

REPORT AND RECOMMENDATIONS

of

Stage 2 Feasibility Research into the Controlled Availability of Opioids

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with a Foreword by

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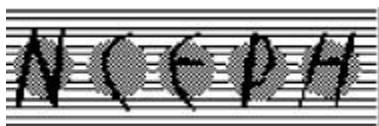
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June 1995



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C R I M I N O L O G Y

Report and Recommendations of Stage 2 Feasibility Research into the
Controlled Availability of Opioids

Gabriele Bammer

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Foreword

The feasibility research described here resulted from a partnership between our two institutions. It has been carried out under the direction of Dr Gabriele Bammer. We have co-chaired the meetings of the Advisory Committee, which have had Australia-wide representation from policy-makers, police, judiciary, treatment-service providers, academics and advocates for illicit drug users. It was agreed at the outset that the Advisory Committee would not take responsibility for the report and its recommendations. That responsibility rests with us and Dr Bammer.

We now have pleasure in presenting the findings of Stage 2 of the feasibility research and believe that it is now both feasible and desirable to proceed to a third stage of two pilot studies to be carried out in the ACT. These studies will determine whether a fourth stage definitive study in three Australian cities is practicable and/or desirable.

We thank the many people who have collaborated in the studies that made up the Stage 2 research; the 19 members of our Advisory Committee; and innumerable others who contributed in smaller, but no less important ways. Over the past four years, the research has painstakingly considered the risks involved in prescribing diacetylmorphine (heroin) to dependent users. We have concluded that the risks could be minimised and that they are outweighed by the potential benefits. The careful design of the clinical service incorporates numerous crucial safeguards.

We have thought carefully about the best form of evaluation for a trial and have concluded that the core should be a randomised controlled trial that will examine the following clinical question:

If maintenance treatment for opioid dependence is expanded so that both injectable diacetylmorphine (heroin) and oral methadone are available, is this more effective than current maintenance treatment which involves the provision of oral methadone only?

In addition to the clinical issues, the research must have a strong criminological component which examines the social impact of expanded maintenance treatment, particularly the effects on crime.

Well-run and rigorously evaluated pilots and a definitive trial will require extensive financial support. The studies carried out over the past four years have cost nearly \$1 million, with a major contribution from the ANU's Strategic Development Fund. We believe this is an issue of national significance and that, while the processes should now be pretested in the ACT, national funds will be needed to carry the issue forward.

There is now a need for wide community discussion of the issues raised by our recommendations. Our research reveals that both the ACT community and the broader Australian community are convinced that new approaches to the "heroin problem" are required. The steps proposed here are designed to move cautiously and with scientific rigour in an evaluation of alternatives. This is an area in which

there is remarkably little hard evidence. Preliminary experience from trials of diacetylmorphine prescribing in Switzerland is, however, reassuring. We believe the proposals described here are practicable, explore new territory and would contribute substantially to sound policy and treatment development for Australia.

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Executive Summary

This report is the culmination of four years of research into the question: *Should a carefully controlled and rigorously evaluated trial be conducted to determine whether or not the prescription of pharmaceutical heroin (diacetylmorphine) is a useful addition to current maintenance treatment for dependent heroin users?*

It recommends that two carefully controlled pilot studies should be conducted in Canberra. However, the addition of diacetylmorphine to maintenance treatment must not be linked with permissive attitudes to illicit drug use and must be coupled with continuing law enforcement and prevention activity against illicit drug use.

There is a sixteen-year history in Australia of government consideration of the issue of diacetylmorphine maintenance treatment. In 1991 the ACT Legislative Assembly Select Committee on HIV, Illegal Drugs and Prostitution asked the National Centre for Epidemiology and Population Health at The Australian National University to investigate the issue and, in collaboration with the Australian Institute of Criminology, research into in-principle and logistic feasibility was undertaken.

It was found that a trial would not place Australia in breach of international treaties. ACT and other laws will have to be changed for a trial to proceed and the Commonwealth must grant licences and permissions.

There is considerable community support, both in the ACT and nationally, for new approaches to the problem of heroin dependence and, although there is a degree of uncertainty about an ACT-based trial, there is more support than opposition to it, particularly in Canberra. There should now be a three-month consultation period to allow the feasibility study findings to be scrutinised and discussed as widely as possible.

Of all the interest groups, the police have the most concerns about a trial, and their concerns were carefully considered in the feasibility investigations. Limiting participant eligibility to restricted numbers of users registered with the ACT methadone program and resident in the ACT since 1993 will minimise the risk that dependent users might move to the ACT from elsewhere in Australia. There are also safeguards to prevent participants from driving while affected by diacetylmorphine and strict security provisions, including administration of diacetylmorphine only at the clinic under close supervision.

Other potential risks were carefully scrutinised and ways to minimise them determined. By minimising the risks, it becomes feasible to evaluate the potential benefits of expanding maintenance treatment to include diacetylmorphine. The potential benefits include decreased crime and improved health and social integration.

The pilots and trial will be of national significance. It is estimated that establishing and conducting an initial six-month pilot with 40 participants will cost around \$800,000 and a second six-month pilot with 250 participants will cost \$1.5 million. These

pilot studies will determine whether or not a multi-centre two-year trial involving three Australian cities should be undertaken. Evidence is accumulating that treatment of illicit drug users is more cost-effective than leaving them in the community untreated or sending them to jail. Initial estimates suggest that expanded maintenance treatment which includes diacetylmorphine would cost the community less than one-tenth of the cost of an untreated illicit heroin user and would be substantially cheaper than some current treatments. The pilots and trial provide the possibility of significantly strengthening treatment options.

Part 3: Results of the feasibility research

Recommendations

Recommendation 1. That two carefully controlled pilot studies are conducted in Canberra to assess the addition of injectable diacetylmorphine to maintenance treatment for registered dependent users. If these produce positive outcomes, that a full-scale trial of expanded maintenance treatment which includes injectable diacetylmorphine is conducted in at least three Australian cities.

Recommendation 2. That the exploration of expanding maintenance treatment to include injectable diacetylmorphine is coupled with continuing law enforcement and prevention activity to control illicit drug use. The addition of diacetylmorphine to maintenance treatment should not be linked with permissive attitudes to illicit drug use.

Recommendation 3. That the first pilot study is conducted with 40 established ACT resident volunteers who have either dropped out of ACT methadone treatment or who are current ACT methadone clients who would prefer the expanded treatment option. That, over a six-month period, the study examines the following questions:

- can the addition of injectable diacetylmorphine to maintenance treatment for dependent heroin users be undertaken successfully on a small scale in the Australian context?
- can dependent heroin users be stabilised on injectable diacetylmorphine or injectable diacetylmorphine plus oral methadone and what are the optimum dosage ranges?
- can injectable diacetylmorphine maintenance treatment be successfully integrated with oral methadone maintenance treatment to provide flexibility in treatment?
- does the expansion of maintenance treatment to include injectable diacetylmorphine improve the health and social functioning and reduce the criminal behaviour of participants?
- is it possible to develop a package of indicators to measure the social impact of adding injectable diacetylmorphine to maintenance treatment?

Recommendation 4: Pilot study 1 will be deemed a success if the following criteria are met:

- that a stable maintenance dose of injectable diacetylmorphine or injectable diacetylmorphine plus oral methadone is found for more than half of the participants;
- that injectable diacetylmorphine maintenance treatment can be successfully integrated with oral methadone maintenance treatment;
- that there are indications of improvements in at least half of the outcome measures pertaining to health, criminal behaviour and social functioning;

- that workable measures of social impact are determined.

Recommendation 5. If pilot study 1 is a success, that a second pilot study is conducted with 250 dependent heroin users drawn from volunteers who have been resident in the ACT since 1993, and who have dropped out of ACT methadone treatment, or who are current ACT methadone clients who would prefer the expanded treatment option. That, over a six month period, this pilot address the following questions:

- does the addition to maintenance treatment of injectable diacetylmorphine attract back and retain in treatment dependent heroin users who have dropped out of methadone treatment?
- does the expansion of maintenance treatment to include diacetylmorphine improve retention in treatment for those drawn from current methadone clients?
- is it possible to conduct a successful randomised controlled trial with dependent heroin users when the highly desirable 'choice' option, which provides injectable diacetylmorphine, is available to only half of the participants?
- does the addition of injectable diacetylmorphine to maintenance treatment produce better outcomes in terms of health, criminal behaviour and social functioning.
- can dependent heroin users be stabilised on injectable diacetylmorphine or injectable diacetylmorphine plus oral methadone, on a large scale?
- can injectable diacetylmorphine maintenance treatment be integrated successfully with oral methadone maintenance treatment to provide flexibility in treatment, on a large scale?
- are the individual measures of outcomes 'workable'; in other words can the questionnaires be administered without undue respondent burden and can the results be analysed in a timely fashion? If new measures are used, are they valid and reliable?
- is the package of indicators developed to measure the social effects of a trial workable? Have there been any major negative social effects?

Recommendation 6: Pilot study 2 will be deemed a success if the following criteria are met:

- that there is an indication that dependent heroin users, who have dropped out of methadone treatment, are attracted back to treatment and that the retention rate for both this group and for those recruited from current methadone clients is better than for participants who receive oral methadone only.
- that the process of randomising participants into two groups, only one of which receives the choice of injectable diacetylmorphine prescription, is shown to be feasible for evaluating the multi-centre two-year trial.
- that at the end of six months, there are indications of improvements in at least half of the outcome measures pertaining to health, criminal behaviour and social functioning.

- that a stable maintenance dose of injectable diacetylmorphine or injectable diacetylmorphine plus oral methadone can be found for more than half of the participants in the 'choice' group.
- that injectable diacetylmorphine maintenance treatment can be integrated successfully with oral methadone maintenance treatment.
- that individual measures of outcomes are determined to be workable.
- that the package of indicators developed to measure the social impact of diacetylmorphine prescribing is workable and there have been no major negative effects.

Recommendation 7: If the pilot studies are shown to be successful, that a two-year trial with 1000 participants is conducted in three Australian cities. That it target three groups of dependent heroin users—those who have never been in treatment, those who have dropped out of treatment, and current methadone clients who would prefer the expanded treatment option. That it address the following questions:

- can the availability of injectable diacetylmorphine as part of maintenance treatment attract into and retain in treatment, people who have not previously been in treatment?
- does the addition to maintenance treatment of injectable diacetylmorphine attract back and retain in treatment dependent heroin users who have dropped out of methadone treatment?
- does the expansion of maintenance treatment, to include diacetylmorphine, improve retention in treatment for those drawn from current methadone clients?
- for each of the three target groups, does providing a choice of treatment which includes the option of injectable diacetylmorphine improve outcomes over the option of oral methadone only? Participants in the 'choice' and 'control' groups will be compared on the following measures: health, criminal behaviours and social functioning. If the outcomes are positive in the first year, all participants will be allocated to the 'choice' group for a second year, to test if the positive outcomes can be sustained.
- what is the social impact of expanding maintenance treatment to include diacetylmorphine prescription?
- is adding diacetylmorphine to maintenance treatment cost-effective?

Recommendation 8. That the service provision for the pilot studies and the ACT component of the trial is provided by the Alcohol and Drug Service of ACT Health. That the independent evaluation is conducted jointly by the National Centre for Epidemiology and Population Health at The Australian National University and the Australian Institute of Criminology. That a committee is established to oversee the running of the pilot studies and the ACT component of the trial. Its membership should include representatives from the clinical staff, participants and researchers; the police and judiciary; the medical profession and non-government treatment services; ACT Health and the ACT Attorney-General's Department; relevant Commonwealth departments; and an ethicist. That this committee will recommend to the ACT Legislative Assembly whether or

not there should be progression from pilot 1 to pilot 2 and from pilot 2 to a trial or if the prescription of injectable diacetylmorphine should be stopped at any time.

Recommendation 9: That, noting the national significance of the ACT-based pilot studies, there is extensive financial support from outside the ACT to fund the pilot studies.

Recommendation 10: That the ACT government institutes a three-month consultation period in which the results of the feasibility research are widely disseminated and discussed. That a committee is established to receive and consider the feedback from groups and individuals. That the committee includes representation from the ACT Health Alcohol and Drug Service; the police and judiciary; the ACT Attorney-General's Department; relevant Commonwealth departments; illicit heroin users; the medical profession and non-government treatment services; an ethicist; and the Director of the Feasibility Research. That the committee reports to the ACT Minister for Health on the results of the consultation no later than 31 October 1995.

Recommendation 11: That the ACT Health Alcohol and Drug Service is proactive in disseminating information about eligibility criteria to drug treatment services and user advocacy groups around Australia.

Recommendation 12: That, to establish the first pilot study, the ACT Legislative Assembly either amend existing legislation or introduce special legislation to make diacetylmorphine available for carefully controlled and limited medical prescription. That the ACT government liaise with the Commonwealth and other States about the passage of relevant legislation and the provision of the necessary licences and permissions. That a service manager and a senior specialist are employed as soon as practicable to establish policy and procedures for the service delivery. That the service manager is also responsible for finding a suitable location for the new clinic; organising refurbishment; and hiring and training non-medical staff.

Part 1: The Proposal Introduction

This report presents the results of more than four years of research addressing the question: *Should a carefully controlled and rigorously evaluated trial be conducted to determine whether or not the prescription of pharmaceutical heroin (diacetylmorphine¹) is a useful addition to current maintenance treatment options for dependent heroin users?*² Two important components to this question must be highlighted. First, the question is about the feasibility of conducting a trial, not about the feasibility of a new treatment option. The results of the trial will enhance significantly the ability to assess whether or not the new treatment option should be introduced. Second, diacetylmorphine is to be trialed as an additional choice for dependent heroin users in current maintenance treatment, not as a separate or replacement treatment.

