Kate Dolan, James Shearer, Bethany White & Alex Wodak

A randomised controlled trial of methadone maintenance treatment in NSW prisons

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A RANDOMISED CONTROLLED TRIAL OF METHADONE MAINTENANCE TREATMENT IN NSW PRISONS

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EXECUTIVE SUMMARY

Evidence of the effectiveness of methadone maintenance treatment (MMT) in reducing heroin injection and HIV infection among injecting drug users (IDUs) in community settings has been well documented (Ward et al, 1998). However, many IDUs spend time in prison where approximately half continue to inject and typically share syringes (Butler et al, 1997). Yet few countries operate methadone maintenance programs for IDUs in prison.

This report documents a randomised controlled study of the NSW prison methadone program. Over 923 inmates were screened for suitability for participation in the trial. Of these, 593 were suitable and 382 agreed to take part in the study. The 382 subjects were interviewed, asked to provide a finger prick blood sample and a hair sample at recruitment and four months later. The blood samples were tested for hepatitis C (HCV) and HIV antibodies. The hair samples were tested for the presence of morphine.

Baseline characteristics
At baseline, subjects in both groups were comparable on all key demographic characteristics, prison histories, injecting drug use and sharing of injecting equipment in prison and in the community. Both groups had the same mean age (27 years), mean age first imprisoned (20 years), had been imprisoned a mean four (treated) and five (control) times, started injecting at mean age 17 years, and commenced daily injecting at mean age 19 (treated) and 18 (control) years. A quarter of both groups were Aboriginal or Torres Strait Islander (22%, 25%). Median length of current sentence was 1.4 years in both the treated (range 0.3-18) and control (range 0.2-21) group. The treated group was significantly more likely to report having shared syringes at some time in the community (76% vs 64%) while comparable proportions of both groups who had injected in prison reported sharing syringes (92%, 87%).

Drug use
Virtually all inmates reported injecting in the month before they entered prison (98% treated, 93% control). The most common drug injected prior to prison entry was heroin (96% treated, 90% control) followed by amphetamine (40%, 40%), cocaine (34%, 35%) and illicitly obtained methadone (26%, 23%). Most inmates in the treated group (69%) and the control group (74%) who had been in prison at least one month before being recruited into the study reported injecting heroin in prison.

Self reported HIV, HCV and HBV prevalence
No-one reported being HIV positive at entry to the study (it should be noted that this was an exclusion criterion for the study). Almost two thirds of treated (64%) and control (63%) subjects reported a previous positive hepatitis C result while one fifth (22%, 19%) of treated and control subjects reported positive hepatitis B (HBV) results. Approximately half of both groups reported having been vaccinated against HBV (49%, 48%).

HIV and HCV seroprevalence
Finger prick blood samples were assayed using an algorithm that has high correlation with assays of venous blood samples (NCCLS, 1998). HIV antibody was detected using Genetic Systems HIV-1 ELISA tests. HCV antibody was detected using a modified third generation enzyme immunoassay (Abbott HCV 3.0, Chicago II). The blood test results revealed 76% of treated and

72% of control subjects had antibodies to hepatitis C. No blood spot samples test positive for HIV.

Hair tests
Quantitative results for hair analysis (nanograms per mg of hair) were analysed. Hair samples were tested for morphine, the metabolite of heroin in the body, by Tricho- Tech Limited, Wales, UK. At baseline, one cm of hair cut from the root was analysed for morphine to assess heroin use in the previous month. The prevalence of morphine positive samples was 82% for the treated group and 83% for controls.

Follow up
The aim was to re- interview after a period of four months. Of the 382 subjects recruited into the trial, follow-up interviews were completed for 313 (82%). The rest were unavailable for follow up because they had been released from prison, declined to be re- interviewed or were incapable. Of the 162 (85%) treated and 152 (80%) control subjects who were re- interviewed, approximately one fifth (20%, 18%) of each group had been released and re-incarcerated between interviews and were excluded from main analysis. As the aim of the study was to assess the impact of methadone maintenance treatment on heroin use, syringe sharing and the prevention of blood borne viral infection (BBVI) in prison, only the 253 subjects who received a second interview and who had remained in prison are included in the current analysis. Therefore 129 (68%) of treated and 124 (65%) of control subjects who had been in continuous custody were included in the analysis for the purposes this report. The mean time period between interviews was 5.2 months for treated and 4.5 months for control subjects.

Drug use
Self- reported use of any illicit drug between interviews remained high at in both the treated and control group. At follow up, a three cm segment of hair was cut from the root, divided into three one cm sections and analysed for morphine to assess heroin use in each of the three months preceding the follow up interview. Hair samples reflecting the first month after recruitment were not tested. This month allowed inmates on methadone to reach an adequate dose (eg 60mg). When determined by both hair morphine concentration and self report, heroin use was significantly lower in the treated group at month two, three and four of follow up compared to the control group. Treated subjects also reported a significantly lower mean number of heroin injections in each month of follow up compared to controls.

Needle and syringe sharing
Treated subjects reported significantly less needle and syringe sharing at follow up compared to control subjects. There was no difference in the median number of sharing partners reported by treated compared to control subjects.

Seroconversion
Four subjects in both groups seroconverted to HCV. No one seroconverted to HIV.

Sexual risk behaviour
One ethics committee precluded questions about sexual activity from the first interview. However sexually contact with others was rarely report at follow up (2% treatment, 2% control) and no sexual behaviour was reported with other inmates.

Conclusion

The study demonstrated that it is possible to conduct a randomised control trial of a prison methadone program. The groups were comparable at baseline. At follow up, the treatment group had benefited from being on methadone as they reported less heroin use, less injecting and less syringe sharing. Combined results from hair analysis and self report also showed less heroin use among the treated group. There were equal numbers of HCV seroconversions and no HIV seroconversions.

This study has prompted further research. We are currently following up subjects to examine drug use, seroincidence, re-incarceration, retention in treatment and mortality (estimated completion in 2003). A cost benefit study of prison methadone is also underway (estimated completion 2003). Finally a new randomised trial of naltrexone, methadone and drug counselling in NSW prisons has started (estimated completion 2005).

1. BACKGROUND

IDUs are at risk of acquiring HIV, HBV and HCV when they share syringes and other injecting paraphernalia. This risk is increased in situations like prison where syringes are scarce and syringe sharing is common.

Documentation of transmission of HBV (Hull et al., 1985), HCV (Vlahov et al., 1993), gonorrhea (van Hoeven et al., 1990), and HIV (Taylor et al., 1995; Dolan & Wodak, 1999) within prison systems confirms that behaviours such as syringe sharing, tattooing and unprotected penetrative sex occur in prison.

IDUs maintained on methadone can reduce their levels of drug injecting and syringe sharing, if criteria concerning dose and duration of treatment are met. Reasons for providing treatment for drug dependent prisoners are: the over representation of IDUs in prison populations; treatment may prevent relapse to drug use on release from prison and that treatment can play a role in the prevention of infections such as HIV, HBV and HCV (Hall et al., 1993).

1.2 Methadone Maintenance Treatment

MMT has been found to prevent HIV infection among IDUs. An inverse relationship was found between duration in methadone treatment and the prevalence of HIV infection in IDUs in New York (Schoenbaum et al., 1989). In Sweden, a methadone treatment group and control group were selected on a random basis, due to the processing of applicants to the methadone program. Of those taken on to MMT before 1983, three percent were HIV positive. Of those who entered in the next three years, six percent were infected and over 50 percent of those entering after 1987 were infected (Blix & Gronbladh, 1991).

MMT reduces mortality (Caplehorn et al., 1994), heroin consumption (Gottheil et al., 1993; Sees et al., 2000), criminality (Newman et al., 1973), HIV transmission (Novick et al., 1990; Metzger et al., 1993) and re- incarceration (Dole et al., 1969) among IDU in the community. MMT attracts and retains more heroin injectors than any other form of treatment (Ward et al., 1998). An increase in MMT places from 19,900 to 34,000 corresponded with 24,900 fewer drug arrests and 1,500 fewer cases of serum hepatitis in New York City in the early 1970s (Joseph, 1988). When MMT was introduced in Hong Kong in 1976, the annual number of addicts admitted to prison decreased from approximately 2,200 to 200 by 1980 (Joseph, 1988).

Adequate doses of least 60 mg per day (Hubbard & French, 1991) and sufficient duration in treatment of at least several months (Ball & Ross, 1991) are necessary for successful treatment (Ward et al., 1998). However, all these studies have been conducted in, and therefore may only apply to, community-based methadone programs. In order for IDUs to enter community based methadone programs they must satisfy standard criteria, most notably heroin dependence. This is usually judged by a recent history of injecting heroin on a daily basis. Yet daily injection of heroin is rare in prison.

Recently methadone programs have shifted their focus from the reduction of criminality to the reduction of HIV infection among IDUs (Ward et al., 1998). Nevertheless, IDUs still generally need to be injecting on a daily basis in order to be considered eligible for community methadone programs. Successful treatment is usually measured by a reduction in injection frequency. It

remains to be determined whether or not methadone maintenance treatment can have an impact on heroin use when the frequency of injection is low as in prison.

Research into community MMT indicates that approximately half of IDUs in treatment cease injecting while most of the remainder substantially reduce their frequency of heroin injection. This residual level of injection suggests a possible 'floor', below which it may be difficult to demonstrate a reduction in the frequency of injection. The frequency of injection in prison is relatively very low- occurring only several times a month (Dolan et al., 1996a). Therefore, it may be unrealistic to expect MMT to have any impact on injection frequency in prison.

Table 1.1 Randomised controlled trials of methadone maintenance treatment (MMT)

Location	Sample	Months of observation	Outcome measure	Reference
New York	32	12	Prison, Heroin	Dole et al., 1969
Hong Kong	100	36	Retention	Newman et al., 1979
Sweden	36	24	Heroin	Gunne et al., 1981
Bangkok	240	1.5	Heroin, retention	Vanichseni et al., 1991
New York	301	1	Heroin, retention	Yancovitz et al., 1991
USA	247	4	Heroin, retention	Strain et al., 1993

The outcome measures in these studies were heroin use as measured by urinalysis, retention in treatment, and re-incarceration (prison).

