0.001	18	2.72	2.13	0.21	0.03
Total number of other drugs used in the month prior to interview	61	0.34	0.50	0.62	0.004	56	1.63	0.77	**0.04**	0.08

Factors	ACT (n=62)					SNSW (n=56)				
	n	β	SE	p-value	R^2	n	β	SE	p-value	R^2
Injected in the month prior to interview *(No)**	29					28				
Yes	33	-1.31	2.01	0.52	0.007	28	0.36	2.02	0.86	0.001
Frequency of injecting in the month prior to interview *(Did not inject)**	29					28				
Once a week or less	15	-1.30	2.54	0.61	0.008	18	-0.64	2.26	0.78	0.05
More than once a week, but not daily	14	-1.49	2.60	0.57		8	0.50	3.00	0.87	
Daily or more than once a day	4	-0.70	4.23	0.87		2	8.75	5.48	0.11	
Shared injecting equipment in the month prior to interview *(No)**	31					28				
1-2 times	2	12.35	4.99	**0.02**	0.17	0			dropped	0.01
> 2times	0			dropped		2	2.58	5.75	0.66	
Living with someone who injects drugs *(No)**	37					33				
Yes	13	-1.28	2.62	0.63	0.01	11	-3.33	2.44	0.18	0.04
Cost per prescriber appointment *(No cost)**	55					42				
Up to $30.00	3	1.31	4.65	0.78	0.004	8	-0.38	2.93	0.90	0.002
> $30.00	4	-1.5	4.06	0.71		6	0.95	3.32	0.78	
Time in between prescriber appointments *(Once a month or >)**	10					21				
3 monthly	50	-3.80	2.65	0.16	0.06	35	0.83	2.08	0.69	0.003
6 monthly	2	3.60	5.90	0.54		0			dropped	
Case manager *(No)**	44					13				
Yes	18	4.63	2.11	**0.03**	0.08	43	1.66	2.38	0.49	0.01
Program satisfaction *(Satisfied)**	43					36				
Unsatisfied	15	5.31	2.27	**0.02**	0.09	18	4.81	2.08	**0.03**	0.09

* *Reference categories*

Appendix 16: Univariate analysis identifying factors significantly associated with injecting within urban and rural study groups

Factors	ACT (n=62)					SNSW (n=56)				
	n	OR	CI	p-value	PsuedoR^2	n	OR	CI	p-value	PsuedoR^2
Age	62	1.00	0.96-1.05	0.89	0.0002	56	1.01	0.96-1.06	0.74	0.002
Gender	62					56				0.003
Male*		0.69	0.25-1.91	0.48	0.006		0.74	0.25-2.17	0.59	
Female										
Education level	61					54				0.10
< Yr 10*										
Completed Yr 10		0.90	0.18-4.41	0.90	0.07		0.80	0.18-3.46	0.77	
Completed Yr 12		0.75	0.15-3.83	0.73			4.80	0.48-48.46	0.18	
Tertiary		3.40	0.75-15.36	0.11			0.33	0.08-1.34	0.12	
Employment status	62					56				0.11
Unemployed*										
Employed		2.75	0.61-12.41	0.19	0.04		0.08	0.01-0.56	**0.01**	
Student		1.00	0.05-18.91	1.00			0.15	0.01-2.29	0.17	
Other (pension, home duties, sick leave)		0.81	0.24-2.76	0.74			0.30	0.07-1.31	0.11	
Main income source in the last 6 months	61					56				0.10
Other*										
Employment sources		3.28	0.99-10.84	**0.05**	0.05		0.46	0.08-2.75	0.40	
Prison history	61					55				0.0002
No*										
Yes		1.6	0.58-4.41	0.36	0.01		1.08	0.37-3.10	0.89	

Factors	ACT (n=62)					SNSW (n=56)				
	n	OR	CI	p-value	PsuedoR^2	n	OR	CI	p-value	PsuedoR^2
Missed doses	62				0.02	55				0.03
None*										
Up to 2		1.04	0.30-3.57	**0.06**			1.10	0.31-3.91	0.88	
> 2		2.09	0.56-7.85	1.09			2.86	0.67-12.11	0.15	
Program Tier	62					56				0.05
Tier 1*										
Tier 2		0.75	0.24-2.38	0.63	0.04		0.26	0.63-1.07	**0.06**	
Tier 3		2.75	0.69-10.92	0.15			0.46	0.13-1.61	0.22	
Length of time on programme (months)	62	1.00	0.98-1.01	0.26	0.01					
Methadone dose (mgs)	60					53				0.11
1-20*										
21-40		6.00	0.89-40.31	**0.07**	0.06		1.67	0.30-9.27	0.56	
41-60		3.33	0.60-18.54	0.17			0.80	0.14-4.53	0.80	
61-80		2.00	0.33-11.97	0.45			0.67	0.11-3.92	0.65	
81-100		1.60	0.24-10.81	0.63			0.10	0.01-1.25	0.15	
>100		1.00	0.06-15.999	1.00						
Cost of methadone per week	62					53				0.05
No cost*										
Up to $15.00		1.08	0.20-5.89	0.93	0.006		0.39	0.12-1.29	0.12	
> $15.00		2.00	0.19-20.61	2.38			0.29	0.05-1.91	0.20	
No. of takeaway doses	61					53				0.05
None*										
Up to 2		0.53	0.14-1.94	0.33	0.01		0.34	0.03-4.27	0.41	
> 2		0.60	0.18-1.94	0.39			0.37	0.11-1.22	0.10	