It was concluded that while there are both potential benefits and potential risks to conducting such a trial, the benefits outweigh the risks. It is recommended that the investigation of the feasibility of a trial now move to a third stage of pilot studies, which should take place in Canberra.³

The research was undertaken after Mr Michael Moore MLA approached the National Centre for Epidemiology and Population Health (NCEPH) at The Australian National University in March 1991. At the time, he was the Presiding Member of the ACT Legislative Assembly Select Committee on HIV, Illegal Drugs and Prostitution. The committee argued that "current policy implementation with regard to controlling and/or reducing the use of illegal drugsÉmight not be effective" (Legislative Assembly for the Australian Capital Territory 1991:1). Members were particularly concerned about the social costs of dependent heroin use, including the potential for spread of HIV/AIDS, both within the illicit drug using community and from that group into the general community. Members recognised that "the Australian official drug strategy of harm minimisation has had considerable success, particularly in combating the spread of HIV" and wanted to explore "what would be the next step if the harm minimisation approach was to be extended" (Legislative Assembly for the Australian Capital Territory 1991:v).

During the course of the feasibility research, evidence began to accumulate that treatment of illicit drug users is more cost-effective than leaving them in the community untreated or sending them to jail (see part 2). This suggests that it will be highly advantageous to society to improve both the attractiveness and effectiveness of treatment.

An expert committee convened by NCEPH in April 1991 overwhelmingly endorsed the need to examine the feasibility of

¹ Throughout this report, diacetylmorphine is used to refer to pharmaceutical 'heroin'. Heroin refers to the illicit drug.

² Maintenance treatment in Australia is currently confined to oral methadone treatment. Maintenance treatment is described in Part 2.

³ Canberra is the only large population centre in the Australian Capital Territory (ACT). The terms Canberra and ACT are used interchangeably.

expanding maintenance treatment to include diacetylmorphine and suggested a four-stage process.

The first stage, undertaken collaboratively between NCEPH and the Australian Institute of Criminology (AIC), found that a trial to assess the therapeutic value of adding diacetylmorphine to the maintenance treatment options for heroin dependence was feasible in principle (NCEPH, 1991*⁴) and it was recommended that the logistic feasibility of a trial be examined. This report marks the end of that second stage. The results show that it is logistically feasible to conduct a trial and it is recommended that the third stage of pilot investigations be undertaken. If those are successful then there should be a full-scale trial, the fourth stage.

The rationale for expanding maintenance treatment to include diacetylmorphine is described in part 2 of this report, where the history and context of this project are also presented. The results of the feasibility investigations are presented in part 3 and a budget for the pilot studies is presented in part 4.

The proposal to pilot and trial the addition of diacetylmorphine to maintenance treatment

Proponents of adding diacetylmorphine prescribing to current maintenance treatment argue that providing the drug (diacetylmorphine) and route of administration (intravenous injection) that users want would bring more dependent heroin users into treatment, keep them in treatment longer and produce outcomes that are better than currently available options. In particular, proponents argue that it will mean that dependent heroin users do not have to commit crime to buy expensive illicit heroin and that it will remove them from the illicit drug scene, so that they no longer use illicit heroin or other drugs. In addition, they argue that access to pharmaceutically pure diacetylmorphine and using it in a clinical environment will remove the health risks associated with heroin use, including the risks of transmission of HIV/AIDS and hepatitis. Finally, removing people from the illegal drug scene and placing them in a treatment environment will give them time and access to resources to allow them to become more socially integrated.

The addition of diacetylmorphine prescribing to currently available maintenance treatment should, if practised on a large enough scale, attract a substantial proportion of dependent heroin users into treatment, so that there should be measurable social benefits. In particular, there should be a noticeable reduction in property crime, as this is the largest social cost associated with dependent heroin use.

The anticipated benefits on both the individual and social levels form testable hypotheses.

Opponents of expanding maintenance treatment to include diacetylmorphine argue that the benefits would not eventuate and

⁴ References marked with * resulted from the feasibility research.

have pointed to a range of risks, including that any city introducing such an option would attract dependent heroin users from around the country; that controlled availability of diacetylmorphine would encourage illicit drug use; and that a trial would face insurmountable logistic problems. Like the benefits, the potential risks also form testable hypotheses. The assessment of the feasibility study is that various safeguards can minimise these risks and that the potential advantages of expanding maintenance treatment to include diacetylmorphine should be investigated.

If pilot studies and a trial are undertaken, it is crucial that the effects are fully and carefully evaluated so that the questions discussed above are addressed and so that a better informed assessment can be made of whether or not diacetylmorphine prescribing is a useful long-term addition to maintenance treatment for dependent heroin users.

There are three population groups of interest: dependent heroin users who have dropped out of currently available treatment options, current methadone clients who would prefer the expanded treatment option and dependent heroin users who have never been in treatment. The first two groups identify themselves as being in need of treatment, but current options are not, or not completely, successful. The third group includes two sub-groups. The first are dependent users whose drug use and lifestyles are relatively stable and who either see little need for help or do not see current treatment services as appropriate. The second are younger users, whose dependence is just beginning to become problematic. These are the 'hard-to-reach' dependent users about whom relatively little is known, including how useful treatment could be.

The treatment to be evaluated is not injectable diacetylmorphine alone, instead the evaluation will examine a treatment option which provides a choice of injectable diacetylmorphine alone, injectable diacetylmorphine plus oral methadone or oral methadone alone and where, within the limits of medical safety, participants can move freely between these options. In addition to assessing whether or not the availability of injectable diacetylmorphine improves the ability to attract and retain people in treatment, the major comparison for a trial will be between participants who are allowed a choice of options which includes injectable diacetylmorphine and participants who have only oral methadone available to them. While a straight comparison between injectable diacetylmorphine and oral methadone would be methodologically neater, it is not clinically sensible. Oral methadone treatment is available, well accepted, has advantages particularly in terms of its long-acting nature⁵ and effectiveness as an oral medication, and is a successful treatment for many dependent users. To reiterate, the key clinical question is: if maintenance treatment is expanded so that both injectable diacetylmorphine and oral methadone are available, is this more

⁵ Oral methadone is effective with a single administration daily. Diacetylmorphine is shorter acting and most dependent users inject more than once a day. Allowing a combination of treatments should give participants maximum flexibility.

effective than current maintenance treatment which involves the provision of oral methadone only?

A strong criminological component which examines the social impact of expanded maintenance treatment, particularly the effects on crime, is also central to the evaluation. To monitor the potential risks, a package of indicators of crime, public order and justice will be developed.

Testing the hypotheses should proceed in careful incremental steps, allowing the research to be halted if there is no indication that the mooted beneficial results will be realised or if there are substantial negative effects. Thus there would be two pilot studies followed—if indicated—by a full-scale trial.

Recommendation 1. That two carefully controlled pilot studies are conducted in Canberra to assess the addition of injectable diacetylmorphine to maintenance treatment for registered dependent users. If these produce positive outcomes, that a full-scale trial of expanded maintenance treatment which includes injectable diacetylmorphine is conducted in at least three Australian cities.

Although exploring the addition of injectable diacetylmorphine to maintenance treatment has implications for illicit drug policy, it must not be used as a lever to weaken law enforcement or prevention activities against illicit drug use.

Recommendation 2. That the exploration of expanding maintenance treatment to include injectable diacetylmorphine is coupled with continuing law enforcement and prevention activity to control illicit drug use. The addition of diacetylmorphine to maintenance treatment should not be linked with permissive attitudes to illicit drug use.

The first pilot study will assess if the addition of injectable diacetylmorphine to maintenance treatment can be conducted in the Australian context on a small scale. All participants will have a choice of treatment options: injectable diacetylmorphine alone, injectable diacetylmorphine plus oral methadone or oral methadone alone. The focus of the pilot will be to determine if participants can be stabilised on injectable diacetylmorphine or injectable diacetylmorphine plus oral methadone; if participants can move readily between the three options, so that there is flexibility in treatment; and if a workable and appropriate clinical service can be provided. For the second pilot study to be started, more than half of the participants in Pilot 1 must be successfully stabilised and there must be clear evidence of successful integration of injectable diacetylmorphine into oral methadone treatment to provide flexibility in treatment.

The effectiveness of the treatment will be assessed using a variety of outcome measures namely health, including HIV/AIDS and hepatitis risk behaviours and licit drug use; criminal behaviour, including illicit drug use; and social functioning. In order to evaluate the impact of the treatment for individuals, these measures will be compared before and after participants enter the study.

There will have to be clear indications of effectiveness on at least half of the outcome measures to warrant proceeding to Pilot 2.

As outlined earlier, potential positive and negative social effects must also be measured. However, methods for evaluation at the social level are much less well developed than examination of individual level outcomes. This pilot will investigate development of a package of indicators to monitor effects on all or some of: crime levels and patterns and public perceptions of crime; illicit drug markets, including leakage of trial drugs onto the illicit market; drug use patterns, especially among young people; heroin users moving to the ACT; offensive public behaviour by illicit drug users, including the discarding of injecting equipment in public places; effects on public health and safety, including numbers of overdoses and drug-related motor vehicle crashes; and effects on other treatment services, law enforcement and the ambulance service.

There will be 40 participants, with equal numbers being drawn from current ACT methadone clients who would prefer the expanded treatment option and from dependent heroin users who have dropped out of methadone treatment in the ACT. There will be equal numbers of men and women. All must have been ACT residents since at least 1993. This pilot will run for 7.75 months and effects will be assessed over six months.

Recommendation 3. That the first pilot study is conducted with 40 established ACT resident volunteers who have either dropped out of ACT methadone treatment or who are current ACT methadone clients who would prefer the expanded treatment option. That, over a six-month period, the study examines the following questions:

- can the addition of injectable diacetylmorphine to maintenance treatment for dependent heroin users be undertaken successfully on a small scale in the Australian context?
- can dependent heroin users be stabilised on injectable diacetylmorphine or injectable diacetylmorphine plus oral methadone and what are the optimum dosage ranges?
- can injectable diacetylmorphine maintenance treatment be successfully integrated with oral methadone maintenance treatment to provide flexibility in treatment?
- **does the expansion of maintenance treatment to include injectable diacetylmorphine improve the health and social functioning and reduce the criminal behaviour of participants?**
- **is it possible to develop a package of indicators to measure the social impact of adding injectable diacetylmorphine to maintenance treatment?**

Recommendation 4: Pilot study 1 will be deemed a success if the following criteria are met:

- that a stable maintenance dose of injectable diacetylmorphine or injectable diacetylmorphine plus oral methadone is found for more than half of the participants;
- that injectable diacetylmorphine maintenance treatment can be successfully integrated with oral methadone maintenance treatment;
- that there are indications of improvements in at least half of the outcome measures pertaining to health, criminal behaviour and social functioning;
- that workable measures of social impact are determined.

Assessment that this pilot study has been a success will warrant proceeding to pilot study 2.

An additional 210 participants will be recruited for Pilot 2, making a total of 250 participants. Recruitment will be gradual. Up to 100 places (80 additional places) will be available for volunteers who are dependent heroin users who have dropped out of methadone treatment in the ACT. One hundred and fifty places (an additional 130 places) will be available for current clients of the ACT methadone program who would prefer the expanded treatment option. To be eligible, participants must have been ACT residents since at least 1993.

One of the research questions this pilot will test is whether or not the availability of injectable diacetylmorphine as a treatment option can attract back into treatment dependent heroin users who have dropped out of methadone treatment and if it can retain them in treatment. It will also test if the retention rate for participants recruited from current methadone treatment is higher than if they had been left on methadone treatment. Like many methadone programs, the ACT methadone program has a relatively high rate of turnover. In both 1993 and 1994, half of the people who entered the program had dropped out within a few months. For the pilot to be deemed successful, there must be an indication that dependent heroin users who have dropped out of methadone treatment are attracted back to treatment and that the retention rate for both this group and for those recruited from current methadone clients is improved.

The 250 participants in pilot 2 will be randomly allocated, on a one-to-one basis, to either the 'choice' or the 'control' groups. The 'choice' group will have the choice of injectable diacetylmorphine only, injectable diacetylmorphine plus oral methadone or oral methadone only. The 'control' group will have only oral methadone available. This pilot will assess whether or not a randomised controlled trial is likely to be a successful evaluation strategy for a full-scale trial. The highly desirable 'choice' option will be available to only half of the participants. If a substantial proportion of those allocated to the 'control' group refuse to participate further in the trial evaluation or drop out of treatment completely, a randomised controlled trial will not be not workable. If a randomised controlled trial cannot be conducted, that would significantly weaken the ability to effectively evaluate

whether or not the outcomes of those allocated to the 'choice' group are better than those of participants allocated to the 'control' group in the main multi-centre two-year trial.

Pilot 2 will also assess the effectiveness of expanding maintenance treatment for the individual participants by examining effects on health, criminal behaviour and social functioning. The 'choice' and 'control' groups will be compared and there will also be comparisons of participants before and after they entered the study. Again, there must be significant indicators of effectiveness for a full-scale trial to be instigated.

The second pilot will also test if the addition of injectable diacetylmorphine to maintenance treatment can be conducted on a large scale in one city. As in pilot 1, the aim will be to determine: if participants can be stabilised on injectable diacetylmorphine or injectable diacetylmorphine plus oral methadone; if participants can move readily between the three options, so that there is flexibility in treatment; and if a workable and appropriate clinical service can be provided, with the investigation on a large rather than a small scale. The pilot will be deemed to be a success if more than half of the participants can be stabilised on the available options and if there is clear evidence of successful integration of injectable diacetylmorphine into oral methadone treatment to provide flexibility in treatment.