1.3 Prison Methadone Programs

There were five prison methadone maintenance programs in operation in the world in 1996 (Dolan and Wodak, 1996). Only the Rikers Island Jail program in New York City (Magura et al., 1993) and the New South Wales program (Hall et al., 1993) have been documented. Methadone provision in Rikers Island Jail began in 1986. Approximately one fifth of the 80,000 prison entrants were detoxified from heroin with methadone in the first year. However, the rapid detoxification program failed to break the criminal cycle as most inmates soon resumed drug use and criminal activities upon release and were re-incarcerated. In 1987, the methadone program expanded to provide inmates with stable, albeit sub-therapeutic (40 milligrams) doses of methadone for the duration of incarceration (which was less than one year). Referral to community methadone programs was arranged for inmate clients after release. Fears of correctional staff were allayed when diversion of methadone and conflicts between inmates did not eventuate. On the contrary, inmates on methadone were less irritable and easier to manage. In addition, virtually all (95%) prisoners who were offered a place joined the Rikers Island Jail methadone program. There is no evidence whether or not the Rikers Island Jail methadone program has had any impact on injecting in prison. However, injecting drug use is reported to be rare in Rikers Island Jail (S. Magura, Personal communication, 31 Jan 1995).

Table 1.2 Prison Methadone Maintenance Programs in 1996

Location	Daily prison census	Methadone places
NSW, Australia	6,400	800
Rikers Island, USA	14,500	400
Catalunya, Spain	2,000	100
Basel, Switzerland	?	180
Denmark	3,574	200

There is a large methadone maintenance program in NSW prisons. Methadone is available to a small number of prisoners in Victoria. South Australia and Queensland introduced a limited number of methadone places in prison in 1999.

Australia's National Methadone Guidelines listed four basic categories where MMT which might be appropriate for prisoners. The categories were: *(1) withdrawal; (2) continuation of treatment for those on methadone prior to imprisonment; (3) commencement of treatment for those who are heroin dependent on prison entry or who have used heroin in prison in a harmful way including those who are HIV positive; and (4) the reduction of intravenous opioid use upon release.* In addition, the Guidelines stipulate that medical staff prescribing methadone in prison should be independent of the Department of Corrective Services to minimise potential conflicts of interest.

The NSW prison methadone program began in 1986 as a pre-release program which targeted IDUs with multiple periods of incarceration. In the late 1980s, the NSW prison methadone program, like the community methadone program, underwent a rapid expansion (from 100 to 463 places) with a broadening of entry criterion in 1992. This number represented seven percent of the prison population (Walker et al., 1992). Eleven studies of the NSW prison methadone program were carried out between 1986 and 1991 by the Department of Corrective Services (Gorta, 1992). A summary of the studies appears in Appendix A. In general, the program appeared to have benefited some inmates by reducing their frequency of drug use in prison and their involvement in the prison drug trade (Wale & Gorta, 1987). Methadone diversion was found to be uncommon as virtually all urine samples tested positive for methadone (which would not have been the case if inmates were diverting methadone) (Gorta, 1987; Bertram, 1991). Previous research found that the NSW prison methadone program had no effect on criminal recidivism (Hall et al., 1993). One explanation offered was that treated inmates had more extensive drug using careers and prison histories than their untreated peers.

Data on the impact of methadone on injecting in prison were not available as no appropriate control group existed. One study found that IDUs on methadone had lower levels of injecting and syringe sharing in and out of prison than IDUs not on methadone (Dolan et al., 1996a). Reductions in both measures were more noticeable among IDUs outside prison, but the trends were also significant among IDUs in prison.

In 1997 the methadone program had an average of 685 inmate clients located across 23 dispensing centres and was the largest methadone program in Australia (Corrections Health Service, 1998).

The NSW prison methadone program has undergone many changes in its short history. The aims have changed from reducing prison recidivism to preventing HIV and hepatitis in prison (Hall et al., 1993).

1.4 The NSW Prison System

The health needs of prisoners in New South Wales are the responsibility of the Corrections Health Service (under the auspices of the Department of Health), which is independent of the Department of Corrective Services. In 1998 there was an average daily population of over 7,900 inmates in NSW, with approximately 15,000 inmates entering and leaving that year. Over 400 needles and syringes were found in NSW prisons in 1990 (Sider, 1994).

1.5 Blood Borne Viral Infection Prevention Programs

The NSW prison system has implemented a broad range of HIV and HCV prevention strategies. Blood Borne Viral Infection (BBVI) prevention programs include a bleach program (Dolan, et al., 1998), a comprehensive HIV peer education program for inmates (Taylor, 1994) and a specialised voluntary unit called the 'Lifestyles Unit' for HIV and hepatitis C positive inmates. Between 1991 and 1997, 77% of 54,809 prison entrants in NSW were tested for HIV and 173 cases of HIV infection (0.4%) were detected (McDonald et al., 1999). Four cases of HIV transmission occurring in an Australian prison have been confirmed (Dolan & Wodak, 1999).

In 1994, the provision of condoms to prisoners in New South Wales was the subject of a Supreme Court case with 52 inmates taking action against the Department of Corrective Services. The case was dismissed on the grounds there were too many claimants. While a new claim was lodged, the Department of Corrective Services introduced a pilot program of condom distribution. Statewide distribution of condoms began in 1997.

An evaluation of this program found that the supply of condoms and dental dams had been quickly accepted by inmates and to a lesser extent by officers (Lowe, 1998). Safe sex practices were found to be above that of the community indicating that the program contributed to minimising the spread of HIV and other STDs. Another study provided further support for the program (Dolan et al., submitted). It found that the majority of inmates supported the program and that most reported condom vending machines were in accessible locations. The harassment of inmates accessing the vending machines was low and importantly, condoms were used when having sex (Dolan et al., submitted).

Disinfectants were first distributed to prisoners in NSW in January 1990 in the form of tablets (Milton Tablets™), generally used in the sterilisation of babies' bottles. In 1993 inmates were instructed to dissolve three Milton Tablets in a cup of water and to use a procedure known as the `2x2x2' method for syringe cleaning. This method recommended that a needle and syringe be flushed twice with water, twice with bleach and twice with water. Liquid bleach was introduced in NSW prisons in October 1992 with the intention of completely replacing disinfecting tablets because tablets were being used to contaminate urine specimens which interfered with urinalysis for drug detection. Liquid bleach should have a minimum concentration of one percent bleach when it reaches inmates. Revised syringe cleaning guidelines now require injecting equipment to be soaked in addition to being flushed with water several times (ANCA, 1993). Disinfectants were available from prison medical staff, prison officers and other inmates on request and at no charge. Two studies of bleach availability and usage found that access improved over time and virtually all IDUs who were sharing syringes cleaned them with bleach (Dolan et al., 1998; Dolan et al., 1999).

2. AIMS AND METHODS

2.1 Aims

The aims of the study were to examine the impact the prison methadone program had on the

1. Prevalence and frequency of heroin injecting as measured by self report data
2. Heroin use as detected by hair analysis
3. Incidence of HIV and hepatitis C as measured by repeat serology
4. The shared use of injecting equipment as measured by self report data

2.2 Design

This study was an open, two-group, pre-post randomised controlled trial. Three hundred and eighty two inmates applying for the NSW prison methadone program who satisfied all inclusion criteria and had none of the exclusion criteria were recruited over fifteen months between August 1997 and October 1998. Inmates accepted into the study were randomly allocated to treatment or control conditions. Inmates in the treatment group joined the prison methadone program. Control group inmates were placed on a four-month wait list for the prison methadone program. Both groups were offered drug-free counselling as the usual care available for all inmates applying for the prison methadone program. At the time of the study the wait-list for the prison methadone program was six months.

2.3 Subjects

2.3.1 Sample Size

Previous research found that 40 percent of inmates who were not receiving methadone treatment and 19 percent of inmates who were receiving methadone maintenance treatment reported injecting heroin in prison (Dolan et al, 1996b; Dolan et al, 1998). Power calculations based on the above studies indicated that 147 subjects in each group would provide power at a level of 90 percent with an α value of 0.01. This meant that there was a ten percent chance of detecting an effect that was not there (type 1 error) and a one percent chance of missing a true effect (type 2 error).

2.3.2 Eligibility Criteria

For a prisoner to be eligible to participate in the trial it was essential to:
be male
have a history of injecting heroin
have a prison sentence of at least four months
be willing to be randomly allocated into treatment or control
be willing to provide blood and hair samples when required and
be willing to grow hair and not bleach it.

Exclusion criteria included:
being HIV positive
having a psychiatric illness and
being female

Prisoners who were HIV positive had immediate access to the methadone program. Instruments and procedures (including the Central Randomisation System) were tested in pilot studies conducted in 1996. The first of these pilot studies indicated that the wait list study design was not feasible for the female prison population. Female prisoners were able to access methadone treatment immediately. Another finding was that the average length of sentence for females (three months) was too short to recruit a sufficient number of female subjects available for the four month follow-up period.

2.4 Central Randomisation System

Group allocation was based on block randomisation. A sequential list of case numbers was matched to group allocations in blocks of ten by randomly drawing five cards labelled 'control' and five cards labelled 'treatment' from an envelope. This procedure was repeated for each block of ten sequential case numbers. The list of questionnaire numbers and group allocation was held by staff not involved in recruiting or interviewing inmates. The trial nurses responsible for assessing, recruiting and interviewing inmates had no access to these lists. Questionnaires were pre-numbered. Once an inmate had been recruited and interviewed, the research nurse contacted the Central Randomisation System via a mobile telephone number to find out the inmate's group allocation.

2.5 Study Procedures

2.5.1 Intake procedure for prison methadone program

Inmates were assessed for suitability for the prison methadone program by initial assessment by trained nurses experienced in conducting a standardised Corrections Health Methadone Assessment. This assessment was followed by a medical review by a Corrections Health career medical officer who would take appropriate medical observations, and confirm drug use history and history of any treatment. Inmates assessed as suitable were then enrolled in the program after the authority to prescribe methadone was issued by the Pharmaceutical Services Branch of the NSW Health Department.