Factors	ACT (n=62)						SNSW (n=56)			
	n	OR	n	OR	n	OR	n	OR	n	OR
Travel time to dose	62					52				
Up to 1 hour*								dropped		
> 1 hour		0.15	0.02-1.37	**0.09**	0.04					
Travel cost to dose	62					56				
≤ $5.00*										
≥ $5.00		0.66	0.16-2.74	0.57	0.004		1.00	0.33-3.07	1.00	0.00
Total number of other drugs used in the month prior to interview	61	2.43	1 43-4.12	**0.001**	0.19	56	2.59	1.47-4.58	**0.001**	0.19
Living with someone who injects drugs	60					44				
No*										
Yes		8.07	1.56-41.73	**0.01**	0.12		15.38	1.75-134.87	**0.01**	0.16
Case manager	62					56				
No*										
Yes		3.12	0.95-10.25	**0.06**	0.04		1.22	0.35-4.24	0.75	0.001
Program satisfaction	58					54				
Satisfied*										
Unsatisfied		0.63	0.29-2.05	0.44	0.007		0.72	0.23-2.23	0.56	0.005

**Reference category*

Appendix 17: Univariate analysis identifying factors significantly associated with injecting within urban and rural study groups

Factors	ACT (n=32)					SNSW (n=28)				
	n	β	SE	p-value	R^2	n	β	SE	p-value	R^2
Age	32	0.37	0.17	**0.04**	0.13	28	-0.13	0.13	0.32	0.001
Gender	32					28	0.39	3.89	0.92	-.0004
Male*										
Female		4.64	3.15	0.15	0.07					
Education level	32					27				
< Yr 10*										
Completed Yr 10		-9.70	5.16	**0.07**	0.18		-5.87	5.20	0.27	0.05
Completed Yr 12		-11.60	5.39	**0.04**			-2.70	5.20	0.61	
Tertiary		-9.58	4.37	**0.04**			-1.40	5.5	0.80	
Employment status	32					28				0.03
Unemployed*										
Employed		-2.74	4.23	0.52	0.13		-5.10	7.39	0.50	
Student		15.71	9.36	0.10			-1.10	10.01	0.91	
Other (pension, home duties, sick leave)		-0.13	4.11	0.98			5.7	3.90	0.16	
Main income source in the last 6 months	31					28				0.05
Other*										
Employment sources		0.67	2.25	0.77	0.003		-8.35	7.05	0.25	
Prison history	32					27				0.03
No*										
Yes		2.22	3.19	0.49	0.02		4.99	3.74	0.20	

Factors	ACT (n=32)					SNSW (n=28)				
	n	β	SE	p-value	R^2	n	β	SE	p-value	R^2
Program Tier	32					28				0.004
Tier 1*										
Tier 2		6.38	3.65	**0.09**	0.17		-1.49	5.58	0.79	
Tier 3		2.75	3.54	0.44			-1.09	4.51	0.81	
Length of time on programme (months)	32	-0.05	0.05	0.33	0.03	28	-0.06	0.05	0.18	0.07
Methadone dose (mgs)	32					28				0.28
1-20*										
21-40		5.44	6.30	0.40	0.06		8.3	4.59	**0.08**	
41-60		4.11	6.30	0.52			-3.17	5.13	0.54	
61-80		2.00	6.69	0.77			-1.80	5.38	0.74	
81-100		1.08	7.22	0.88			-6.00	9.59	0.54	
>100		-2.67	10.92	0.81			dropped			
Cost of methadone per week	32					27				0.04
No cost*										
Up to $15.00		5.36	5.55	0.34	0.03		Dropped			
> $15.00		4.75	6.94	0.50			-4.34	3.05	0.17	
No. of takeaway doses	32					27				0.42
None*										
Up to 2		6.93	3.88	**0.08**	0.15		29.76	8.02	**0.001**	
> 2		-2.57	3.46	0.46			-4.57	3.21	0.17	
Missed doses	32					28				0.08
None*										
Up to 2		0.81	4.04	0.84	0.09		-1.09	4.76	0.81	
> 2		7.49	3.98	**0.07**			4.71	4.67	0.32	
HCV status	32					26				
Negative*										
Positive		5.98	3.48	**0.10**	0.12		-7.62	5.29	0.16	

Factors	ACT (n=32)					SNSW (n=28)				
	n	β	SE	p-value	R^2	n	β	SE	p-value	R^2
Travel time to dose	32					28				
Up to 1 hour*										
> 1 hour		-5.97	9.15	0.52	0.01			dropp d		
Travel cost to dose	32					28				0.006
≤ $5.00*										
≥ $5.00		3.96	4.80	0.42	0.02		-1.60	3.98	0.69	
Total number of other drugs used in the month prior to interview	32	1.50	1.22	0.23	0.05	28	1.79	1.58	0.27	0.01
Frequency of injecting	32				0.24	28				0.46
Did not inject*										
Weekly or greater		-13.65	4.53	**0.005**			-25.61	5.47	**<0.0001**	
>weekly but < daily		-10.02	4.60	**0.04**			-23.75	5.80	**<0.0001**	
Daily or > once a day		dropped					dropped			
Living with someone who injects drugs	32					23				0.0005
No*										
Yes		1.82	3.67	0.62	0.01		-0.47	4.42	0.92	
Case manager	32					28				0.06
No*										
Yes		4.08	3.23	0.22	0.05		5.62	4.41	0.21	
Program satisfaction	31					27				
Satisfied*										
Unsatisfied		-5.83	3.48	0.16	0.11		3.77	3.99	0.35	0.03

**Reference category*