This pilot will also test the feasibility of integrating a large scale evaluation into a treatment program. It will examine whether or not the proposed trial evaluation strategy can be conducted without undue respondent burden and will set in place processes so that the results can be made available in a timely fashion. It is also likely that some new measures will be used as part of the evaluation and this pilot will test their validity and reliability.

This pilot will also begin to measure the package of indicators of social effects developed in pilot 1.

Pilot 2 will take 10.25 months to conduct and will measure effects over six months.

Recommendation 5. If pilot study 1 is a success, that a second pilot study is conducted with 250 dependent heroin users drawn from volunteers who have been resident in the ACT since 1993 and who have dropped out of ACT methadone treatment or who are current ACT methadone clients who would prefer the expanded treatment option. That, over a six-month period, this pilot address the following questions:

- does the addition to maintenance treatment of injectable diacetylmorphine attract back and retain in treatment dependent heroin users who have dropped out of methadone treatment?
- does the expansion of maintenance treatment to include diacetylmorphine improve retention in treatment for those drawn from current methadone clients?
- is it possible to conduct a successful randomised controlled trial with dependent heroin users when the highly desirable 'choice'

option, which provides injectable diacetylmorphine, is available to only half of the participants?

- does the addition of injectable diacetylmorphine to maintenance treatment produce better outcomes in terms of health, criminal behaviour and social functioning?
- can dependent heroin users be stabilised on injectable diacetylmorphine or injectable diacetylmorphine plus oral methadone on a large scale?
- can injectable diacetylmorphine maintenance treatment be integrated successfully with oral methadone maintenance treatment to provide flexibility in treatment on a large scale?
- **are the individual measures of outcomes 'workable', in other words can the questionnaires be administered without undue respondent burden and can the results be analysed in a timely fashion? If new measures are used, are they valid and reliable?**
- **is the package of indicators developed to measure the social effects of a trial workable? Have there been any major negative social effects?**

Recommendation 6: Pilot study 2 will be deemed a success if the following criteria are met:

- that there is an indication that dependent heroin users, who have dropped out of methadone treatment, are attracted back to treatment and that the retention rate for both this group and for those recruited from current methadone clients is better than for participants who receive oral methadone only;
- that the process of randomising participants into two groups, only one of which receives the choice of injectable diacetylmorphine prescription, is shown to be feasible for evaluating the multi-centre two-year trial;
- that at the end of six months, there are indications of improvements in at least half of the outcome measures pertaining to health, criminal behaviour and social functioning;
- that a stable maintenance dose of injectable diacetylmorphine or injectable diacetylmorphine plus oral methadone can be found for more than half of the participants in the 'choice' group;
- that injectable diacetylmorphine maintenance treatment can be integrated successfully with oral methadone maintenance treatment;
- **that individual measures of outcomes are determined to be workable;**
- **that the package of indicators developed to measure the social impact of diacetylmorphine prescribing is workable and there have been no major negative effects.**

Assessment that this pilot study has been a success will warrant proceeding to a full-scale trial.

As outlined above, the trial will focus on three population groups—dependent heroin users who have dropped out of currently available treatment options, current methadone clients who would prefer the expanded treatment option and dependent heroin users who have never been in treatment. For the first and last of these

groups, evaluation would assess whether or not the addition of injectable diacetylmorphine to maintenance treatment improved the ability to attract dependent heroin users into treatment. For all groups, there would be assessment of whether or not expanding maintenance treatment to include injectable diacetylmorphine improved the ability to retain participants in treatment. In addition, there would be assessment of whether or not participants randomly assigned to a 'choice' group (with options of injectable diacetylmorphine alone, injectable diacetylmorphine plus oral methadone or oral methadone alone) had better outcomes than participants randomly assigned to a 'control' group, where only oral methadone was available. The outcomes would again be health, including HIV/AIDS and hepatitis risk behaviours and licit drug use; criminal behaviour, including illicit drug use; and social functioning.

The trial will last for two years. If the outcomes are positive in the first year, all participants will be offered the expanded treatment option which includes injectable diacetylmorphine in the second year. This has three advantages. First it will test the ability to sustain the positive effects with a larger number of participants. In addition, there is likely to be less intense interest in the trial in the second year and this will give a more accurate indication of the ability to sustain positive effects in the long term. Third, availability of diacetylmorphine in the second year should maximise the likelihood that the 'control' group will continue to participate in the trial, so that meaningful comparisons of outcomes can be made between the 'choice' and 'control' groups in the first year. If the results show that there is no additional advantage to prescribing injectable diacetylmorphine over the prescription of oral methadone alone or that expanding maintenance treatment by prescription of injectable diacetylmorphine has value for only a subgroup of dependent heroin users, the second year should be used to limit or wind down the prescribing of injectable diacetylmorphine and to gradually return those in the 'choice' group to other treatment options.

For a randomised controlled trial to produce useful results which are generalisable, it must be conducted in more than one city. The illicit drug scene varies from city to city, as does the provision of maintenance treatment. In addition, the results have national implications and, if the Canberra-based pilots have been successful, it will be appropriate to examine the research questions more broadly. Thus, if a full-scale trial proceeds, it should be conducted in three Australian cities. Each will limit participation to established residents. There will be 1000 participants, with 350 drawn from dependent heroin users who have dropped out of currently available treatment options, 350 from current methadone clients who would prefer the expanded treatment option and 300 from dependent heroin users who have never been in treatment. There will be at least 100 participants from each group in each city.

The package of social indicators will measure potential positive and negative social effects. Cost-effectiveness, as well as effectiveness, will be measured and will take into consideration the

ability to attract and retain people in treatment, and individual and social effects.

Criteria for the success of the trial are not stipulated. These should be determined before the trial is run, but in light of experience with the pilot studies.

It is worth noting that the research questions to be addressed by this trial are much broader than those being investigated by the Swiss trials. The Swiss trial focus on those for whom other treatment options have not been successful.

Recommendation 7: If the pilot studies are shown to be successful, that a two-year trial with 1000 participants is conducted in three Australian cities. That it target three groups of dependent heroin users—those who have never been in treatment, those who have dropped out of treatment, and current methadone clients who would prefer the expanded treatment option. That it address the following questions:

- can the availability of injectable diacetylmorphine as part of maintenance treatment attract into and retain in treatment, people who have not previously been in treatment?
- does the addition to maintenance treatment of injectable diacetylmorphine attract back and retain in treatment dependent heroin users who have dropped out of methadone treatment?
- does the expansion of maintenance treatment to include diacetylmorphine improve retention in treatment for those drawn from current methadone clients?
- for each of the three target groups, does providing a choice of treatment which includes the option of injectable diacetylmorphine improve outcomes over the option of oral methadone only? Participants in the 'choice' and 'control' groups will be compared on the following measures: health, criminal behaviours and social functioning. If the outcomes are positive in the first year, all participants will be allocated to the 'choice' group for a second year, to test if the positive outcomes can be sustained.
- what is the social impact of expanding maintenance treatment to include diacetylmorphine prescription?
- is adding diacetylmorphine to maintenance treatment cost-effective?

Although the proposal involves expanding current maintenance treatment to include diacetylmorphine, the pilots and trial will require the establishment of a new and separate clinic, which is specifically tailored for the provision of this new treatment option. Additional medical, nursing and counselling staff must also be employed. Diacetylmorphine hydrochloride can be purchased as a sterile powder through legal commercial channels outside Australia. Diacetylmorphine will only be available for injection at the clinic; there will be no take-away doses. Oral methadone will be available as take-away doses in accordance with current guidelines. Injectable diacetylmorphine will be available up to three times per day, oral methadone will be available once a day. The clinic will have opening hours in the morning, early afternoon and early evening. Doses will be individually tailored, but, based on Swiss experience, there will

be an upper limit of 800 mg diacetylmorphine per day. Apart from features specific to the provision of injectable diacetylmorphine, guidelines established for the provision of oral methadone will be followed. There will be strict security procedures and the injection of diacetylmorphine will be closely supervised to prevent diversion and to ensure that safe practices are followed. Trial participants will be assessed for their 'fitness' to leave the clinic and particularly to drive a motor vehicle.

Recommendation 8. That the service provision for the pilot studies and the ACT component of the trial is provided by the Alcohol and Drug Service of ACT Health. That the independent evaluation is conducted jointly by the National Centre for Epidemiology and Population Health at The Australian National University and the Australian Institute of Criminology. That a committee is established to oversee the running of the pilot studies and the ACT component of the trial. Its membership should include representatives from the clinical staff, participants and researchers; the police and judiciary; the medical profession and non-government treatment services; ACT Health and the ACT Attorney-General's Department; relevant Commonwealth departments; and an ethicist. That this committee will recommend to the ACT Legislative Assembly whether or not there should be progression from pilot 1 to pilot 2 and from pilot 2 to a trial or if the prescription of injectable diacetylmorphine should be stopped at any time.

Conducting the pilots and trial will be require a significant financial commitment. A number of factors contribute to the expense. The cost of diacetylmorphine itself is relatively high, because only small quantities are produced by limited numbers of legal commercial producers. The need for high security during production, shipment, storage and dispensing adds to the cost. Because diacetylmorphine can only be administered at the clinic, there are costs associated with staffing the treatment centre for extended hours. Ironically, if expanding maintenance treatment by including diacetylmorphine is successful in attracting people into treatment and in retaining them, this will also add to the costs. Finally, high quality evaluation is expensive.

There will be a preparatory phase which will last at least six months; pilot 1 will take 7.75 months; pilot 2 10.25 months; and the trial will take two years.

It is estimated that establishing and conducting an initial six-month pilot with 40 participants will cost around \$800,000 and a second six-month pilot with 250 participants will cost \$1.5 million. Initial estimates suggest that expanded maintenance treatment which includes diacetylmorphine would cost the community less than one-tenth of the cost of an untreated illicit heroin user and would be substantially cheaper than some current treatments.

Recommendation 9: That, noting the national significance of the ACT-based pilot studies, there is extensive financial support from outside the ACT to fund the pilot studies.

Implementation

Although the process of developing this proposal has been highly consultative, none of the major interest groups have seen the final report and recommendations. There must be an opportunity for the report and recommendations to be scrutinised, discussed and, if necessary, modified before the proposal is implemented. Three months should be allowed for this consultation process, which should be overseen by a committee with representation from the Alcohol and Drug Service, the police and judiciary, the ACT Attorney-General's Department, relevant Commonwealth departments, illicit heroin users, the medical profession and non-government treatment services, an ethicist and the Director of the Feasibility Research. The consultation process should end on 30 September 1995 and the committee should report to the Minister for Health in the ACT on the results of the process by 31 October 1995.

Recommendation 10: That the ACT government institutes a three-month consultation period in which the results of the feasibility research are widely disseminated and discussed. That a committee is established to receive and consider the feedback from groups and individuals. That the committee includes representation from the ACT Health Alcohol and Drug Service; the police and judiciary; the ACT Attorney-General's Department; relevant Commonwealth departments; illicit heroin users; the medical profession and non-government treatment services; an ethicist; and the Director of the Feasibility Research. That the committee reports to the ACT Minister for Health on the results of the consultation no later than 31 October 1995.

Immediate steps must be taken to minimise the possibility of illicit heroin users from around Australia moving to the ACT. The ACT Health Alcohol and Drug Service should write to drug treatment and user advocacy groups around Australia informing them of the current status of considerations about the pilot studies and of the eligibility criteria, so that dependent heroin users will be aware that moving to the ACT will not give them access to the pilots or trial.

Recommendation 11: That the ACT Health Alcohol and Drug Service is proactive in disseminating information about eligibility criteria to drug treatment services and user advocacy groups around Australia.

Recommendation 12: That, to establish the first pilot study, the ACT Legislative Assembly either amend existing legislation or introduce special legislation to make diacetylmorphine available for carefully controlled and limited medical prescription. That the ACT government liaise with the Commonwealth and other States about the passage of relevant legislation and the provision of the necessary licences and permissions. That a service manager and a senior specialist are employed as soon as practicable to establish policy and procedures for the service delivery. That the service manager is also responsible for finding a suitable location for the new clinic; organising refurbishment; and hiring and training non-medical staff.

Part 2: The rationale for expanding maintenance treatment to include diacetylmorphine and the history and context of the feasibility research **The Rationale for Expanding Maintenance Treatment to include Diacetylmorphine**

It is beyond the scope of this report to reiterate the history of government responses to the use of heroin and other psychoactive drugs (excellent reviews are available in Manderson 1993 and Musto 1987) or to examine critiques of that response (there are many; eg see Fox and Matthews 1992; Kaplan 1983; Rainforth 1991*). Suffice to say that there have been strenuous national and international efforts which have made heroin use illegal and maintained this illegality.

Both nationally and internationally, there is long-standing and continuing government and public concern about the use of mood-altering drugs in which the use of heroin looms large. In Australia, since 1971, there have been at least ten Royal Commissions, Committees of Inquiry or Parliamentary Committees which have dealt with drugs, drug use and ways of ameliorating the effects of drug use. Since 1979 these enquiries have considered the option of diacetylmorphine maintenance treatment, and although they have recommended against it (with some suggesting that the prescription of diacetylmorphine may have value for a small number of dependent users), the issue has persisted (Hartland 1991*; Hartland et al. 1992*).

There has been international as well as national interest in diacetylmorphine maintenance treatment. In 1994, the Swiss government began trials of diacetylmorphine maintenance treatment for heroin dependence and in mid-June 1995, the Health Council of the Netherlands recommended that Dutch trials should be undertaken. Diacetylmorphine maintenance prescription for heroin dependence continues to be a treatment option in the United Kingdom, although it is no longer as widely practised as it was in the 1960s and 1970s. A randomised controlled trial conducted in the 1970s to assess the value of the, then, new methadone maintenance treatment against that of the, then, established diacetylmorphine maintenance treatment produced equivocal results. Hence debate continues. Serious consideration was also given to the prescription of diacetylmorphine in the USA in the 1970s, but political considerations prevented a trial from eventuating (Working Paper A in preparation).