Availability of places on the prison methadone program was limited by the number of prisons within the system that offered methadone maintenance and other resource constraints of the Corrections Health Service. Once inmates were assessed as suitable for the program they were placed on a wait list which at the time of the study was approximately six months. Inmates who were HIV positive or otherwise assessed as requiring priority placement into the methadone program commenced treatment immediately.

In 1997 the prison methadone program was available at 12 out of 26 prisons for males during the study period (1997-1998). Methadone was available at five prison complexes in the Sydney metropolitan area (Parramatta, John Morony, Long Bay Complex, Metropolitan Remand Centre, Silverwater) and seven prisons outside the Sydney metropolitan area (Bathurst, Cessnock, Goulburn, Grafton, Junee, Lithgow, Tamworth). Inmates not in these prisons were moved to prisons where the prison methadone program was offered, when possible.

2.5.2 Study Recruitment Procedure

Prisoners who applied for methadone maintenance treatment were asked to participate in the trial. Inmates were advised that they had a 50% chance of gaining a place on the prison methadone program immediately; otherwise they would join a four month wait-list for a methadone place. In addition to the normal intake procedures for the methadone program, the trial nurses explained the study, obtained informed consent and invited inmates to participate. Subjects were interviewed and samples of hair and blood were collected. An advertisement was place in inmate newsletter 'The Stacked Deck', which is distributed to every inmate in New South Wales Prisons. Respondents were not reimbursed for their participation.

2.5.3 Treatment

Inmates joining the prison methadone program commenced on a 30mg dose which increased by five mg every three days until 60mg was achieved. Treatment was subject to the usual security arrangements which meant that it was subject to 'lock downs' and other unscheduled movements that may have interrupted treatment or extended stabilisation periods. Drug and alcohol counselling was available to all inmates.

2.5.4 Follow-up procedure

All subjects were scheduled to be re- interviewed at four months after their first interview. Trial nurses located inmates and conducted the follow-up interviews and took the follow-up hair and blood samples. Follow-up was subject to delays and interruptions due to security factors including 'lockdowns' and unscheduled movements. Where inmates did not or could not respond to calls for clinic attendances they were contacted in writing and alternate arrangements for interviews and sample collections were made. Inmates who left the NSW prison system were not followed-up for the purposes of the current study. Inmates who were released but then re-incarcerated were followed-up although they are excluded from current analysis. All inmates enrolled in the study were offered methadone maintenance at baseline or at four month follow-up for the duration of their sentence.

2.6 Outcome measures

2.6.1 Blood samples

Finger prick blood samples were collected with a single use lancet. Inmates' fingers were dabbed onto blotting cards filling three circles (1 cm in diameter). Samples were tested for antibodies to HIV and hepatitis C by the Centre for Immunology, St. Vincent's Hospital, Sydney. The samples were assayed using an algorithm that has a high correlation with assays of venous blood samples (NCCLS, 1988). HIV antibody was detected using Genetic Systems HIV-1 ELISA tests, and if reactive twice, underwent Western blot confirmatory testing. Specimens were tested for HCV antibody using a modified third generation enzyme immunoassay (Abbott HCV 3.0, Chicago II). A modified cut-off value for optical density was calculated to capture greater than 95% of the seronegative population. Specimens were considered positive for anti-HCV if the optical density cut- off ratio was greater or equal to 1.0 on initial and subsequent testing. The date of seroconversion was taken as the midpoint between the last negative and first positive antibody tests.

2.6.2 Hair Analysis

Hair analysis offers the longest window of detection (7 to 100+ days) of all drug tests (United Nations International Drug Control Program, 1998). Infrequent drug use is more likely to be detected by hair analysis due to this long window period of detection. Quantitative results for hair analysis (nanograms per mg of hair) were analysed. Over 50 hairs were cut approximately 2 mm from the scalp at the vertex. Hair samples were tested for morphine by Tricho-Tech Limited, Wales, UK. At baseline, one cm of hair cut from the root was analysed for morphine to assess heroin use in the previous month. At follow-up, a three cm segment of hair cut from the root was divided into three, one cm sections and analysed for morphine to assess heroin use in each of the three months preceding the follow-up interview.

Stock and working solutions of morphine and 6-mono-acetylmorphine were prepared in methanol, fresh for each assay, to give concentrations in acid ranging from 2.5 to 50 ng/ml. The internal standards, D-3-morphine and 6-mono-acetylmorphine were purchased as 0.1 mg/ml solutions in methanol and acetonitrile respectively.

All hair samples were decontaminated to remove exogenous contaminants. Hair samples were washed with 5ml methanol, followed by 5ml 0.01M hydrochloric acid, and finally 5 ml methanol before drying. The hair samples were weighed and cut into fragments of 5 mm length or less. The weighed portions of hair were placed in a glass tube containing 2 ml 0.25M hydrochloric acid and incubated overnight at 45 0 C.

Standards, controls and hydrolysed hair samples were neutralised with 2 ml borate buffer and 0.3ml 1M sodium hydroxide to achieve a pH of 8.3-8.5. 5 ml of the extraction solvent (90:10 chloroform:isopropanol) was added. The tubes were rotated for 30 minutes. Following centrifugation (3500rpm) for 10 minutes, the aqueous layer was aspirated. One millilitre of 0.1M sufuric acid was added to the organic layer and the tubes rotated for 30 minutes. Following centrifugation (3500rpm) for 10 minutes, the organic layer was aspirated. The acid layer was neutralised with 1ml borate buffer and 0.8 0.1M sodium hydroxide to receive a pH of 8.3-8.5. Five millilitres of the extraction solvent (90:10, chloroform:isopropanol) was added and the tubes rotated for 30 minutes. After centrifugation (3500rpm) for 10 minutes the aqueous layer was aspirated and the organic layer was evaporated to dryness.

The dried extracts were derivatised with 50ìl of pentafluouropropanol and 50ìl pentafluouropropionic anhydride for 45 minutes at 75 0 C. The derivatised extracts were finally evaporated to dryness under nitrogen and reconstituted with 100ìl ethyl acetate.

Results have been reported in terms of sample weight, calculated limit of detection (LOD) and concentration of morphine (ng/mg). Morphine concentrations greater than the calculated LOD for each individual sample were deemed presumptive of heroin use. For a sample weight of 10 milligrams the calculated LOD was1 nanogram per milligram of hair.

2.6.3 Interview Schedule

The baseline interview schedule covered basic demographic characteristics, prison history, and drug use history both in the community and in prison and the results of recent HIV, hepatitis C and hepatitis B tests if any. Inmates were asked about drug use, injecting and sharing in the month (or less) preceding interview while they were in prison. At follow up inmates were asked about drug use, injecting and syringe sharing over the past three months. Questions about other

risk behaviour including tattooing and sexual activity were also asked at follow up. Inmates in the treated group were asked about their experience with the methadone program. Control subjects were asked whether they were still interested in joining the methadone program. All subjects were asked whether their decision to participate in the methadone program was influenced by others. Inmates were also asked to report medical complaints and any prescribed medication they had received.

2.7 Data Analysis

Data were analysed using SPSS for Windows (version 9.0). An Intention-to-treat analysis was used to examine differences between study groups at baseline and follow-up. The intention-to-treat population was defined as those subjects who enrolled in the trial and were randomised and who had not been released into the community between baseline and follow up interviews. All statistical tests were two-tailed using a 0.05 level of significance and 95% confidence intervals. T-tests and analysis of variance (ANOVA) were used for continuous variables. Medians and ranges were reported for skewed data and analysed using Mann- Whitney U, Wilcoxon and Kruskal-Wallis tests. The chi-square statistic was used for categorical data. HCV incidence was calculated using the person years method with ninety five percent confidence intervals using an exponential error factor for incidence rates (Breslow & Day, 1987)

2.8 Ethical Approval and payment of subjects

Ethical approval were obtained from the Committee on Experimental Procedures involving Human Subjects at the University of NSW, the Research Ethics Committee of St. Vincent's Hospital, the Research Ethics Committee of Corrections Health Service and the Institutional Ethics Committee of the NSW Department of Corrective Services. Subjects were not remunerated for their participation.

2.9 Steering Committee

A steering committee was constituted to oversee the project. The Committee comprised; Dr Alex Wodak, St. Vincent's Hospital, Dr Richard Matthews, Ms Sue Jefferies, Dr Phil Brown (up to January 1998) from the Corrections Health Services, Ms Deborah Allen and Mr Gino Vumbaca, Department of Corrective Services, Professor Wayne Hall, Associate Professor Richard Mattick, James Shearer and Dr Kate Dolan, National Drug and Alcohol Research Centre. An inmate representative from the Long Bay Prison Complex joined the Committee.

3. RESULTS

3.1 Sample Characteristics

Between August 1997 and October 1998, 933 consecutive applicants for the prison methadone program were assessed for the study; 340 (36%) applicants did not meet study criteria and 211 (23%) declined to participate. The remaining 382 applicants (63% of eligible applicants) were randomly allocated to methadone maintenance (treated) or routine care (control) (Figure 3.1).