The arguments against diacetylmorphine maintenance prescribing are not presented here. The arguments and their analysis form a substantial proportion of Part 3 of this report.

There are a number of reasons for the persistence of this issue. First, the arguments put by proponents have not been properly tested. These arguments have been outlined in Part 1, but are basically that expansion of maintenance treatment to include diacetylmorphine will have beneficial effects for individual patients and will ameliorate some of the social problems caused by dependent use of illegal heroin.

Changing conditions have also given impetus to the prospect of expanding maintenance treatment to include diacetylmorphine. The advent of HIV/AIDS has been particularly potent. Concerns about its transmission through the intravenous drug using community and fears that the intravenous drug using community might be a conduit for the spread of the disease into the general population have led to consideration and implementation of a range of preventative options, one of which is to add diacetylmorphine to maintenance treatment.

Most recently, evidence about the cost-effectiveness of treatment has begun to accumulate and has spurred thinking about new treatment possibilities. In 1991 the National Institute on Drug Abuse in the USA collated evidence from a number of studies to show that treatment of illicit drug users is more cost-effective than leaving them in the community untreated or sending them to jail. The untreated dependent user was estimated to cost society \$US43,000 per year, imprisonment costs \$US40,000 per year, whereas methadone treatment costs \$US3,500 per year and treatment in a therapeutic community costs around \$US16-20,000 per year (National Institute on Drug Abuse 1991).

A study of Californian drug and alcohol treatment showed that the benefits of treatment outweighed the costs by ratios of 4:1 to 12:1, depending on the type of treatment (Gerstein et al. 1994). The estimated cost to tax-paying citizens of a dependent heroin user in the year before entering methadone maintenance treatment was \$US19,334, with about one-quarter being the value of cash and property stolen.

Australian evidence is comparable, except that the costs to the community before a dependent user enters treatment are estimated to be substantially higher. A study commissioned by the therapeutic community Odyssey House in Victoria estimated that the cost to society of a dependent user in the year before entering the therapeutic community is \$A75,000, with \$A53,000 being the cost of drug-related crime. The study also estimated that incarcerating dependent users costs \$A48,000 and that treating them at Odyssey House costs \$A15,600 per year (Odyssey House, no date). Calculations based on preliminary results from a South Australian study, estimate the cost of criminal activity (excluding drug dealing) at \$A130,000 per year before a dependent user enters methadone treatment and that methadone treatment costs just over \$A2,000 per year (Ryan et al. 1995; Jason White, personal communication 1995).

The budget for the clinical service in pilot 2 suggests that expanding maintenance treatment to include diacetylmorphine would cost a maximum of \$10,000 per participant per year (see Part 4). This is about one-tenth the cost to the community of an untreated dependent heroin user. Although it is substantially more expensive than methadone treatment, there is a much higher component of counselling and social support. The cost is significantly less than that of a therapeutic community.

Currently, the main forms of treatment for heroin dependence are methadone maintenance, detoxification, counselling and therapeutic communities (and combinations of these). The introduction of methadone maintenance treatment by Dole and

Nyswander in the 1960s marked a significant advance. In a review of evaluations of methadone treatments in 1992, Ward and colleagues concluded that "methadone maintenance is the best of the available alternatives. Other forms of treatment attract and retain fewer patients, and do not produce superior outcomes among those who complete treatment" (p. 285). However, they also pointed out that methadone treatment is not a panacea. On average, within 12 months, about half of those who enter methadone treatment either leave or are discharged (many programs have sanctions against continuing illicit drug use). Methadone programs also vary in their effectiveness in reducing criminal behaviour, including illicit drug use. Finally, the benefits of methadone maintenance continue only as long as the person remains in treatment; relapse to heroin use is high for those who discontinue treatment. There is little research evidence on either the proportion who eventually become drug-free or of the success of planned withdrawal and rehabilitation.

This evidence suggests that there is merit in investigating other drugs to determine if they can, like methadone, meet the following criteria for effective maintenance treatment:

- there should be cross tolerance and cross dependence with the psychoactive substance causing dependence
- the drug should reduce craving and suppress withdrawal
- administration of the drug should result in stabilised consumption (within a defined therapeutic range)
- it should result in improvement in physical health
- it should facilitate psychosocial wellbeing with an emphasis on habilitation and rehabilitation
- it should be acceptable to clients
- it should be acceptable to professionals
- it should be acceptable to the general community

- there should be no long-term toxic effects resulting from therapeutic administration
- it should be both affordable and available for use.

(These draft criteria were proposed at a Program on Substance Abuse Consultation on the World Health Organization Drug Substitution Project in Geneva in May 1995 [proceedings forthcoming].)

Possible candidates for expanded maintenance therapy include buprenorphine, LAAM (levomethadyl acetate), naltrexone, injectable methadone and diacetylmorphine. The feasibility study originally intended to consider a range of opioids, but at the end of Stage 1 narrowed the field to diacetylmorphine. This option has been the most discussed but least researched and is a highly-preferred option for most dependent heroin users.

The criteria listed above in essence reword the research questions which the pilots and trial have been designed to explore.

The pilot studies will address the question of whether or not administration of diacetylmorphine or diacetylmorphine plus oral methadone can result in stabilised consumption (within a defined therapeutic range).

The trial will examine effects on physical health, psychosocial wellbeing (habilitation and rehabilitation) and affordability.

The research to date has established acceptability, at least in principle, to clients, professionals and the general community (see Part 3) and the known properties of diacetylmorphine meet the criteria of cross tolerance and cross dependence, elimination of craving and withdrawal, and no long-term toxicity.

However, as the discussion above shows, questions about assessment of the therapeutic value of diacetylmorphine are asked in a highly politicised context and the issues which need to be addressed in a feasibility study encompass a range of topics not normally weighed in the balance when deciding whether or not to trial a drug clinically. These issues include the legal status of prescribing the drug and an assessment of social risks, including the dangers of escalating non-therapeutic use of the drug and of attracting dependent heroin users to the city where the trial is to be conducted.

This feasibility study is a systematic in-depth examination of the scientific, clinical and political issues involved in a trial of expanding maintenance treatment to include diacetylmorphine prescription. It concludes that diacetylmorphine maintenance treatment may be a valuable addition to current treatment options and thus that its efficacy should be trialed and carefully evaluated. There must be appropriate safeguards against the likely risks. The proposed trial will address long-standing questions about whether adding diacetylmorphine to maintenance treatment is an effective additional treatment option or has no value and should be abandoned.

A Brief History of the Feasibility Study

As outlined above, there is a sixteen-year history in Australia of government consideration of the issue of diacetylmorphine maintenance treatment. In 1989, the newly formed ACT Legislative Assembly established a Select Committee on HIV, Illegal Drugs and Prostitution. It had representatives from both the Labor and Liberal parties and was presided over by Mr Michael Moore, then a member of the Residents' Rally and later an independent member. As part of its deliberations the committee examined the issue of diacetylmorphine maintenance treatment.

In March 1991, the Presiding Member approached the Director of NCEPH, Professor Bob Douglas, to discuss the possibility of a trial of such treatment. In April a group of experts in drug treatment and drug policy assembled at NCEPH, endorsed the need for a study into the feasibility of diacetylmorphine maintenance treatment and suggested a four-stage process. Each stage was to be self-contained, ending with a decision about whether or not to proceed further. The first stage was to consider the issue of feasibility in principle; the second to consider logistic feasibility; the third to pilot procedures; and the fourth stage was to be the trial itself.

Stage 1 was completed in three months, with a recommendation to proceed to Stage 2 being made at the end of July 1991. This report ends the Stage 2 research and recommends that two Stage 3 pilot studies are undertaken. The Stage 1 and 2 research was undertaken jointly by NCEPH and AIC.

Volume 1 of the Stage 1 report was reprinted in full in the Second Interim Report of the Select Committee on HIV, Illegal Drugs and Prostitution (Legislative Assembly of the ACT 1991), which was presented to the ACT Legislative Assembly in August 1991. Debate on the report was rapidly adjourned and the committee lapsed after the ACT Legislative Assembly elections in February 1992.

In April 1992, the then Minister for Health, Mr Wayne Berry, took the issue of the feasibility study to the Ministerial Council on Drug Strategy (MCDS). MCDS is comprised of two Ministers, one each from health and law enforcement, from each jurisdiction (the Commonwealth and each Australian state and territory). MCDS noted "the progress made by the National Centre for Epidemiology and Population Health (NCEPH) in undertaking a feasibility study, not involving the distribution of any drugs, into heroin treatment options" and recommended that "the results of the feasibility study be reported to MCDS". In subsequent years progress reports about the study were noted and in 1994 a subcommittee of the National Drug Strategy Committee (NDSC) was established to consider the Stage 2 report when it was released. NDSC is a similarly representative committee of senior officers (public servants and police), which supports MCDS. This committee has overall responsibility for the implementation of Australia's national drug strategy.

NCEPH and AIC decided to proceed with the Stage 2 feasibility research after strong support at a one-day national seminar "Heroin Treatment—New Alternatives" in November 1991 (Bammer & Gerrard 1992*). The decision was made possible by a peer-reviewed

competitive grant of \$445,000 over five years from The Australian National University's Strategic Development Fund, which aims to "identify and develop new areas of research perceived as particularly fruitful, in the national interest and inadequately addressed elsewhere in the country". A further \$115,000 was raised through other competitive peer-reviewed grants to fund a number of specific sub-projects. (A list of grants is presented at the end of the report.) In total the feasibility research has cost close to \$1 million.

The complexity of the issues and the lack of already available information on which to base decisions meant that the Stage 2 research took longer than originally anticipated. Making final recommendations was postponed more than once, so that the issues could be properly considered. This final Stage 2 report and recommendations will be presented to the current ACT Minister for Health, Mrs Kate Carnell (who is also the Chief Minister), on 27 June 1995 and it is anticipated that she will present the findings to the Ministerial Council on Drug Strategy.

The Process of Conducting the Feasibility Research

The Stage 2 research into logistic feasibility had three components: an assessment of risks, development of a proposal for service provision and development of a proposal for evaluation. Much of the research broke new ground.

The process was guided by a nineteen member Advisory Committee which met three times in 1992 and annually thereafter. The Committee had Australia-wide representation from academics, advocates for illicit drug users, judiciary, police, policy makers, and treatment service providers. In order to ensure that a balance of views was represented on the Advisory Committee, it was agreed at the outset that the Committee would not be asked to formulate or endorse the final recommendations.

As discussed in more detail below, there was emphasis on an open, consultative process. As sub-projects were completed, the results were published as working papers, so that they were available for scrutiny and discussion. Newsletters summarising the research results and providing updates of political events surrounding the feasibility considerations were published from time-to-time. Key decision makers, locally, nationally and internationally, were briefed about results and asked for input. The media was kept informed about the study and there were numerous radio, television and newspaper reports. The ABC current affairs series *Attitude* produced a program about the feasibility study which was screened in June 1994. Papers were also presented at national and international conferences and are being published in peer-reviewed journals. One of the study aims is to facilitate informed debate about the issues.

There was also considerable interchange of information with Swiss policy makers, health professionals and researchers who are involved in the trials of diacetylmorphine maintenance prescribing

which began in 1994. The Swiss trials strongly influenced the proposal for service provision.

Three principles guided the conduct of the feasibility study:

- the research should have intrinsic value, so that regardless of whether or not a trial goes ahead, the research should be of value to treatment services or to drug policy generally
- research should be conducted in all relevant disciplines and the disciplinary findings should be integrated to address the central problem
- the process should involve to the greatest extent possible the key interest groups—illicit drug users, service providers, police, policy makers and the community.

The first principle meant that research questions were framed broadly, so that the issues relevant to the feasibility investigations were embedded in a wide context, which provided valuable information in itself, but also enriched the information needed for the feasibility considerations. This can be illustrated by three examples: the study of ex-users, the study of unmet needs and the studies of the illicit drug market.

For the feasibility research, the study of ex-users had three purposes—to determine whether or not ex-users supported a trial of expanding maintenance treatment to include diacetylmorphine and why; to try to establish whether or not there was a risk that such a trial would make it harder for dependent heroin users to become abstinent; and to try to establish if there was a risk that a trial would tempt ex-users to start using again. These questions were embedded in a study about stopping dependent use—why people had stopped, how they had stopped and how they had maintained abstinence. This was the first Australian study of its kind and pointed to ways in which drug treatment might be more successfully geared towards attaining abstinence (Bammer & Weekes 1993* 1994*).

Another important consideration for the feasibility research was the views of those who were potential participants—were they interested in participating and how would they want a trial to be run? These feasibility research questions were set in the context of unmet needs for treatment. Information was gathered on why dependent heroin users do and do not enter treatment, whether treatment needs are met successfully and why users drop out of treatment. Again this study has many unique aspects and the results can help improve existing treatment services (Working Paper B in preparation).

Understanding the drug market is important to the feasibility study for both risk assessment and for potentially measuring trial outcomes. The feasibility research brought together academic researchers, police, and law enforcement intelligence analysts to discuss ways in which data sources and skills could be better shared in order to improve understanding of illicit drug markets (Bammer 1993b*). In addition, the feasibility research examined new ways in which the illicit drug market could be monitored, including an examination of fatal and non-fatal heroin overdoses (Bammer and Sengoz 1994* 1995*; Bammer et al. 1995c*).