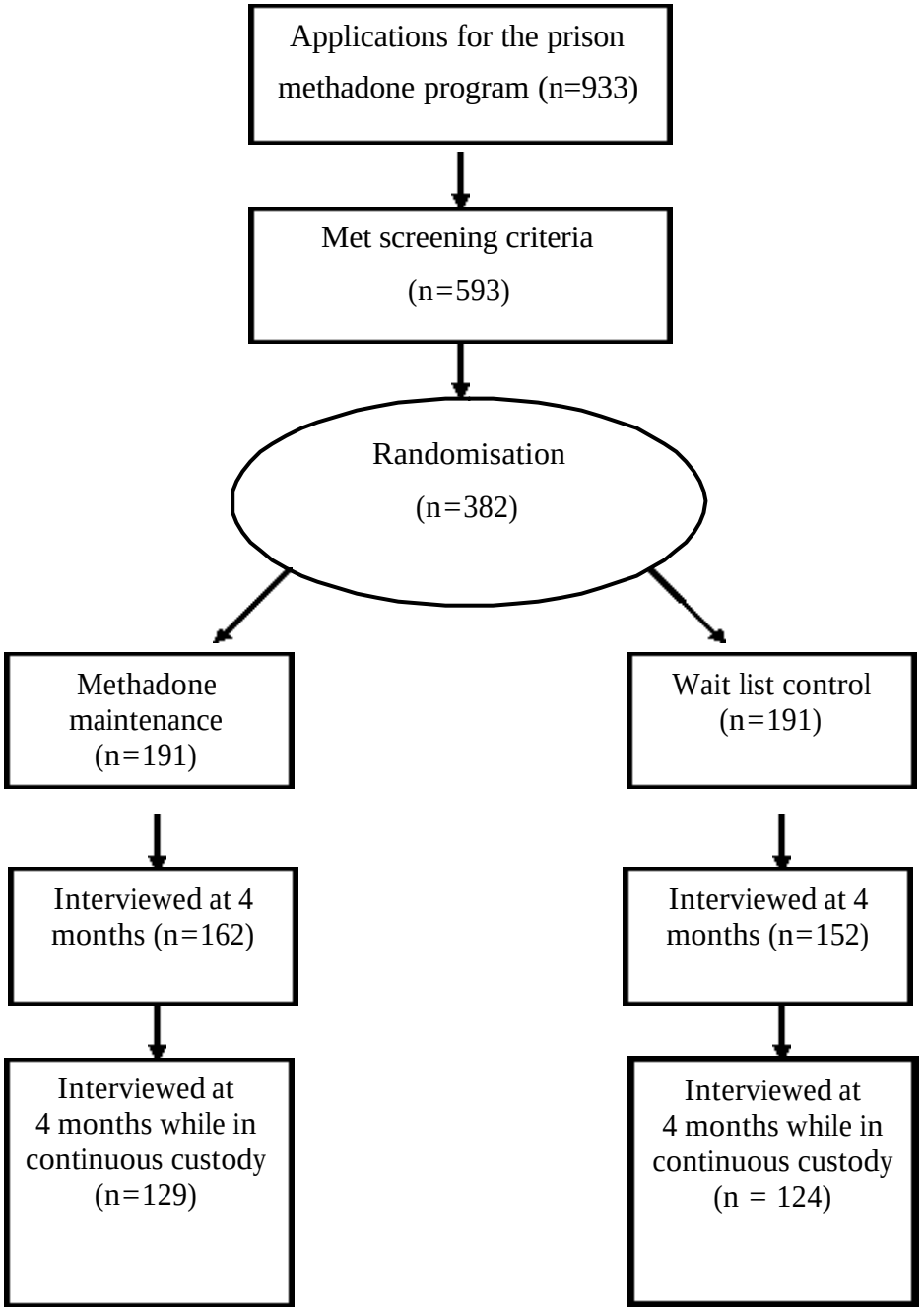

Figure 3.1 Subject Flow Chart

Of the 382 subjects recruited into the trial, 314 (82%) completed a follow up interview. All interviews were carried out with subjects while in custody. The remaining 68 (18%) subjects were unavailable for the follow up interview as they had been released from prison, declined to be re-interviewed or were incapable of being interviewed. There were no between group differences in attrition (15% vs 20%, 1df, χ^2= .229). Of those who were followed up, 20% of treated and 18% of control subjects had been released into the community and re-incarcerated between interviews.

Those who remained in continuous custody were compared to those who received a follow up interview after being released and re-incarcerated and those who were lost to follow up (Table 3.1).

Table 3.1 Baseline characteristics of subjects followed up in continuous custody, subjects followed up who had been released and re-incarcerated between interviews and subjects lost to follow up

Variable	Continuous (n= 253)	Re- incarcerated (n= 61)	Lost to follow up (n= 68)
Mean age (sd)	27 (6)	26 (6)	27 (6)
Aboriginal or Torres Strait Islander %	23	30	22
Mean age first imprisoned (sd)	20 (5)	19 (3)	20 (3)
Mean times in prison (sd)	5 (5)	5 (7)	5 (3)
Mean age first in prison (sd)	17 (4)	17 (3)	17 (5)
Ever share syringes community %	70	74	74
Ever inject in prison %	88	79	81
Of those who had ever injected in prison			
Ever share in prison %	89	85	91
Median mths in prison at baseline (R)	1.8 (1.3- 247)	0.8 (0.3- 130)	1.0 (0.3-36.0)*
Median sentence length yrs (R)	1.4 (0.2- 20.9)	0.7 (0.1- 10.0)	0.9 (0.2- 4.0)**

***p=.01**
****p=.002**

Baseline differences in follow up status were examined using ANOVA and the Kruskal- Wallis test. The three groups were comparable on all key demographic characteristics except prison sentence length. Subjects who had been in continuous custody between interviews had been in prison for a significantly longer period of time at baseline (p=.01). They also reported a significantly longer sentence (p=.002) at baseline interview, as would be expected (Table 3.1).

As the aims of the study were to determine the impact of methadone maintenance treatment on heroin use, syringe sharing, and the prevention of blood borne viral infection (BBVI) in prison, those who had been released and re-incarcerated between interviews were excluded from the present analysis.

3.1.1 Demographic characteristics of treated and control subjects who remained in continuous custody

Treated and control subjects who remained in continuous custody at follow up were compared (Table 3.2). Baseline characteristics were similar among both groups except for having ever shared syringes in the community, with the treated group significantly more likely to report having done so (76 vs 64%, $\chi^2 = 4.2$, $p = .04$)

The average age was 27 years and about a quarter of treated (22%) and control (25%) subjects identified as Aboriginal or Torres Strait Islander. Both groups had the same mean age when first imprisoned (20 years) and had been in prison an average of four (treated) and five (control) times (Table 3.2).

Similar reports of Most Serious Offences were made by both treated and control subjects and included robbery, assault and break and enter. Approximately one third of treated (33%) and control (37%) subjects had an unclassified security classification (Table 3.2).

Median current sentence length was 1.4 years in both treated (range 0.3- 18) and control (range 0.2- 21) groups. Median time in prison at recruitment was also comparable between groups (1.5 months (range 0.3- 104) vs 2 months (range 0.3- 247) (Table 3.2).

Both groups reported their first injection was at a mean age of 17 and commencement of daily injecting at a mean age of 19 (treated) and 18 (control) years. Of the treated (84%) and control (91%) subjects who injected in prison, most reported sharing syringes (92%, 87%). The majority of subjects reported sharing a syringe at some time either in or out of prison (89%, 90%) (Table 3.2).

Table 3.2 Baseline characteristics of treated and control subjects

Variable	Treated (n=129)	Control (n=124)
Mean age (sd)	27 (6)	27 (6)
Aboriginal or Torres Strait Islander %	22	25
Mean age first imprisoned (sd)	20 (3)	20 (4)
Mean times in prison (sd)	4 (3)	5 (6)
Most Serious Offence		
Robbery%	38	32
Break and Enter%	23	22
Assault%	16	25
Security Classification		
Maximum%	16	21
Medium%	14	12
Minimum%	14	16
Escapee%	22	13
Unclassified%	33	37
Not reported%	2	1
Median mths in prison at baseline (R)	1.5 (0.25-104)	2 (0.25-247)
	n= 65	n= 66
Median sentence length yrs (R)	1.4 (0.3-18)	1.4 (0.2-21)
Mean age first injection (sd)	17 (3)	17 (4)
Mean age daily injection (sd)	19 (4)	18 (4)
Ever shared syringes in community %	**76**	**64***
	n= 93	n= 79
Mean yrs since shared syringes in community (sd)	2.3 (6.6)	1.7 (2.7)
Ever injected in prison %	84	91
	n= 125	n= 123
Started injecting in prison %	7	12
	n= 107	n= 113
Ever shared syringes in prison %	92	87
	n= 96	n= 97
Mean mths since shared syringes in prison (sd)	5(10)	4 (7)
Ever shared syringes in community or prison %	89	90
Self reported HIV prevalence %	0	0
Self reported HCV prevalence %	64	63
HIV seroprevalence %	0	0
HCV seroprevalence %	76	72

***p= .04**

3.2 Drug use in the community one month prior to imprisonment

Virtually all treated and control subjects reported using drugs in the month prior to imprisonment (100%, 99%) and most reported injecting drugs (98%, 93% respectively). Heroin was the most commonly injected drug by treated (96%) and control (90%) subjects, followed by amphetamine (40%, 40%), cocaine (34%, 35%) and illicitly obtained methadone (26%, 23%).

Only a small proportion of subjects were enrolled in methadone treatment prior to entering prison (10%, 7%), although close to half (43%, 47%) reported using methadone obtained illicitly.

Table 3.3 Drugs used and injected in the community one month prior to imprisonment

Drug	Treated % (n=129)		Control % (n=124)	
	Used	Injected	Used	Injected
Any Drug	100	98	99	93
Heroin	98	96	92	90
Prescribed methadone	10	4	7	2
Illicitly obtained methadone	43	26	47	23
Amphetamines	45	40	44	40
Cocaine	37	34	40	35
Ecstasy	9	2	12	2
Tranquilisers	71	14	69	15
Steroids	2	2	1	1
Cannabis	81	-	84	-

3.3 Drugs used and injected in the past month or less in prison

The majority of subjects in both the treated and control groups reported the use (92%, 94%) and injection (64%, 70%) of drugs in the previous month or less in prison. Heroin was the most commonly injected drug by treated (60%) and control (68%) subjects. The use of cannabis (64%, 70%), tranquilisers (61%, 65%) and illicitly obtained methadone (24%, 27%) were also commonly reported. No subject was in methadone treatment at baseline.

Table 3.4 Drugs used and injected in the past month or less in prison (Baseline).

Drug	Treated % (n=129)		Control % (n=124)	
	Used	Injected	Used	Injected
Any Drug	92	64	94	70
Heroin	64	60	71	68
Prescribed methadone	0	0	0	0
Illicitly obtained methadone	24	1	27	3
Amphetamines	7	6	9	7
Cocaine	4	3	5	5
Tranquilisers	61	2	65	4
Steroids	1	0	2	0
Cannabis	64	-	70	-

3.4 Length of time in prison at baseline

The majority of treated (71%) and control (69%) subjects had been in prison for more than one month when recruited. Inmates who had been in prison for at least one month were compared to those who had been in for less than one month in terms of drug use and injection (Table 3.5).

Subjects in both groups who had been in prison for the entire month reported more heroin use and injecting, more injecting of any drug, more illicitly obtained methadone use and more cannabis use in prison than those in prison for less than a month. Subjects who had been in prison for less than a month reported more tranquiliser use in prison than those who had been in for more than one month. All differences were significant at p=.05 (Table 3.5). These differences may indicate that illicit drugs are not immediately available to inmates upon arrival to prison. The high level of tranquiliser use reported by subjects in prison for less than one month may reflect the prescription of these drugs as part of the prison detoxification regime.

Table 3.5 A comparison of the drugs used and injected in prison by those who had been in prison for at least one month prior to baseline and those who been in prison for less than one month.

Drug	Treated %				Control %			
	1mth (n=91)		<1mth (n=38)		1mth (n=85)		<1mth (n=39)	
	used	**inject**	**used**	**inject**	**used**	**inject**	**used**	**inject**
Any Drug	92	79	90	47*	93	82	95	60*
Heroin	74	69	40**	37**	78	74	56*	54*
Prescribed methadone	1	0	0	0	0	0	0	0
Illicit methadone	32	1	5**	0	35	5	10*	0
Amphetamines	10	9	0	0	12	9	0	0
Cocaine	6	4	0	0	6	6	3	3
Tranquilisers	53	1	82*	3	58	4	80*	5
Steroids	0	0	3	0	1	0	3	0
Cannabis	74	-	42**	-	78	-	51*	-

***p=.05**
****p<.001**

3.5 Non Injecting Routes of Administration

Heroin use other than by injection (i.e. smoking, inhalation, snorting or swallowing) was rarely reported both before prison (5%, 7%), or during the last month or less in prison (9%, 11%). The seven treated and seven control subjects who used heroin without injecting, reported doing so at a much higher rate in the community at a mean of 68 and 70 times respectively in the month before entering prison, compared to a mean of 2 and 4 times respectively in the month in prison prior to baseline (Table 3.6).

3.6 Self reported heroin use and injection

In the month prior to entering prison both groups reported comparable amounts of risk behaviour. The treated group reported a mean of 136 occasions of heroin use and the controls an average of 142. Prevalence of the injection of any drug was similar in both treated and control subjects, averaging 186 and 203 occasions respectively (Table 3.6).

During the period one month or less in prison before baseline, both groups estimated using heroin a mean of nine times. The treated group reported the injection of any drug a mean of 15 times and the control group a mean of 14 times in that month (Table 3.6).

Table 3.6 Heroin use and injecting; in the community one month prior to imprisonment and in prison one month prior to baseline

	Treated %		Control %	
	Community (n=125)	Prison (n=129)	Community (n=112)	Prison (n=122)
Mean times used heroin (sd)	136(117) n=7	9(22) n=9	142(101) n=7	9(19) n=7
Mean times used heroin without injecting (sd)	68(70)	2(1)	70(65)	4(4)
Mean times injected any drug (sd)	186(156)	15(27)	203(183)	14(21)

3.7 Re- use, cleaning and sharing of injecting equipment

The reported re- use of syringes was higher for both groups in the past month or less spent in prison (88%, 85%) than in the month before prison (43%, 40%) (Table 3.7). However, the reported use of bleach to clean re-used syringes every time was higher in prison (68%, 59%) than before prison (6%, 8%). Rates of sharing injecting paraphernalia such as spoons, filters, tourniquets and water were lower in prison (58%, 65%) compared to in the community (98%, 91%) (Table 3.7).

Table 3.7 Re- use, cleaning and sharing of injecting equipment; in the community one month prior to imprisonment and in prison one month prior to baseline

	Treated %		Control %	
	Community (n=126)	Prison (n=77)	Community (n=113)	Prison (n=82)
Re-used syringes	43	88	40	85
Bleach every time	6	68	8	59
	n=129	**n=129**	**n=124**	**n=124**
Shared spoons	84	49	65	48
Shared filters	70	45	56	44
Shared tourniquet	10	2	13	5
Shared water	74	48	58	46
Shared other	5	2	2	1
Shared any equipment	98	58	91	65

3.8 Self reported syringe sharing at baseline

Syringe sharing practices in the community the month before imprisonment were compared to those in the past month or less in prison (Table 3.8). Of those who reported sharing syringes in the community, treated and control subjects reported doing so a with a median of one person (treated range: 1- 40, control range:1- 4). This was compared to a significantly higher median of two people in prison the month before baseline (treated range: 1- 30, $p<.001$, control range: 1- 64, $p=.05$). Similarly, both groups reported a median of one new sharing partner in the community one month before prison (treated range: 1-8, control range: 1-4) and two new

partners in prison the month before baseline (treated range 1-14, control range 1-30) (Table 3.8). The difference between the median number of new sharing partners in the community and prison was significant in the treated (p=.05) but not the control group (Table 3.8).

When group allocation was ignored the median number of syringe sharing events (0 vs 4, z= -5.1, p<.001), the median number of people shared with (1 vs 2, z= -6.2, p<.001) and the median number of new people shared with (0 vs 1, z= -4.5, p<.001) were all significantly higher in the month or less in prison compared to in the community one month before entering prison.

Table 3.8 Syringe sharing; in the community one month prior to imprisonment and in prison one month prior to baseline

	Treated %		Control %	
	Community	Prison	Community	Prison
	n=50	n=68	n=45	n=68
Median times shared syringes (R)	5(1-360)	5(1-95)	4(1-176)	6(1-120)
	n=50	n= 54	n=45	n= 57
Median no. of people shared with (R)	1(1-40)	2(1-30)*	1(1-4)	2(1-64)**
	n=20	n= 43	n=15	n= 47
Median no. of new people shared with (R)	1(1-8)	2(1-14)**	1(1-4)	2(1-30)

*p<.001
**p= .05

3.9 Self reported HIV, hepatitis B and hepatitis C status

Approximately half of both treated (49%) and control (48%) subjects reported having been vaccinated for HBV at baseline interview. All subjects were to be offered HBV vaccination as part of the recruitment procedure for the study.

The majority of all subjects reported having been tested for HBV (90%, 96%), HCV (94%, 97%) and HIV (95%, 98%).

Table 3.9 Self reported HIV, hepatitis B and hepatitis C status

Status	Treated % (n=129)	Control % (n= 124)
HBV positive	22	19
HCV positive	64	63
HIV positive	0	0

One fifth of both groups reported being HBV positive (22%, 19%), while almost two thirds reported testing positive to HCV (64%, 63%) (Table 3.9). The average length of time between their first HCV positive result and interview was 2.9 years in the treated group and 2.8 years in the control group. No subject reported being HIV positive (this was an exclusion criterion of the study).

3.10 Serology for hepatitis C and HIV

Finger prick samples of blood were tested for HCV and HIV antibodies (Table 3.10). Approximately three quarters of treated (76%) and control (72%) tested positive to HCV while no one tested positive to HIV. Serology found a higher prevalence ($p<0.001$) of HCV than self reports. Blood samples were not tested for HBV antibodies for the purposes of this study.

Table 3.10 HIV and hepatitis C Serology

Antibody	Treated % (n=129)	Control % (n= 124)
HCV positive	76	72
HIV positive	0	0

3.11 Prescribed medication

Both groups reported having been prescribed similar types of medication, with pain medication (60%, 61%), other medication (47%, 46%) and sleeping pills (40%, 39%) being the most common.

Table 3.11 Self reported prescribed medication

Medications prescribed in the last month	Treated % (n=129)	Control % (n=124)
Pain medication	60	61
Other	47	46
Sleeping pills	40	39
Cough/ cold medication	12	9

3.12 Follow up

The aim of the study was to follow up subjects after four months. Follow up interviews were conducted with 162 (85%) treated and 152 (80%) control subjects. One fifth (20%, 18%) of both groups had been released into the community between interviews and were excluded from the current analysis. The remaining 129 (68%) treated and 124 (65%) control subjects who remained in continuous custody had a mean duration to follow up of 5.2 months (range: 2.9 to 21.4 months) and 4.5 months (range: 1.8- 17.8 months) (p= .05). Most had changed prisons since baseline (70%, 74%).

3.13 Heroin use as measured by hair analysis and self report

Over 80% of subjects in both groups had morphine positive hair results at baseline ($\div^2$=1.1, P=.31). Heroin use (measured by self report or positive hair sample) was significantly lower in treated subjects at month two (32 vs 77, $\div^2$=51.1, p<.001), three (27 vs 73, $\div^2$=54.1, p<.001) and four (25 vs 68, $\div^2$=46.9, p<.001) of follow up.