The second principle involved integrating a multi-disciplinary approach. Academic colleagues with a range of disciplinary skills donated time to the project—the disciplines covered included anthropology, clinical science and health care, criminology, demography, economics, epidemiology, law, pharmacology, philosophy, political science, policy analysis, psychology, sociology, and statistics.

The third principle was to involve the relevant interest groups. Martin (1991*) analysed the role of interest groups in shaping debates about drug policy and in determining the issues and arguments brought to bear. The aim here was primarily to use interest groups to ensure that all potential issues, especially risks, had been identified and to determine the level of support for a trial of expanded maintenance treatment to include diacetylmorphine prescribing.

Both formal and informal consultation processes were used. The formal processes were surveys, a reference group and workshops. The informal process was discussion, both one-to-one and small group. The key interest groups consulted were the general community, the police, illicit drug users, service providers, ex-users and policy makers.

ACT community surveys were conducted in 1991 and 1994; Sydney and Queanbeyan residents were surveyed in 1991; and a national survey was conducted in 1995. There were also informal discussions with individuals and particular community interest groups including Drugs in the Family (a self-help group of, predominantly, parents of illicit drug users) and the Victims of Crime Assistance League (VOCAL ACT Inc).

The police were surveyed in 1991, were involved in a workshop about drug markets in 1992 and in a workshop specifically on policing issues for a trial in 1994. There were regular discussions with the ACT Drug Squad and the Australian Bureau of Criminal Intelligence. There were also discussions with the Australian Federal Police Association (Federal and ACT branches) and individual ACT and interstate police.

Illicit drug users in and out of treatment were surveyed in 1991 and 1993. A reference group of people who are advocates for illicit drug user interests (without necessarily being users or ex-users themselves) was also consulted regularly and there were many informal discussions with individuals and advocacy groups, locally and interstate. There was also participation in public meetings organised by the ACT Intravenous Drug Users League (ACTIV) and the Dependency Care Foundation.

Service providers were surveyed in 1991 and attended workshops on medical issues involved in prescribing diacetylmorphine in 1994, cost considerations for service provision in a trial in 1994, and the contribution of childhood sexual abuse to alcohol, heroin, and other drug problems in 1993. There were a number of discussions with staff from the ACT Health Alcohol and Drug Service and staff from non-government organisations, particularly Assisting Drug Dependants Inc and the Alcohol and Drug Foundation of the ACT. There were also discussions with the Australian Medical Association, the Australian

Salaried Medical Officers Federation and individual doctors, pharmacists and other health professionals.

Some service providers are also ex-users and so contributed to both perspectives. Other ex-users were surveyed in 1991 and 1993 and there were also informal discussions.

While a highly consultative process has been used in the formulation of this final report and recommendations, none of the above groups has yet seen the report and recommendations and all wanted an opportunity to consider and comment on them. It is therefore recommended that there is a three-month consultation period before the ACT Legislative Assembly makes a decision about whether or not to proceed (Recommendation 10).

The Context of the Feasibility Research

This proposal must be viewed in terms of the Australian and particularly the ACT context of illicit drug use. Australia has a population of around 17.5 million. The ACT is a landlocked territory surrounded by the state of New South Wales and houses the national capital, Canberra, with a population of about 300,000. Canberra adjoins the New South Wales city of Queanbeyan, with a population of some 25,000. Compared to the rest of Australia, the ACT population is younger, better educated and more affluent. Unemployment is lower than elsewhere in Australia and more than half of the workforce is employed in the public sector, compared to less than one-third nationally (see Stevens et al. 1991*). An outline of factors which might influence movement into and out of Canberra is presented in Bammer and colleagues (1994a*).

The tangible and intangible economic costs of illicit drug use in Australia in 1988 were conservatively estimated at \$1,441 million, which is ten per cent of the costs of all drug use (including alcohol and tobacco; Collins & Lapsley 1991).

The 1993 National Drug Household Survey (National Drug Strategy 1993) found that 34 per cent of those aged 14 years or older had ever tried marijuana, with 13 per cent having used in the last 12 months. The next most commonly used illicit drugs were the amphetamines with eight per cent having tried them and two per cent having used in the last 12 months. Heroin and cocaine/crack use were comparable with two per cent having ever tried and one per cent having used in the last 12 months. Many dependent users in the ACT use a range of drugs, but for a substantial proportion heroin is the drug of choice (Stevens et al. 1991*; Bammer & Crawford 1991*; Working Paper B in preparation). Injection is by far the most common route of administration of heroin, but smoking and other forms of inhaling ("chasing the dragon") also occur (Australian Bureau of Criminal Intelligence 1995; Stevens et al. 1991*; Bammer & Crawford 1991*; Working Paper B in preparation).

In 1988 there were estimated to be 30,000–50,000 dependent heroin users in Australia (National Campaign Against Drug Abuse 1988). Estimates conducted as part of the feasibility study vary somewhat, but suggest that there are likely to be around 1,000 dependent heroin users in the ACT (Larson 1992*; Larson et al.

1994*; Larson & Bammer 1995*; Stevens et al. 1991*). A 1991 ACT school survey of students' drug use found that three per cent of males and four per cent of females had ever used opiates (ACT Government Alcohol and Drug Service 1991). In a survey of 155 ACT people aged 12 to 17 who, because of family problems, were living away from home or had lived away from home in the last 12 months, eight (5%) had ever used heroin, mostly only once or twice, and none would have been eligible for inclusion in a trial (Sibthorpe et al. 1993*)

A series of vignettes about the range of lifestyles of illicit drug users in the ACT was presented in Stevens and colleagues (1991*). This illustrated that while some users fit with the common stereotype of alienated individuals with problematic lifestyles, others are well integrated into mainstream society. The surveys conducted as part of the Stage 2 research attracted few users who were not in treatment, and they were generally not typical of the stereotyped image (Working Paper B in preparation). As is expected from the results of other methadone programs (Ward et al. 1992), a proportion of methadone clients were still using illicit drugs and committing crime (Bammer et al. 1994b*; Working Paper F in preparation).

According to the Australian Bureau of Criminal Intelligence (1995), heroin is "usually encountered as a white powder known as No. 4 heroin, indicating a high purity product"; however, other forms are also available. In 1994 the Australian Customs Service reported 56 seizures of heroin, totalling around 248.5 kg. In the same year, the price of a street gram of heroin in the ACT ranged from \$50 to \$500.

Sydney, the largest city in Australia, is 300 km from Canberra, a three to four hour drive, and is the main source of supply for heroin in the ACT. The ACT drug market seems to have well-established and effective systems of operation, with a high degree of flexibility and adaptability that makes law enforcement difficult. Eleven ACT drug dealers were in prison in 1993 (Bammer & Sengoz 1994*).

Nationally, in 1991 7.5 per cent of prisoners had a drug-related charge as their most serious offence, with almost six per cent having drug trafficking as their most serious offence (Department of Health, Housing and Community Services 1992). Attempts to estimate the percentage of other crimes which are drug-related are fraught with difficulties (Australian Bureau of Criminal Intelligence 1995). However, many Australians feel that they have been affected by drug-related crime. In the 1991 survey of the ACT community, 25 per cent reported that they or someone close to them had been affected by a crime that they thought was committed by illegal drug users (Bammer & Crawford 1991*; Bammer et al. 1995b*) and similar percentages were reported in the 1994 ACT and 1995 national surveys (Working Paper C in preparation).

Otherwise, as far as the general community is concerned, there is little visible evidence of illicit drug use in Canberra. There are no congregations of illicit drug users and no areas that ordinary citizens are advised to avoid. There are, however, some

areas of public housing that are seen to be undesirable and an association with illicit drug use is one reason for this. It is rare for discarded injecting equipment to be found in public places, although a Needle and Syringe Exchange Program distributes around 130,000 needles and syringes per year. Public health measures, such as disposal shutes for injecting equipment in some public toilets, a mobile bus that provides AIDS education, including free condoms and needle and syringe exchange, and various centres that provide information, advice and other services or treatment are discreet and well tolerated (Bammer et al. 1994a*).

In 1991, just over 3,000 people in Australia were notified AIDS cases; five per cent were attributed to intravenous drug use (National Campaign Against Drug Abuse 1992). The seroprevalence of HIV infection among intravenous illicit drug users is low (under 5%), but Hepatitis B and C prevalence is high (around 70% or more; discussed in Bammer et al. 1994a*). In 1990 there were 457 opiate-related deaths in Australia (National Campaign Against Drug Abuse 1992). From 1988-1991 there were three deaths from accidental opioid poisoning in the ACT and between August 1990 and July 1993 there were an estimated 36 non-fatal heroin overdoses attended by the ACT Ambulance Service (Bammer & Sengoz 1994*; Bammer et al. 1995c*).

A national census of drug treatment service agencies conducted in 1992 identified 465 treatment agencies (National Campaign Against Drug Abuse 1992). In 1991 there were more than 9,500 people on methadone programs nationally (Department of Health, Housing and Community Services 1992). In the ACT a range of government and non-government agencies provide treatment and/or support for illegal drug users. When the feasibility research began in 1991, the government-run oral methadone program had 100 places (85 on maintenance and 15 on withdrawal regimens) and the waiting period for entry was about two months. During the Stage 2 research, the methadone program underwent a period of expansion; when the surveys of methadone clients were conducted in 1993, there were around 260 people on the program and by the end of Stage 2 the program had reached the projected limit of expansion with 350 clients. There are now plans to increase dispensing through pharmacies and to introduce prescription through private general practitioners. Other treatment services include a therapeutic community, counselling, detoxification centres and a range of self-help groups. There are also half-way houses and referral and information services (based on Stevens et al. 1991*, which gives a fuller description of the ACT situation in 1991). The ACT also has active advocacy groups both for drug treatment clients and for illicit drug users outside treatment—the ACT Intravenous Drug Users League (ACTIV), the Dependency Care Foundation and Methadone Action Consumer Empowerment.

As this description of context shows, the feasibility research has contributed to the understanding of illicit drug use in the ACT. The main results from the feasibility research are presented in Part 3.

Part 3: Results of the feasibility research

The Stage 1 feasibility research found that expanding maintenance treatment to include diacetylmorphine was feasible in principle. The Stage 2 research found that it is also feasible logistically.

The key results of the Stage 1 research are reiterated here, along with the results of the Stage 2 research. The following issues are covered: the level of support among a range of interest groups for a trial of expanding maintenance treatment to include diacetylmorphine; an examination of the legal aspects of a trial; an assessment of the risks associated with a trial and how the risks could be minimised; the development of a proposal for the service provision aspects of a trial; and the development of a proposal for evaluation. The Stage 1 and Stage 2 research also increased understanding about illicit drug use in the ACT; these results are presented in Part 2.

Throughout this section, the discussion does not generally differentiate between the pilots and the trial; the same concerns are usually relevant to both, but for the sake of brevity reference is only made to the "trial".

1. Support for a trial among different interest groups

The most important group is the general community. The Canberra, Sydney and Queanbeyan communities were surveyed as part of the Stage 1 research. The Canberra community was surveyed again in considerable detail towards the end of Stage 2 and subsequently there was a national survey. In Stage 1, four other key groups were surveyed: police, providers of treatment and other services to illicit drug users, illicit drug users and ex-users. There was further research with both users and ex-users in Stage 2 and, during this Stage, the views of the local Aboriginal community were also sought. In Stage 1 there was an analysis of the views of the main political parties which is not reported here (Hartland 1991*).

The general community

Overall, there is support in the general community for a "heroin trial". There is substantial support in the ACT and this support has been sustained over time. The Australian community generally supports the idea of prescribing through special clinics, but there is a level of uncertainty about an ACT based trial, although there is more support than opposition to it. Opinion is fairly evenly divided between those who support, oppose and are uncertain about trials of diacetylmorphine prescribing in their own states, although there is more opposition than support. There is clear opposition to divorcing maintenance treatment which includes diacetylmorphine from an ultimate goal of abstinence.

In 1991 the following question was put to a random sample of the Canberra, Sydney and Queanbeyan communities (as well as police, service providers and users and ex-users—see below; Bammer et al. 1995b*; Bammer & Crawford 1991*), and the question was asked again

of a Canberra sample in late 1994 (see Table 1; Working Paper B in preparation):

Some people think there are so many problems caused by illegal drug use that something new urgently needs to be tried. They would say that a proposed trial should go ahead.

Other people think setting up a trial is just too risky because it might make the problems even worse. They would argue that it should not go ahead.

Do you think the trial should go ahead or that a trial should not go ahead?

Table 1

	Canberra 1991 %	Canberra 1994 %	Sydney 1991 %	Queanbeyan 1991 %
go ahead	66 (62,70) ⁶	54 (50,58)	58 (54,62)	43 (36,50)
not go ahead	27	34	34	46
don't know	7	12	8	10
N	516	664	520	212
response rate	77%	52%	61%	74%
type of survey	telephone	mail	telephone	telephone

The responses for the Sydney and Queanbeyan samples are for a trial in Canberra. Forty-four percent of both Sydney and Queanbeyan respondents supported a Sydney-based trial (48% opposed in Sydney and 47% in Queanbeyan; Bammer et al. 1995b*).

In the 1994 Canberra and 1995 national study, questions about support for a trial were asked in a variety of ways and the level of support varied depending how the question was asked (Table 2). The national survey results are based on the first 1,915 responses to questions included in the 1995 Australian component of the International Social Science Survey. Five thousand questionnaires were mailed out, but the survey was not finished when this report was written. Detailed results for the Canberra and national surveys are presented in Working Paper C in preparation.

The questions were:

Question A (after a series of detailed questions about a trial)

Now that you have heard about some of the potential benefits and potential problems of a heroin trial in the ACT, is your reaction to it?

Question B

*What do you think about these different policies?
A policy with heroin available to addicts in treatment, but only at specific clinics; otherwise laws against heroin use enforced as at present*

Question C

Now we'd like to ask about different kinds of treatment programs that try to deal with heroin addicts
b. *In a second kind of program, addicts*
• *visit a medical clinic regularly for counselling, and they can take a drug to stop heroin craving if they want, but*

⁶ The 95 per cent confidence intervals for the percentages supporting the trial are presented in brackets throughout. This means that if the survey had been repeated independently there is a 95 per cent chance that the support reported would have fallen within the values in brackets. The confidence intervals have not been adjusted for possible bias because of differences between those who did and did not respond to the survey. However, as is discussed in the original papers, this bias is generally thought to be low.

- can also choose to get a safe, legal injection of heroin, as often as three times a day to keep them in the program.

- The aim is to get addicts to lead a normal, healthy life—to have a regular job, support their family, not break the law—

- and *EVENTUALLY* to get them to stop using heroin.

How do you feel about this program?

Question D

In another kind of program, addicts

- visit a medical clinic regularly for counselling, and they can take a drug to stop heroin craving if they want, but*

- can also choose to get a safe, legal injection of heroin, as often as three times a day to keep them in the program.*

- But the program does not try to get addicts to give up heroin;*

- instead its aim is just to get them to lead a normal, healthy life with a regular job, support their family, and not break the law.*

How do you feel about this program?

(There were some wording changes between the ACT and national surveys.)

Table 2

	Support trial %	Oppose trial %	Don't know %
Question A: Canberra	62 (68,65)	17	21
Question A: National	41 (38,43)	30	29
Question B: Canberra	58 (54,61)	25	18
Question B: National	57 (55,59)	24	19
Question C: Canberra	39 (35,42)	25	37
Question C: National	36 (34,38)	27	37
Question D: Canberra	11 (9,13)	61	28
Question D: National	18 (17,20)	49	33

It can be seen that a high percentage of respondents were undecided. Of those who felt able to make a decision, a higher percentage supported a trial than opposed it (Table 3), except for a program which did not have abstinence as the ultimate aim (Question D).

Table 3

	Support trial %	Oppose trial %
Question A: Canberra	78	22
Question A: National	58	42
Question B: Canberra	70	30
Question B: National	70	30
Question C: Canberra	61	39
Question C: National	57	43
Question D: Canberra	15	85
Question D: National	27	73

In the national survey, 34 per cent (32,36) supported a trial occurring in their own city, 39 per cent were opposed to a trial in their own city and 27 per cent were undecided. The results for supporting an ACT trial (Question A, above) and for supporting a trial in their own city are presented by state in Table 4.

Table 4

	New South Wales %	Victoria %	Queenslan d %	Western Australia %	South Australia %	Tasmania %	Northern Territory %	ACT %
support for an ACT trial	41 (37,45)	46 (41,51)	31 (25,37)	40 (32,48)	42 (34,50)	35 (25,45)	35 (24,46)	49 (38,60)
opposition to an ACT trial	32	25	38	29	27	28	43	26
undecided	27	30	31	31	31	37	22	25
N	527	437	204	154	137	91	77	81
support for a trial in their own city	35 (31,39)	38 (34,42)	23 (18,29)	38 (30,46)	36 (28,44)	17 (9,25)	23 (14,32)	53 (42,64)
opposition to a trial in their own city	41	35	46	33	36	44	55	26
undecided	24	27	31	29	29	39	22	21
N	522	430	222	150	136	88	78	81

Views about other policy and treatment options were also examined. In particular, policy questions from the 1993 National Drug Household Survey were repeated (National Drug Strategy 1993). Similar results were obtained to questions about support for the personal use of heroin being made legal and increased penalties for the sale/supply of heroin. Across all surveys, there is little support for legalisation of personal use and strong support for increased penalties for sale and supply of heroin (Table 5). The similarity in responses between the National Drug Household Survey and the ACT and national surveys conducted as part of the feasibility research increases the confidence in the feasibility study results indicating support for a trial. It also suggests that attitudes to one policy option cannot be extrapolated to other policy options.

Table 5

	Legalise personal use			Increase penalties for sale/supply		
	NDS 1993 %	Canberra 1994 %	National 1995 %	NDS 1993 %	Canberra 1994 %	National 1995 %
support	8	9	10	87	85	91
oppose	87	80	82	8	7	6
don't know	6	11	8	4	8	3

The ACT and national surveys also found that more than 80 per cent of respondents supported methadone maintenance treatment and therapeutic communities (Working Paper C in preparation).

Stepwise logistic regression on the data from the 1991 Canberra, Sydney and Queanbeyan surveys showed that those who supported a trial were more likely to be aged 30-39; to have more years of formal education; to not be currently practising a religion; to know someone close who used illegal drugs; and to live in Canberra (Bammer et al. 1995b*).

The 1994 Canberra survey showed that the government has more to gain than to lose by running a trial. In response to the question "If the ACT government decided go ahead with a trial, would that make you more or less likely to support them?", 35 per cent (31,38) reported that they would be more likely to support the government, 50 per cent that it would make no difference and 16 per cent that they would be less likely to support the government. In addition, in response to the question: "If the ACT government decided NOT to go ahead with a trial, would that make you more or less likely to support them?", 24 per cent (20,27) reported they would be less likely to support the government, 66 per cent that it would make no difference and 11 per cent that they would be more likely to support the government (Working Paper C in preparation).

Police

The police were only surveyed in 1991. A self-completion mail questionnaire was sent to 1173 ACT members of the Australian Federal Police Association, which represents 98 per cent of all Canberra-based police. Because of time restrictions there was only one reminder notice, nevertheless there was a 40 per cent response rate.

Police were asked the same question as the general community (see the 1991 question above) and, of the 446 police who responded, 31 per cent (28,34) thought a trial should go ahead, 63 per cent that it should not and seven per cent did not know (Bammer et al. 1995b*; Bammer & Crawford 1991*). The police are the only major interest group opposed to a trial and their lack of support reflects a value system, pessimism about the outcomes of a trial and concern about the potential risks that could be associated with a trial. A number of police comments reflected a negative view of heroin users, a feeling that they were being given preferential treatment over more deserving groups and a feeling that a trial was giving in to the drug problem rather than solving it (Stevens et al. 1995*). Some representative police comments are:

"Épeople who take drugs are either mentally sick or hell bent on self destruction. They have no self discipline. They have, in most cases, a total disregard for the law and for the community".

"There are many tax-paying residents of this country deprived of medical treatment for any number of reasons—locality, non-availability of service and money. The ill who have contracted illness through no fault of their own deserve assistance before one who is self inflicted."

"Are we going to make females and children available to rapists? Are we going to give money to bank robbers? Drugs, rape and armed hold up are all illegal."

The police were much less likely than the general community to agree with statements that a trial would improve the health of users, reduce the spread of HIV/AIDS in the community, reduce crime or corruption or to agree that "there will always be some people who take heroin/opiates so it is important to provide them with it in the safest way" (Bammer et al. 1995a*; Bammer & Crawford 1991*). On the other hand, police were more likely than the general community to agree with statements that a trial would increase the number of people taking heroin, remove incentives for users to give up or cut back, set a bad example for young people, would be bad for road safety and to agree that "since governments are worried about the consumption of drugs like alcohol and tobacco, it seems illogical to provide heroin/opiates to users" (Bammer et al. 1995a*; Bammer & Crawford 1991*).

The concerns of police are important and formed the basis of the analysis of risks; however, the views of police should not predominate over the views of other key groups, particularly the general community.

Service providers

The providers of treatment and other services to illicit drug users were also only surveyed in 1991. Self-completion mail questionnaires were distributed through relevant agencies; more than 90 per cent of appropriate agencies agreed to participate. Ninety-four service provider questionnaires were returned and it was calculated that this represented 38 per cent of potential respondents (although there is no certainty that all those eligible received questionnaires and some may have completed the user/ex-user questionnaire; Bammer & Crawford 1991*).

Seventy-one per cent (64,79) of service providers thought a trial should go ahead 19 per cent thought it should not and nine per cent were undecided (Bammer et al. 1995b*; Bammer & Crawford 1991*). Only 36 per cent of those with a personal philosophy of abstinence were in favour of a trial compared with 86 per cent support from those who did not report an abstinence philosophy. There was no difference in support for a trial by whether or not service providers had ever used an illegal drug (two-thirds had used an illegal drug; Bammer & Crawford 1991*).

Illicit drug users

In the Stage 1 survey illicit drug user respondents were divided into two groups: those who were current users of heroin or other illegal opioids (n=62; about half were non-dependent users) and those who used or had used illicit drugs but who had never used heroin or other opioids (n=24). Illicit drug users were accessed through agencies providing treatment and other services and through four friendship networks. The difficulty with surveying illicit drug users is that there is generally no way of knowing how representative respondents are.

Of the respondents who currently used opioids, 93 per cent thought a trial should go ahead, three per cent that it should not and three per cent were undecided. Of the respondents who used illicit drugs but had not used opioids, 63 per cent thought a trial should go ahead, 25 per cent that it should not and 13 per cent were undecided. The views of the second group were similar to those in the general community (Dance et al. 1995*). Eighty-two per cent of current opioid users reported that they would be interested in a place on a trial (Bammer & Crawford 1991*).

In Stage 2, only dependent heroin users were surveyed. Respondents were divided into three groups: people currently in methadone treatment, people who had never been in treatment and people who had dropped out of treatment. There were two separate surveys of people in methadone treatment. There was a 65 per cent response to a short self-completion questionnaire which was given to 225 of the 260 clients on the program. In addition, 65 clients were interviewed; not all had completed the short questionnaire.

It can be seen that although there was a high level of support for a trial, a substantial percentage of respondents did not want a place on a trial or were undecided (Tables 6 and 7; Working Paper C in preparation).

Table 6

	Methadone clients %	Methadone clients %	Never in treatment %	Treatment drop-outs %
trial should go ahead	82	87	100	100
trial should not go ahead	8	8	0	0
undecided	10	5	0	0
N	146	63	14	8
type of survey	self- completion	interview	interview	interview

Table 7

	Methadone clients %	Methadone clients %	Never in treatment %	Treatment drop-outs %
want a place on a trial	64	68	50	63
do not want a place on a trial	17	14	14	13
undecided	19	19	36	25
N	146	65	14	8
type of survey	self- completion	interview	interview	interview

Ex-users

As with illicit drug users, the problem with surveying ex-users is that it is not possible to draw a random or even representative sample. In the Stage 1 survey, people who had been dependent on heroin in the past were accessed, along with users (and using the same questionnaire), through agencies providing treatment and other services and through four friendship networks. Forty-five ex-users responded. In Stage 2 a variety of methods was used to recruit people who had given up in four different ways— with minimal or no formal treatment, through detoxification, through a methadone program and through a therapeutic community. There were eighteen participants.

In the Stage 1 survey, 62 per cent of respondents supported a trial, 22 per cent were opposed and 16 per cent were undecided; their views were similar to those of the general community (Dance et al. 1995*; also Appendix in Bammer & Weekes 1993*). In the Stage 2 survey, 47 per cent of respondents supported a trial, 41 per cent opposed it and 12 per cent were undecided. There was no relationship between support for a trial and the way the participants had stopped dependent use. Those who supported a trial generally felt that it would provide a new treatment option and that it would have positive

effects on health and criminal behaviour. Some also argued that it would be easier to become abstinent from heroin than from methadone. Those who opposed a trial generally reported that it would work against helping people find the motivation to deal with underlying problems and therefore would not return them to a normal life. They also argued that there would be a range of logistic problems and risks (Bammer & Weekes 1993* 1994*).

The Aboriginal community

It is important to know if a trial of controlled diacetylmorphine availability would have a particular impact on local Aboriginal heroin users and on the Aboriginal community generally. Nineteen Aboriginal community leaders and 28 service providers were interviewed. Among the community leaders, 53 per cent thought a trial was appropriate for Aboriginal heroin users, 42 per cent did not and five per cent were undecided. Of the service providers, 53 per cent thought a trial was appropriate, 25 per cent did not, four per cent thought 'maybe' and 18 per cent did not know. Three of the service providers interviewed were Aboriginal and all thought that a trial was appropriate. In general, both the advantages and disadvantages of the trial proposal were seen to apply equally to Aboriginal and non-Aboriginal users (Humes et al. 1993*).

2. The legal aspects of a trial

Drug legislation

In Stage 1, there was examination of international treaties which Australia has ratified and Commonwealth, State and Territory legislation which would impact on a trial (Norberry 1991*). Civil and criminal liability issues were examined in Stage 2 (Cica 1994*; Bronitt 1995*).

The relevant international treaties are:

- the Single Convention on Narcotic Drugs 1961 as amended by the 1972 Protocol; and
- the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988.

A trial expanding maintenance treatment to include diacetylmorphine, that was conducted for a medical or scientific purpose would not place Australia in breach of international treaty obligations (Norberry 1991*). Norberry also argued that while, in these circumstances, controlled availability of diacetylmorphine to heroin dependent persons was unlikely to involve a breach, inclusion in a trial of users who are not dependent could be more problematic.

Relevant Commonwealth legislation includes:

- Customs Act 1901 (Cwlth)
- Customs (Prohibited Imports) Regulations
- Narcotic Drugs Act 1967 (Cwlth)
- Therapeutic Goods Act 1989 (Cwlth)
- Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990 (Cwlth).