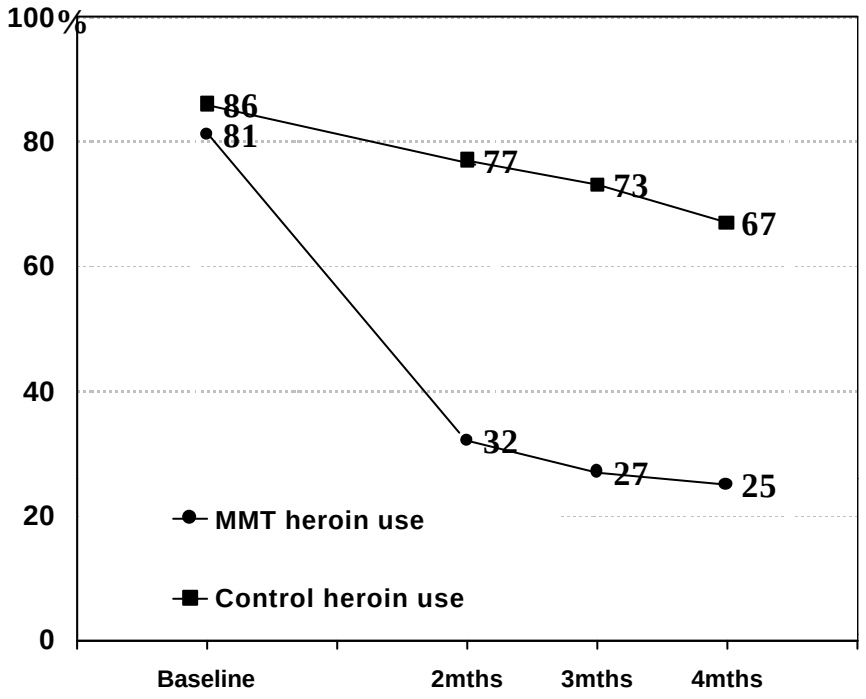

Figure 3.2 Percentage of subjects who either reported heroin use or hair test positive for morphine

3.14 Heroin use as measured by hair analysis

A general linear model for repeated measures showed there were no between-group differences in hair analysis results either as measured by nanograms (ng morphine/ mg hair) (F=0.57, p=0.45) or proportions of morphine positive hair results at month two ($\div^2$= 2.0, p= .158), month three ($\div^2$= 2.2, p= .143) or month four ($\div^2$= 1.1, p= .294) (Table 3.12). Some subjects in the treated group (33%) were not offered methadone due to operational reasons specific to one

prison or did not receive methadone treatment for the duration of the follow up period. Some control subjects (32%) received methadone treatment prior to follow-up interview. When these subjects were removed from the analysis, the between-group difference in proportions of hair positive for morphine was significant at month four (27% vs 42% $\div^2$ =4.3 p=.05) (Table 3.12). This suggests that treatment effect may have been compromised by contamination of original group allocation. With a longer follow up period a between group difference may have been evident at more time points.

Table 3.12 Percent positive for morphine and median nanograms in hair at baseline and follow up months two, three and four

	Intention to treat		Exposure to treatment	
	Treated	**Control**	**Treated**	**Control**
Baseline	(n=128)	(n=123)	(n=87)	(n=84)
Positive %	82	83	82	82
Median (R) (ng morphine /mg hair)	0.6 (0–40)	0.7 (0–47.6)	0.7 (0-40)	0.7 (0-47.6)
Month 2	(n=87)	(n=82)	(n=62)	(n=56)
Positive %	33	43	34	52
Median (R) (ng morphine /mg hair)	0 (0–4.4)	0 (0–16.6)	0 (0-4.4)	0 (0-16.6)
Month 3	(n=106)	(n=95)	(n=75)	(n=66)
Positive %	31	41	32	48
Median (R) (ng morphine /mg hair)	0 (0–3.9)	0 (0–13.9)	0 (0-3.9)	0 (0-13.9)
Month 4	(n=125)	(n=117)	(n=86)	(n=81)
Positive %	31	37	27	42*
Median (R) (ng morphine /mg hair)	0 (0–5.8)	0 (0–8.8)	0 (0-5.8)	0 (0-8.8)

*p=.05

3.15 Self reported heroin use and injection

At follow up the average number of heroin injections reported per month was significantly lower among treated subjects at month two (t= -5.0, p<0.001), three (t= -5.3, p<0.001) and four (t= -4.1, p<0.001) compared to control subjects (Table 3.13, Figure 3.3).

Table 3.13 Mean times subjects reported heroin use in prison; one month prior to baseline and months two, three and four of follow up

Mean times used heroin in each month	Treated (n=129)	Control (n=124)
Baseline (sd)	9(22)	9(19)
Month 2 (sd)	1(4)	8(14)*
Month 3 (sd)	1(4)	9(16)*
Month 4 (sd)	1(5)	9(19)*
Total (Months 2,3,4) (sd)	1(4)	8(14)*

*p<0.001

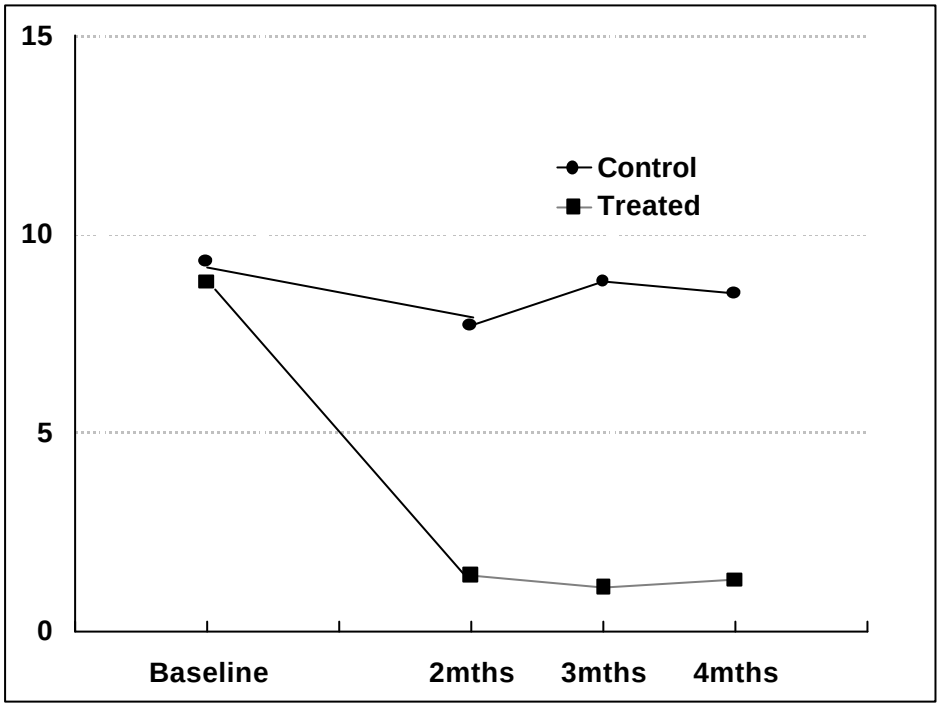

Figure 3.3 Average number of times subjects reported heroin use at baseline and months two three and four of follow up

3.16 Self reported drug use and injection in the three months prior to follow up

In the period between interviews, 85% of treated and 94% of control groups had used illicit drugs however the treated group reported significantly less injection of any drug than the control group (34% vs 75%, $p<0.001$) (Table 3.14). The reported use of heroin (33% vs 78%, $p<0.001$) and its injection (32% vs 74%, $p<0.001$) was significantly lower among the treated group than the control group. The use of illicitly obtained methadone, tranquilisers and cannabis was also significantly less among the treated compared to control subjects (Table 3.14).

Table 3.14 A comparison between groups: Self reported drug use and injection in the three months in prison prior to follow up

Drug	Treated % (n=129)		Control % (n=124)	
	Used	Injected	Used	Injected
Any Drug	95	34	95	75*
Heroin	33	32	78*	74*
Prescribed methadone	69	1	11*	0
Illicit Methadone	12	1	34*	0
Amphetamines	4	2	10	7
Cocaine	2	2	5	5
Tranquilisers	25	2	39**	3
Steroids	0	0	2	0
Cannabis	71	-	87*	-
Other	3	1	7	0

*p<.001
**p=.012

3.17 Self reported drug use and injection in prison the month prior to baseline and three months prior to follow up.

Treated subjects' self reported use of heroin (64% vs 34%, p<0.001) and illicitly obtained methadone (24% vs 12%, p<0.001) decreased significantly during the follow up period while the self reported use of heroin (71% vs 78%, p=.08) and illicitly obtained methadone (27% vs 34%, p=.07) by controls did not) (Table 3.15). Control subjects' self reported use of cannabis increased significantly (70% vs 87%, p<0.001) between interviews and there was a significant decrease of tranquilisers use in both groups. The different time periods in this analysis should be noted. At baseline drug use referred to the last month while at follow up drug use refers to the previous three months.

Self reports by treated subjects of drug injection (64% to 34%, p<0.001) and heroin injection (60% to 32%, p<0.001) decreased significantly during the study period but such reports by controls (70% to 75%, p=0.3, and 68% to 74%, p=0.4) did not (Table 3.15). Again it should be noted that the time periods at baseline and follow up were not comparable.

Table 3.15 A comparison within groups: Self reported drug use and injection in prison the month prior to baseline and three months prior to follow up

Drug	Treated % (n=129)				Control % (n=124)			
	Baseline		Follow up		Baseline		Follow up	
	used	**inject**	**used**	**inject**	**used**	**inject**	**used**	**inject**
Any Drug	92	64	95	34*	94	70	95	75
Heroin	64	60	33*	32*	71	68	78	74
Prescribed methadone	0	0	69	1	0	0	11	0
Illicit methadone	24	1	12*	1	27	3	34	0
Amphetamines	7	6	4	2	9	7	10	7
Cocaine	4	3	2	2	5	5	5	5
Tranquilisers	61	2	25*	2	65	4	39*	3
Cannabis	64	-	71	-	70	-	87*	-

*p<.001

3.18 Self reported syringe sharing in prison

Over three quarters of subjects in each group reported sharing a syringe in prison the month before baseline (76%, 79%). At follow up, treated subjects were significantly less likely to report the shared use of syringes than control subjects (31%, 74%, p<0.001). There was no significant difference between groups in the median number of sharing partners or new sharing partners in prison reported at baseline or at follow up (Table 3.16).

Table 3.16 Median number of syringe sharing partners in prison; one month prior to baseline and months two, three and four of follow up

Median no. sharing partners	Treated (n=19)	Control (n=56)
Baseline sd (range)	n=54 2 (1-30)	n= 57 2 (1-64)
Month 2 sd (range)	n= 18 1 (1-8)	n= 57 2 (1-8)
Month 3 sd (range)	n= 17 1 (1-8)	n= 54 2 (1-8)
Month 4 sd (range)	n=20 2 (1-3)	n= 48 2 (1-10)
Median no. of new sharing partners		
Baseline sd (range)	n= 43 2 (1-14)	n= 47 2 (1-30)
Month 2 sd (range)	n=9 1 (1-8)	n=33 2 (1-8)
Month 3 sd (range)	n=5 1 (1-8)	n=20 2 (1-15)
Month 4 sd (range)	n=6 1 (1-3)	n=19 2 (1-10)

3.19 Hepatitis B vaccination

At follow- up 10% of treated and 15% of control subjects reported having been vaccinated for hepatitis B.