The Commonwealth controls the importation of narcotic goods and has extensive powers in relation to therapeutic goods. The Commonwealth and the states also regulate the manufacture of narcotic goods. In the case of imported heroin, a trial could only proceed legally if the requisite Commonwealth licences and permissions were obtained and if the Commonwealth agreed to notify estimates for heroin importation to the International Narcotics Control Board (Norberry 1991*; Bronitt 1995*).

The relevant ACT provisions prohibiting possession, supply, administration and self-administration of heroin are found in:

- Drugs of Dependence Act 1989 (ACT).

Under current ACT legislation, a trial to provide opioids, such as heroin, in a controlled manner would not be lawful. For a trial to be able to proceed, one of three changes would have to be enacted:

- a non-enforcement agreement involving the Commonwealth, ACT, some State governments (probably) and a range of agencies including the Australian Federal Police, the Director of Public Prosecutions and the ACT Board of Health,
- amendments to existing ACT legislation, or
- special legislation.

Of these options, the second or third are most desirable (Norberry 1991*; Bronitt 1995*).

Unless the strict requirements for manufacture of heroin which exist in Victoria could be met, legislative change would be needed if the diacetylmorphine was to be manufactured in Australia (Norberry 1991*); it is more likely, however, that the diacetylmorphine would be purchased through legal commercial channels outside Australia. There may also need to be legislative change in some states to enable the diacetylmorphine to be transported into the ACT (Bronitt 1995*).

Liability for harm to participants

In terms of civil liability, researchers or clinical staff will be liable in negligence to a trial participant or other person affected by the conduct of the trial if the following elements are all present: the researcher owed a duty of care to that person; the duty was breached; the breach caused that person to suffer damage; and the damage is compensable at law. Liability in negligence will only attach where the harm caused is the result of breach of duty to conduct procedures with reasonable care by researchers or clinical staff (Cica 1994*).

Civil liability in battery arises out of the touching of another person without that person's legally valid consent (Cica 1994*). In addition, failure to obtain effective and valid consent from trial participants would give rise to criminal liability for assault and/or related offences, except where treatment is provided in emergency situations. The "public interest" places limits on consent where the activity involves the risk of bodily harm. It is unclear, under the present law, whether the treatment or procedures during the trial could be justified under the existing "medical treatment" exception, or some other "public interest" exception (Bronitt 1995*).

To avoid liability for homicide, researchers and clinical staff must ensure that both foreseen and reasonably foreseeable risks of death to participants during a trial are minimised (Bronitt 1995*).

The provision of diacetylmorphine to participants may give rise to liability under poisoning offences. It is unclear whether, and to what extent, the consent of participants would operate as a defence (Bronitt 1995*).

To avoid civil liability in battery, the following requirements must be satisfied: the trial participant must be competent to consent; the consent must be based on adequate information; the consent must be voluntarily given; and the consent must not be against the public interest (Cica 1994*). There are less stringent requirements for consent in the criminal law, which requires participants to comprehend only the physical nature of the treatment and procedures (Bronitt 1995*). However, for both legal and ethical reasons, trial participants should be fully informed, both in writing and orally, about the nature, purpose, significance and context of the treatment and procedures before and during the trial.

In addition, it would be appropriate for the ACT legislature to enact a special "consent" defence for assault and related offences (including poisoning offences), which would clarify that staff who administer diacetylmorphine during the course of a trial can raise the consent of the participants as a defence (Bronitt 1995*).

Ancillary liability

Criminal liability for the crimes committed by trial participants was also examined (Bronitt 1995*). In the ACT the common law offence of misprision of felony is no longer available: mere knowledge that a participant has committed an offence, and failing to report that offence to the relevant authorities, is not

sufficient to impose criminal liability on researchers or clinical staff. However, liability as an accessory after the fact could occur where the knowledge is accompanied by positive acts of assistance, which enable the perpetrator to escape punishment or to dispose of the proceeds of the offence.

An important issue is that of clinical staff potentially aiding and abetting driving offences, notably driving under the influence or culpable driving, either through (a) the act of supplying the diacetylmorphine or (b) the failure to take steps to prevent the participants from driving while under the influence of the drug. Clinical staff, however, would ordinarily lack the requisite intention to be guilty of aiding and abetting and may in any event avoid liability by taking steps to dissociate themselves from the criminal purpose of the participant (Bronitt 1995*).

To avoid liability for public nuisance, which is both a crime and a tort, researchers and clinical staff must ensure that dangers to the general public are kept to a minimum. Such steps would include, for example, the establishment of procedures for the safe disposal of used needles and syringes and effective security for diacetylmorphine kept on the premises. The conduct of groups of participants may attract police intervention through public order offences and the powers to deal with individuals who are intoxicated in public. To avoid this, the congregation of participants in the immediate vicinity of the treatment centre should be deterred (Bronitt 1995*).

Confidentiality

The trial would be covered by the *Epidemiological Studies (Confidentiality) Act 1992 (ACT)*, which imposes a statutory duty to maintain confidentiality. This legislation prohibits anyone involved in conducting the proposed trial from directly or indirectly "making a record of, divulging or communicating to any person" any information concerning the affairs of another person, where that information was acquired by virtue of the conduct of the trial (Cica 1994*). There is some uncertainty over the scope of the powers of law enforcement agencies to search and seize confidential information gained during the trial and this should be clarified in this legislation so that information gained during the trial cannot be subject to search and seizure by law enforcement authorities. Procedures should be drawn up in cooperation with law enforcement agencies to resolve disputes over the privileged nature of the information gained during the trial and whether or not that information can properly be the subject of a search warrant (Bronitt 1995*).

In conclusion, if there was a willingness to make appropriate legislative changes, other legal issues would not constitute a barrier to a trial proceeding. In particular, an appropriately designed and conducted trial would not be in breach of Australia's obligations under international conventions dealing with narcotics. High professional and ethical standards would be expected from

researchers and clinical staff as a matter of course and these would additionally minimise the risk of civil and criminal liability.

3. Risks associated with running the trial

There are a number of potential risks associated with trialing the inclusion of diacetylmorphine in expanded maintenance treatment. Identifying these risks, finding ways to minimise them and, in the end, assessing whether or not the potential benefits of conducting a trial outweighed the risks, were essential elements of the Stage 2 research.

The surveys, workshops, discussions with interest groups and the published literature were all useful in identifying potential risks. The cause of greatest concern was that dependent heroin users from around Australia would move to Canberra. In addition, there is a view that a trial might be the harbinger of more permissive attitudes to illicit drug use, which could have negative effects including increased drug use. There are also inter-related risks concerning opportunity costs, long-term costs and the possibility that, once diacetylmorphine maintenance is trialed, the decision will be irrevocable. A fourth set of risks relates to trial logistics and how the running of the trial might pose problems for the community, participants or other dependent heroin users. Finally there is risk that the trial will not achieve the proposed benefits. In this section related issues about the morality of a trial and possible manipulation of public opinion by those with vested interests are also discussed.

Dependent users from around Australia may move to Canberra

This potential problem has three dimensions: the number of people who might move, the length of time they might stay and the consequences of their movement. Possible negative consequences for Canberra are an increase in visibility of the illicit drug 'scene'; an increase in crime, an increased demand on drug-related and other services, and increased health problems. These issues were investigated by examining factors that influence migration, so-called push-pull factors, and by analysing situations that provide analogies to what may happen in Canberra. These included migration to Brisbane and Canberra when the New South Wales government moved to abandon methadone programs between 1978 and 1985 and an investigation of factors causing open drug scenes in Zürich, Switzerland and Nimbin, Australia (Bammer et al. 1994a*).

There is a risk of an influx of users to Canberra if a trial of controlled availability of diacetylmorphine proceeds, but measures can and should be taken to minimise the risk. These measures must aim to discourage non-Canberra residents from even trying to get a place on the pilots or trial. This can be accomplished by a combination of trial design, residency criteria and appropriate pre-trial publicity about these.

Eligibility for participation in the Canberra-based pilot studies and trial should be restricted to those able to prove residency since 1993. (1993 was originally chosen to discourage non-

residents from moving to Canberra during the Stage 2 research. In addition, it would be difficult for people to fake residency proofs for such an extended period.) Potential proofs of residency include: bank, credit union or building society account; driver's licence; social security records or employment records or education enrolment records; electoral roll; electricity, gas or telephone accounts; and land or water rates notices or rent receipts or leases (Bammer et al. 1994a*). More than one proof of residency will be required.

In addition to the residency criteria, there should also be restrictions related to trial design. The first restriction is to limit the numbers on the pilots and trial. Second, the pilot studies will be restricted to dependent heroin users who are or have been on the ACT methadone program. The combination of limited places and strict eligibility criteria will greatly reduce both the likelihood and the perception of the likelihood of non-residents obtaining a place. Thus to be eligible for one of the 40 places on pilot 1 or the 210 additional places on pilot 2, the following criteria will have to be met:

a) ACT resident since 1993

AND

b) currently on the ACT methadone program or dependent heroin user who has dropped out of the ACT methadone program

The trial itself will also be open to long-term ACT residents who have never been in treatment. To minimise the risks to the ACT, it is recommended that the trial should only proceed if at least two other Australian cities agree to participate.

These eligibility criteria should be widely disseminated. Agencies, Australia-wide, which provide treatment and other services to illicit drug users should be thoroughly briefed on the eligibility criteria by the ACT Health Alcohol and Drug Service (Recommendation 11).

Negative consequences in terms of increased crime, increased demand on drug-related and other services, and increased health problems can all be best avoided by discouraging non-residents from moving to the ACT. However, the potential consequence of increased visibility of the illicit drug 'scene' is more likely to result from an atmosphere of permissiveness towards illicit drug use than from an influx of users, *per se*. As discussed in the next section, a trial should be divorced from such permissiveness and there should be stringent enforcement of laws against the consumption and sale of illicit drugs whenever this occurs in public places. Visibility can also be minimised by choosing trial site location(s) with physical attributes that discourage congregation, including no space in which to gather and lack of other facilities (Bammer et al. 1994a*).

A trial may lead to more permissive attitudes to illicit drug use

This concern is manifested in two major ways. One worry is that prescription of diacetylmorphine will be the 'thin edge of the wedge' and will lead to full-scale legalisation of illicit drug use.

Another is that a trial will send a message either that illicit drug use is acceptable or that it is less risky (because if people get into difficulty they can obtain medically prescribed diacetylmorphine). The concern is that the consequences of such a message may be to increase drug use. There is also a worry that a perception of a more permissive attitude in Australia will have international consequences, either pressure on Australia to reverse its policy or a loss of credibility in international fora on drugs.

While these concerns are legitimate, none is an inevitable consequence of expanding maintenance treatment to include diacetylmorphine prescribing. Diacetylmorphine prescription can and should be divorced from permissiveness towards illicit drug use. Law enforcement and educational strategies against illicit drug use should be maintained. Ideally the introduction of diacetylmorphine maintenance prescribing should be low-key, but intense media interest makes this impossible. Nevertheless, where possible, communication with the media should reinforce the disassociation between diacetylmorphine prescribing and permissive attitudes towards illicit drug use.

It is also worth pointing out that, for illicit drug use to be legalised, Australia would have to breach the international conventions, whereas this is not the case for the expansion of maintenance treatment to include diacetylmorphine (Norberry 1991*). In addition, the availability of diacetylmorphine on prescription in the United Kingdom has not led to legalisation, nor is there evidence that there have been more permissive attitudes towards illicit drug use or greater increases in use than in other western countries (Working Paper A in preparation).

Opportunity costs, long-term costs and "you can't turn the clock back"

There are a number of interrelated concerns which are underpinned by the high costs of prescribing diacetylmorphine. They are that trialing an expansion of maintenance treatment to include diacetylmorphine will prevent other initiatives from being tried (opportunity costs); that the expense of diacetylmorphine prescribing cannot be sustained in the long-term (long-term costs); and that once diacetylmorphine maintenance treatment is tried it will be difficult to return to the current policy where diacetylmorphine is completely unavailable ("you can't turn the clock back").

To a large extent, these are political concerns rather than research issues, but some commentary based on research evidence can be made. The first area to examine is the cost of diacetylmorphine prescribing.

Because only small quantities are produced by limited numbers of legal commercial producers, the cost of diacetylmorphine itself is relatively high. The need for high security during production, shipment, storage and dispensing further adds to the cost. In the Australian and Swiss contexts where diacetylmorphine would be/is administered at a clinic, there are substantial costs associated with staffing treatment centres for extended opening hours. In the

United Kingdom, where diacetylmorphine is dispensed at pharmacies, there are high costs associated with packaging the drug in sterile ampoules and there are relatively high dispensing fees (Working Paper A in preparation).

Thus, the addition of the option of diacetylmorphine to maintenance treatment will be more expensive than methadone maintenance alone. Estimates based on the budget for pilot 2 suggest that this option will be in the mid-range of costs of treatment for drug dependence—more expensive than methadone, but cheaper than therapeutic communities, which are relatively expensive, although still cost-effective. The larger numbers of staff needed in a program where diacetylmorphine is dispensed will also allow more counselling and social assistance to be provided than in a standard methadone program.

Ironically, if expanding maintenance treatment by including diacetylmorphine is successful in attracting people into treatment and in retaining them, this will also add to the costs.

Finally, quality evaluation is expensive. While this will not be a major on-going cost, it is part of the opportunity cost of conducting a trial of maintenance including diacetylmorphine rather than some other treatment option. The highly political nature of diacetylmorphine prescribing and the need to monitor a number of social effects would make evaluation of this option more expensive than evaluation of many other options.

It was not within the scope of the feasibility study to examine other new treatment options which might be trialed or to evaluate whether treatment for drug dependence is more pressing than other health priorities. However, as has been pointed out earlier, there have been long-term and persistent calls to trial diacetylmorphine maintenance prescribing, which have emanated from a number of government enquiries.