3.20 Seroincidence of HIV and hepatitis C

HIV prevalence was zero at baseline and at follow up for all subjects. Baseline HCV antibody seroprevalence was 76% in the treated group and 72% in the control subjects.

Table 3.17 HCV incidence among treated and control subjects

Follow up	Treated	Control
Number at risk	32	35
Number of sero-conversions	4	4
HCV incidence per 100 PY	24.3	31.7
95% Confidence Intervals	7 – 62	9 – 81

Of 32 treated and 35 control subjects who were HCV antibody negative at baseline, four subjects in each group had seroconverted by follow up (Table 3.17). Hepatitis C incidence was lower, but not significantly, in the treated rather than the control group. When analysed by group, there were no significant predictors of HCV in the treated or control subjects (Table 3.18).

Table 3.18 Predictors of HCV transmission among treated and control subjects

Variable	Treated			Control		
	No of cases/ No at risk	**Rate per 100 PPY**	**95% CI**	**No of cases/ No at risk**	**Rate per 100 PPY**	**95% CI**
Age group						
<25 years	2/18	17.4	2.1 - 63	1/24	10.6	0.3 - 59
25+ years	2/14	40.0	4.8 - 144	3/11	96.0	19.7 - 280
Aboriginal						
Yes	1/9	19.5	0.5 - 109	0/8	0	0
No	3/23	26.0	5.4 - 76	4/27	41	11 - 105
Inject heroin, FU						
Yes	1/5	32.9	0.8 - 183.3	3/21	36.5	7.5 - 107
No	3/23	21.9	4.5 - 63.9	1/7	29.2	0.7 - 163
Shared, FU						
Yes	1/5	32.9	0.8 - 183.3	2/15	32.9	4.0 - 118.8
No	3/23	21.9	4.5 - 63.9	1/7	36.5	0.92 - 203
Tattooed, FU						
Yes	1/3	58.4	1.5 - 325.3	1 / 4	54.8	1.4 - 305
No	3/25	18.3	3.8 - 53.4	3/27	25.6	5.3 - 74.8
Any inject, FU						
Yes	1/5	32.9	0.8 - 183.3	3/21	36.5	7.5 - 106.5
No	3/23	21.9	4.5 - 63.9	1/10	18.3	0.5 - 102

3.21 Predictors of HCV transmission for all subjects

Among all subjects, seroconversion to HCV antibody during the follow up period were more likely to be aged 25 years or older (p=.02), to have been tattooed in prison during the study period (p=.01), and to report heroin injection at follow up (p=.05).

3.22 Tattooing and sexual risk behaviour

Twelve percent of each group reported receiving a tattoo between interviews. Four percent of treated subjects and three percent of controls reported sharing a tattoo needle. Of those who were tattooed, four percent of treated subjects and five percent of controls reported cleaning the tattoo needle before reusing it. No subject reported having sex with another prisoner at follow up.

Table 3.19 Tattooing

	Treated % (n=129)	Control % (n=124)
Tattooed	12	12
If yes		
Shared tattoo needle	33% (5/15)	27% (4/15)
Cleaned tattoo needle	33% (5/15)	40% (6/15)

3.23 A comparison of ATSI and non- ATSI subjects

When compared to non- indigenous subjects, indigenous subjects were significantly younger at age of first imprisonment (18 vs 20, p<.001) and had previously been imprisoned on more occasions (6 vs 4, p=.02) (Table 3.20). They were comparable on other baseline and treatment variables.

Table 3.20 Comparison of ATSI and Non- ATSI Subjects

Variable	ATSI (n= 59)	Non- ATSI (n=194)
Mean age (sd)	27	27
Prison history		
Mean age first imprisoned (sd)	18 (2)	20 (4)**
Mean times in prison (sd)	6 (5)	4 (5)*
Security Classification %		
Maximum	22	18
Medium	15	12
Minimum	10	17
Escapee	15	18
Unclassified/ unknown	37	36
Median mths in prison at baseline (R)	1(.25- 247) n=25	2 (.5- 130) n=106
Median sentence length yrs (R)	2 (.2- 21)	1 (.2- 15)
Drug use history		
Mean age first injection yr (sd)	16 (3)	17 (4)
Mean age daily injection began yr (sd)	18 (3)	19 (4)
Ever shared syringes in community %	72	69
Drug use in prison		
Ever injected in prison %	91	87
Ever shared syringes in prison %	78	77
Serology		
HCV positive %	73	74
HIV positive %	0	0

***p=.02**
****p<.001**

3.24 Self reported MMT experience

Over two thirds (69%) of the treated group remained in methadone treatment for an average of 20 weeks (range 0.7- 76) (Table 3.21). Their mean dose of methadone was 61 mg (range: 5- 150), with most (62%) reporting a stable dose of methadone at follow up. Methadone treatment was discontinued for 28 subjects (22%) in the treated group during the study, after an average of nine weeks in treatment (range 0.7- 35). Twelve subjects in the treated group (9%) did not commence treatment.

Nineteen percent of control subjects commenced methadone treatment during the study period (Table 3.21). The mean dose of methadone prescribed for the 23 controls at follow up was 64 mg (range: 10- 120). Sixteen percent of control subjects received methadone for the entire duration of the study period (mean duration 20 weeks, range 0.3- 59). A further two percent of controls received methadone for part of the study period (mean duration 6 weeks, range: 0.9- 15).

Table 3.21 Methadone maintenance treatment dose, attitudes and difficulties reported by subjects who received treatment for the duration of the follow up period

	Treated (n= 82)	Control (n= 15)
Weeks in treatment (range)	20 (0.7- 76)	20 (0.3- 59)
	n= 77	
Mean current methadone dose at follow up mg (sd)	61(37)	64(42)
(R)	5- 150	10-120
Methadone dose stability		
Stable %	62	80
Increasing %	9	7
Reducing %	29	13
Opinion of methadone dose		
Okay %	55	60
Too high %	4	-
Too low	41	40
Ease of changing methadone dose		
Very easy %	4	7
Easy %	51	53
Difficult %	20	27
Very difficult %	11	7
Impossible %	3	7
Never tried %	12	-
Dose received		
Morning %	93	100
Afternoon %	4	-
Both %	4	-
Problems when receiving doses %	23	27
Expect to stay on MMT for rest of sentence %	56	60

3.25 Subjects who received MMT

Approximately one quarter (23%, 27%) of both groups reported problems when receiving their dose (Table 3.21). Common reasons given as causing problems were being on escorts, having to attend court appearances and lock downs. These occurrences not only delayed dosing times, but also would sometimes result in a dose not being received.

Other inmates (49%, 35%), family (29%, 27%) and prison officers (26%, 20%) were the ones subjects most often reported as suggesting they cease methadone treatment (Table 3.22). Two percent of treated subjects reported their family suggested ceasing methadone treatment for parole reasons.

Table 3.22 Subjects who received MMT: reports of pressure to cease methadone maintenance treatment from various individuals

Various individuals	Treated % (n=82) Discontinue MMT	Control % (n=15) Discontinue MMT
Other inmates	49	35
Family	29	27
Prison officer	26	20
D &A Counsellor	9	13
Doctor	4	-
Nurse	4	-
Psychologist	2	-
Solicitor	2	-
Review or parole board	2	-

Most subjects (67%, 47%) had received a medical examination by the prison methadone prescriber. Additionally, more than half of those treated in both groups (54%, 60%) had been seen by at least one healthcare worker, including their prescriber, regarding their methadone treatment prior to follow up (Table 2.23).

Table 3.23 Subjects who received MMT: healthcare workers that were seen or wanted to be seen about methadone maintenance treatment since baseline interview

Healthcare worker	Treated % (n=82)		Control % (n=15)	
	Did see	Wanted to see	Did see	Wanted to see
Prescriber	17	21	33	36
Nurse	22	19	27	29
Other doctor	17	17	20	21
D&A counsellor	17	11	7	7
Psychologist	1	4	7	14

Over two thirds of both groups were very satisfied or satisfied with the prison methadone program (69%, 80%) (Table 2.24).

Table 3.24 Subjects who received MMT: Satisfaction with the prison methadone program

Level of satisfaction	Treated % (n= 82)	Control % (n= 15)
Very Satisfied	10	13
Satisfied	59	67
Indifferent	11	13
Dissatisfied	17	-
Quite dissatisfied	4	7

3.26 Control subjects

Of the 66% of control subjects who were still interested in entering methadone treatment at follow- up, over two thirds (74%, n=61) expected to stay on the methadone maintenance program until they completed their sentence. There were also six subjects in the treated group yet to commence treatment who wished to do so. The majority (83%, n= 5) expected to remain in treatment until the end of their sentence. Subjects in the treated group yet to receive treatment were excluded from the following analysis due to the small number.

Table 3.25 Control subjects' reports of pressure not to commence methadone maintenance treatment from various individuals

Various individuals	Not to commence MMT % (n= 82)	Not to commence MMT due to parole % (n= 82)
Other inmates	60	1
Family	18	-
Prison officer	12	-
D&A Counsellor	6	1
Solicitor	4	1
Psychologist	1	-
Parole officer	1	1
Review or parole board	1	1
Serious offenders review council	1	1

Subjects reported another inmate (60%), a family member (18%), a prison officer (12%) or a drug and alcohol counsellor (6%) were most likely to have suggested that they should not commence methadone treatment, although rarely was this due to parole reasons (Table 3.25).

3.27 Self reported medical complaints

A range of medical complaints were reported by subjects. The majority of problems were comparable between groups although headaches (66% vs 50%) were reported by a significantly lower proportion of treated subjects (p= .015) Significantly more headaches were also reported by seroconverters (n=8) (p=0.05) (Table 3.26).

Table 3.26 Self reported physical complaints

Physical complaint	Treated % (n=129)	Control % (n=124)
Headache	50	66*
Aches in muscles or joints	54	55
Darkened urine	47	45
Abdominal pain	34	39
Loss of appetite	45	36
Sore throat	30	35
Influenza	35	34
Nausea	33	32
Hot/ cold shivers	36	32
Fever	13	21
Diarrhoea	14	19
Pain under rib cage	28	17
Rash	9	13
Jaundice (skin, eyes)	2	2

*p=.015

3.28 Prescribed medication

Not surprisingly, treated and control subjects had been prescribed a range of medication, with pain medication (64%, 57%), other medication (52%, 49%) and sleeping pills (16%, 19%) being the most commonly reported respectively. About one sixth of both groups reported being prescribed no medication at all (Table 3.27).

Table 3.27 Comparison of self reported prescribed medication

Medications prescribed in the last month	Treated % (n=129)	Control % (n=124)
Pain medication	64	57
Other	52	49
Sleeping pills	16	19
No medication	19	16
Cough/ cold medication	18	14

4. DISCUSSION

This randomised, controlled study demonstrated that MMT provision in a prison healthcare setting was effective in reducing heroin use, drug injection and syringe sharing among incarcerated heroin users. Heroin use, as measured either by positive hair test or self-report, declined significantly in the treated group compared to the wait-list control group. Consistent with reduced heroin use, self-reported drug injection and syringe sharing also declined significantly in the MMT group compared to control. No cases of HIV seroconversion were detected in either group. The rate of hepatitis C seroconversion was lower, but not significantly so, in the MMT group compared to the control group. The ability to detect significant differences in hepatitis C incidence rates was limited by the high prevalence of hepatitis C in the study groups and the relatively brief period of follow up. Nevertheless, the serology will permit a longer follow up period that may allow detection of a significant between-group difference, if one exists. This study also demonstrated that a randomised controlled trial of methadone treatment in prison was feasible.

Risk factors for HIV/hepatitis C transmission other than injecting drug use include tattooing and sex. In this study, independent predictors of hepatitis C seroconversion were being tattooed in prison during the study period, being older than 25 years and heroin injection during study period. Efforts need to be directed at reducing the prevalence of tattooing in prison or making it safer. Sexual risk behaviour for HIV could not be examined as one ethics committee precluded the inclusion of such questions. At follow up no subjects reported sex with another inmate although the response rate to this question was low. In subsequent studies, the HIV Risk Behaviour Scale (HRBS) including the sexual and injecting behaviour components has been approved. This will be particularly important to studies of HIV transmission in prison. Fortunately, no HIV transmissions were detected in the present study.

Reported syringe sharing was high at baseline in both groups but reduced significantly between interviews in subjects who received MMT. Given the high HCV prevalence across both groups, and the potential for a HIV epidemic (Dolan & Wodak, 1999), a reduction in the main route of blood borne virus transmission is important evidence for the provision of MMT to IDUs in prison. Offering treatment to IDUs while in prison provides an opportunity to treat those who might otherwise be difficult to reach in the community. More importantly it also reduces HIV and HCV risk behaviour in prison. All subjects reported numerous medical complaints and received a range of prescribed medication. IDUs may be more inclined to seek medical attention while in prison. This represents an opportunity to provide treatment to those who may not otherwise seek it. A small proportion of subjects started injecting while in prison. This suggests MMT should be initiated in prison as well as continued for those entering prison while in treatment. Jurisdictions that limit MMT programs to remanded inmates already in community MMT programs should consider extending MMT programs to include initiation of MMT treatment in prison.

The main limitation for the study was the high prevalence of hepatitis C which precluded the detection of significant between-group differences in this sample size and over the relatively short follow up observation period. This coupled with the high prevalence of hepatitis C infection precluded the possibility of detecting a difference in hepatitis C incidence between

groups. The duration of follow up was shorter than the time taken to access MMT in prison. Prolonging the duration of follow up would have seriously compromised the recruitment of subjects. In retrospect, hepatitis C negative inmates should have been over sampled.

Another limitation of the study was that only two thirds of treated subjects remained in treatment although this is comparable to MMT retention in the community. Subjects reported that other inmates, family members and staff discouraged them from remaining in or entering methadone treatment. Inmates, families and prison staff should be educated about the benefits of MMT. Also subjects in this study were on moderate doses of methadone (61mg) and outcomes may have improved with slightly higher doses (Dolan et al., 1998). It is possible that the trial attracted more desperate subjects as controls were promised access to methadone at the end of the trial. If so then the results would not be generalisable to the rest of the prison population with a heroin problem. However it is also likely that desperate cases did not apply for the trial (nor treatment). The sample reflected the general populations of prisoners who have a heroin problem.

There was potential for contamination through control subjects starting methadone before follow-up interview and treatment group subject not starting MMT. Analyses were stratified to test for potential bias by removing these subjects. This did not change outcomes with the exception of proportions of morphine positive hair samples which were significantly higher in the control group in the final month of follow up. This suggests that the treatment effect in terms of reduced heroin use may have been suppressed by control subjects receiving treatment before their follow-up interview and hair sample collection.

Methadone treatment reduced drug use and injection in prison. The implications from this study are far reaching as very few jurisdictions provide MMT to prisoners. This study suggests that prison based methadone should be provided in countries where community based programs operate (Dolan, et al, 2001). Further research is currently underway. A follow up study of subjects in this trial has investigated possible long term outcomes of MMT such as reduced rates of re-incarceration, mortality and HCV and HIV incidence over a five year period. A randomised controlled trial of naltrexone vs methadone vs counselling in NSW prisons has commenced. The difficulties of conducting research in prisons should not be under-estimated. Controlled trials are very rare in correctional settings. This study was fortunate in the support and commitment of all stakeholders; research, corrections health and custodial. Their continuing support will be vital for the on-going task of follow-up this treatment cohort.

This study builds on other RCTs of MMT in that those in treatment reduce their heroin use. The implications from this study are far reaching. Very few countries provide MMT to prisoners although many countries operate MMT programs in the community setting. This study raises the issue of whether countries that provide community based MMT programs should also provide prison based methadone programs. This issue is even more apparent as this prison based methadone program has the potential to reduce hepatitis C transmission among IDUs. If health departments are serious about controlling hepatitis C transmission among IDUs they must take responsibility for health services, including methadone maintenance programs, for prisoners in their jurisdictions.

5. RECOMMENDATIONS

The findings of this study are consistent with the methadone literature which shows that methadone maintenance significantly reduced heroin use, injecting behaviour and other associated health risks both in community, post-release and now prison settings.

1) This study found that prison based methadone programs are safe and effective in reducing heroin use, drug injecting and sharing. The risk of hepatitis C and HIV transmission is higher in prisons than in the community. MMT reduces HIV and HCV risk behaviour in prison. In the light of these findings MMT should be considered as a gold standard for the treatment of heroin users in prison.

2) MMT should be made available to all prisoners with heroin use problems throughout their period of imprisonment.

3) Jurisdictions that only provide MMT to those prisoners who were receiving MMT on prison entry should extend such programs to all prisoners at risk of heroin injecting.

4) Further studies are needed to monitor the transmission of hepatitis C and HIV in prison. Given the high prevalence of hepatitis C, more research is needed to focus on hepatitis C negative injecting drug users in prison with longer periods of follow-up.

5) Randomised trials of interventions for injecting heroin users in prison settings may be difficult but this study shows that they are feasible. Randomised controlled interventions of alternative opioid pharmacotherapies such as naltrexone and burprenorphine and other harm minimisation interventions such as needle and syringe programs are recommended.

6) Tattooing was identified as an independent predictor of hepatitis C seroconversion. Efforts need to be directed at reducing the prevalence of tattooing in prison or reducing the harm of this behaviour.

7) Sexual behaviour is a risk factor for HIV that was not directly examined in this study. Future studies should include questions regarding sexual behaviour.

8) Prejudice and misunderstanding can undermine MMT programs and the aim to reduce the risk of HIV and HCV transmission in prison. Education regarding harms of heroin use in prison and benefits of treatment for inmates, families and custodial staff is an on-going need.

9) Adequate methadone doses (80 mg) are needed to ensure the success of prison MMT programs.

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APPENDIX A SUMMARY OF RESEARCH INTO THE NSW PRISON METHADONE PROGRAM

The NSW Department of Corrective Services has conducted 11 studies of the prison methadone program. The first study provided a profile of the first 129 inmates who were assessed as suitable for the pilot pre-release program (Wales & Gorta, 1987a). In the second study, 36 clients' views of their experience of being in the program were surveyed (Wales & Gorta, 1987b). Study three reported clients' (n=201) contact with methadone services after release (Gorta, 1987a). Study four reported on 300 tests on urine samples from 63 prisoners on the program (Gorta, 1987b). The views of key personnel involved in the administration of the methadone program were solicited in study five (Hume & Gorta, 1988a). The results of community urinalyses for clients were examined in study six (Hume & Gorta, 1988b). The seventh study investigated criminal recidivism and retention in community methadone programs (Hume & Gorta, 1989). Study eight canvassed the views of recidivists who had been released on methadone (Bertram & Gorta, 1990a). In Study nine, inmates' perceptions of the role of the methadone program preventing HIV were canvassed (Bertram & Gorta, 1990b). Study ten examined the results of 3,700 urinalyses taken from 235 prisoners (Bertram, 1991). This study found 10 percent of inmates gave urine samples that contained morphine (heroin), but there was no comparison group. Study eleven examined the change over of administrative responsibility from the Department of Corrective Services to the Department of Health (Wolk & Eyland, 1991).

APPENDIX B TIMETABLE OF THE STUDY

Approval from one Ethics Committee precluded the inclusion of sexual risk behavioural questions.
Obtaining approval from all four Committees was a protracted process.

One committee required that extra places be created on the methadone program for research purposes. This required extra funding to be obtained.

Problems Encountered

The first attempt to obtain funding for the study in 1995 was unsuccessful. Numerous delays were experienced in obtaining ethical approval. An impasse between researchers and two Ethics Committees led to a suspension of funding for four months until these differences were resolved.

1994	First Meeting of Stakeholders
1995	Application for funding unsuccessful Ethics committee applications (4)
1996	Funding from RIDAC $210,00 First Pilot study carried out
1997	Second Pilot Study carried out St.Vincent's' Ethics Approval UNSW Ethics Approval DOCS Ethics Approval CHS Ethics Approval Recruitment started Funding from Glaxo-Wellcome $40,000 Funding from NSW Health $19,500
1998	Funding from Commonwealth $26,950 Recruitment Completed
1999	Follow Up Completed
2000	Hair results received Serology received