The concern about long-term costs relates to financial pressures in the health care system as a whole. Although there is no rigorous recent evaluation of the effectiveness of diacetylmorphine maintenance treatment, there is pressure on individual prescribers in the United Kingdom to stop or limit this treatment as a result of restrictions on health care expenditure (Working Paper A in preparation). There are similar pressures in Australian, and particularly the ACT, health care systems. Evidence for the cost-effectiveness of drug treatment generally has been presented earlier, but whether or not diacetylmorphine prescribing is affordable is still largely a political decision. Certainly if a trial proceeds evaluation of cost-effectiveness is critical.

The final concern is about the irrevocable nature of the decision to pilot and trial maintenance treatment which includes the option of diacetylmorphine.

Part of this concern is that even if a trial is found to be unsuccessful for the majority of participants, there will be pressure for diacetylmorphine maintenance prescribing to continue for a minority. From previous experience with the prescription of diacetylmorphine and other maintenance drugs, there are examples of where this has happened, as well as examples of programs which have

been completely shut down (Working Paper A in preparation). The problem again is predominantly political.

A second component to this concern is that allowing diacetylmorphine maintenance prescribing to be tried (or even thinking about it seriously) raises expectations among dependent heroin users and may make them less likely to be satisfied with other (cheaper or less politically sensitive) options.

Another way of describing these concerns is that the political costs of a trial may be substantial. While there is a real research question to be addressed and some persistent pressure to address it, expectations that it will be addressed (at least in Australia) are currently low. Conducting the pilots and trial will change those expectations and will have long-term political, and probably financial, implications.

Risks associated with trial logistics

There are a number of potential risks related to the running of the trial. Some are risks to the community, others are risks to participants or other illicit drug users. Potential risks to the community include trial participants driving while affected by trial drugs; law enforcement becoming more difficult; trial diacetylmorphine becoming available on the black market; and trial participants congregating at or near the trial site. Risks to participants or other illegal drug users include the potential of violence to participants from non-participants; possible health problems for babies born to women on the trial; and the risk of a trial providing inappropriate incentives or of institutionalising or further marginalising dependent heroin users.

a) Risks from trial participants driving while affected by trial drugs

Both the Stage 1 and Stage 2 surveys show that a substantial proportion of those likely to be eligible for a place on the trial drive motor vehicles and that this would be a significant means of transport to and from the trial (Bammer and Crawford 1991*; Working Paper B in preparation). Thus concerns about effects on driving must be considered seriously.

Participants in the Swiss trials must surrender their drivers' licences, but this option is unlikely to be workable in Canberra where the public transport system is much poorer. It is likely that a proportion of participants would simply drive without a licence, so the risk would remain.

Methadone maintenance treatment does not impair the ability to drive a motor vehicle (Chesher et al. 1989) and the best currently available evidence suggests that trial participants who are stabilised on diacetylmorphine or diacetylmorphine plus methadone will also not be impaired (Working Paper D in preparation).

The ability for participants to be stabilised on diacetylmorphine or diacetylmorphine plus methadone will be tested in Pilot 1 and unless a significant proportion can be stabilised, there will be no progression to Pilot 2 (Recommendation 4).

Driving skills are likely to be affected if participants use doses of diacetylmorphine which induce drowsiness; experience significant withdrawal symptoms between dosing sessions; and/or use other drugs like benzodiazepines and alcohol. As discussed in the section on evaluation these are all indicators of whether or not stability has been attained.

It will be a condition of involvement in the pilots and trial that participants undertake not to drive while their skills are impaired. Clinics will be equipped with a computer-based battery of tests which assess human performance skills related to those required to drive a motor vehicle with safety. Participants who have concerns about their driving ability will be able to do the tests and staff can require participants to test their ability before they leave the clinic. If at any time clinic staff have concerns about the ability of a participant to drive safely, they must advise that participant that driving while impaired is not only dangerous but is also an offence, and that if the participant intends to do so, the staff are obliged by law to contact the police and can provide no further assistance to the participant (see Bronitt 1995*).

Ethical concerns are also relevant here and to some of the other risks discussed in this section (especially the risks to babies of trial participants). The issue of acts and omissions concerns the distinction between the blame attaching to harms which one has somehow caused to happen, as opposed to those which one has merely let happen. The distinction is, for example, between someone being involved in a car accident after receiving diacetylmorphine as part of a trial, as compared to an accident after taking heroin illegally. Ethicists themselves are deeply divided on the moral importance of this distinction. Some argue for a deontological approach, namely that there is an enormous difference between causing harm and allowing harm to happen, so that harm resulting from an intentional intervention is a major problem, even if similar or greater harms might otherwise have happened. Other ethicists argue for a more utilitarian approach, which judges the harms caused by the intervention in light of those which would have happened had there been no intervention. The deontological approach sets a presumption against any interventions designed to alleviate social problems. By weighting the harms caused as a consequence of the intervention more heavily than ones which happened independently, deontologists make it difficult to trial new approaches. While there needs to be reasonable certainty that the risks involved in interventions can be minimised, too heavy a bias in that direction seems difficult to defend (Ostini & Bammer 1991*; Ostini et al. 1993*).

b) Law enforcement will be made more difficult

A concern voiced particularly by some police was that law enforcement might be made more difficult, because they would not be able to differentiate between lawful and unlawful heroin use or because receiving government-supplied diacetylmorphine would be used as a 'defence' when trial participants were prosecuted for other offences, such as driving under the influence (Stevens et al. 1995*). Neither of these should eventuate. The only place where

trial participants would legally be in possession of trial diacetylmorphine would be at the clinic and they would not be immune from prosecution for other offences or from offences committed under the influence of trial diacetylmorphine.

c) Risks of the trial diacetylmorphine becoming available on the black market

The requirement that trial diacetylmorphine must be injected on site under strict supervision greatly minimises the risk that participants will divert this drug.

Strict security and accounting procedures will further minimise the risk of trial diacetylmorphine becoming available on the black market.

The experience with the current Swiss trials shows that the risks can be effectively minimised.

d) The risk of trial participants congregating at or near the trial site

There are two components to congregation. One is that participants may gather shortly before opening time, the other is that they may congregate between sessions. The clinic will be closed between dosing sessions and overnight. There will be five hours between sessions and 11 hours overnight in pilot 1 and 3.5 hours between sessions and 11 hours overnight in pilot 2 and, most likely, the trial.

If participants are properly stabilised, they should not be in withdrawal at opening time, so this should remove one potential reason for congregation. Other reasons for congregation at opening times (for example, the need to get to work in the morning) should be examined and, if necessary, opening times adjusted. The provision of a waiting room at the clinic should help minimise congregation and clinic location should also be considered from this perspective. For example, siting a clinic near a shopping centre or park or other area where there is space or other things to do can encourage congregation.

It is most likely that clinic staff can prevent congregation by making it clear to participants that it is unacceptable. In the worst case scenario, police have a range of powers to prevent a breach of the peace (Bronitt 1995*).

e) The risk of violence to participants from non-participants

The survey results indicate that illicit drug users, police and service providers all perceive that trial participants are likely to be at risk of violence from non-participants (Bammer & Crawford 1991*). The main reason for the risk is that non-participants may try to intimidate participants out of their diacetylmorphine prescription. This risk can be minimised by making it clear that there are no take-away doses of diacetylmorphine, that administration on site is under strict supervision and that participants who divert their prescription will be expelled from the trial.

If only one member of a couple where both members are dependent on heroin has a place on a trial, this could also provoke violence. Couples will, therefore, be invited to apply for a place together and to be randomised as a single unit, so that both receive the same treatment options.

f) The risk of problems for babies born to women on the trial

It is generally accepted that the babies of drug dependent women are at greatest risk when their mothers are using illegal drugs, mainly because of fluctuating blood levels of drugs, other drugs that may be used to try to alleviate withdrawal symptoms, and lack of ante-natal and post-natal care. Stabilising heroin dependent pregnant women on methadone is an accepted way of minimising these risks and the limited research evidence available suggests that this does not have major adverse consequences for their children (eg. see Finnegan & Kandall 1992). There is no evidence about the effects if women are stabilised on diacetylmorphine or diacetylmorphine plus methadone.

One option would be to bar women from the trial. However, there is a growing ethical, social and political debate surrounding the question of excluding pregnant or potentially pregnant women from therapeutic research (see Cica 1994*). In this case it can be argued that the risks to the children of women excluded from the trial are likely to be greater than those for children of women on the trial. While most women are concerned about the potential harms drug use can have on their babies, many have little knowledge about these harms and, in any case, find it difficult to modify their drug use (eg see Appendix in Bammer & Weekes 1993*). Excluding women from the trial would perpetuate this situation, whereas including them would give them access to reliable information on which to make informed decisions, as well as ante-natal and post-natal care.

The civil liability aspects of including pregnant women on the trial are discussed by Cica (1994*). Liability will only attach where harm caused is the result of breach of duty to conduct procedures with reasonable care. Ethically, the issue is a question of what is best for the woman and baby on medical, pharmacological and social grounds. The issue of acts and omissions discussed above is also relevant here (Ostini & Bammer 1991*; Ostini et al. 1993*).

g) The risk of a trial providing inappropriate incentives or of institutionalising or further marginalising dependent heroin users

There are a number of components to the risk of inappropriate incentives: non-dependent users increasing their use in order to qualify for the trial, ex-users starting to use again and lack of incentives for users to stop. There is also the question of whether it is appropriate to allow people who are currently in treatment to qualify for a place on the trial, in other words to provide an incentive for people to leave current treatment options. In addition, there is the risk that bringing dependent users into treatment will result in institutionalisation or further marginalisation.

The results of surveys with non-dependent users and ex-users (Bammer & Crawford 1991*; Bammer & Weekes 1993* 1994* Dance et al. 1995*) indicated that there are risks that some non-dependent users will increase their use in order to get on a trial and that some ex-users will be tempted to relapse. However, the surveys indicate that

these risks are small and that the eligibility restrictions will reduce them further.

The problem of a lack of incentives to stop using is potentially more serious. Some dependent users decide to become drug free when they 'hit rock bottom', in other words when they find themselves in a crisis which leads to a realisation of how much drug use has cost them and, often, that they may die if they do not stop (Bammer & Weekes 1993*; 1994*). A trial may mean that participants do not 'hit rock bottom'. There is a paucity of evidence about stopping dependent use, so that it is not possible to gauge the relative importance of 'hitting rock bottom' compared with other motivations for becoming abstinent, nor is it possible to gauge whether or not hitting rock bottom inevitably leads to abstinence. A counter argument is that there are a number of reasons why dependent users eventually decide to stop and that it is important to keep them healthy, socially integrated and outside the criminal subculture while they are using, so that decision to stop is easier to make and more likely to be achieved. The pilots and trial may be able to collect evidence which can shed light on these counter claims.

There is a similar paucity of evidence for meaningful reflection on the possible incentive of attracting participants from other treatments. It is not possible to determine whether it will happen or how problematic it is. Of most concern, however, is that current methadone clients will be allowed to apply for a place on the pilots and trial. However, it is also problematic to refuse them a place, given the high drop-out rate from methadone treatment. The pilots and trial will provide an answer to the question of whether methadone clients are better or worse off when given access to expanded options for maintenance treatment.

Ethical considerations relevant to this issue are discussed in Ostini & Bammer (1991*) and Ostini and colleagues (1993*). It is argued that it is never enough simply to say that incentive effects exist. Undesirable incentive effects must be balanced against possible positive outcomes.

There is also a risk that a trial will institutionalise and further marginalise dependent heroin users. Again, there is little evidence that can be brought to bear on this question and evidence must be collected as part of the measurement of the effects on social integration.

The trial will not achieve the proposed benefits; a trial is morally wrong; and the possible manipulation of public opinion by those with vested interests

Many of those who oppose a trial believe that the proposed benefits will not be achieved (see eg the police response discussed earlier) and therefore that a trial risks wasting money and effort. If there were certainty about the outcomes of a trial, it would not be necessary or ethical to conduct it. However, that certainty does not exist and, as discussed in Part 2, has been one reason for the persistence of debate about diacetylmorphine maintenance treatment. Thus there is a risk that the trial will not produce the proposed benefits, but, because of the importance of resolving the debate, that risk should be taken. A negative result would also be useful. It would significantly mute the debate and allow more attention to be focused on other possibilities for treatment.

Opposition to a trial is often associated with a value system which holds illicit drug users in scant regard or a moral position which is opposed to maintenance treatment. Ward and colleagues (1992) have discussed the latter as it applies to methadone maintenance treatment and that argument is also relevant to expanding this treatment to include diacetylmorphine. Some critics find it unacceptable to replace "one drug of dependence with another" (Ward et al. 1992, p. 6) and argue that dependent users should become drug-free. As Ward and colleagues discuss, showing that a moral position is empirically impossible, or at least extremely difficult to meet, provides a good reason for rejecting or modifying it. Indeed proponents of methadone maintenance argue on moral utilitarian grounds that the benefits of the treatment to both the patients and the community outweigh the costs. A trial will examine if the same holds if maintenance treatment is expanded to include diacetylmorphine.

This discussion also raises ethical issues related to countermobilisation (Ostini & Bammer 1991*; Ostini et al.; 1993*). There are two main sources of opposition to a trial. The first is from people who feel such a trial is wrong or have genuine anxiety about its likely outcomes. This opposition is legitimate and must be respected. The second is from people who have a vested interest in heroin remaining completely illegal, for example, because they benefit financially from the sale of illegal drugs. There is a risk that people in the second group will use the legitimate concerns of the first group for their own ends; in other words legitimate concerns could be illegitimately exploited. Apart from being aware of the issue and evaluating debate, there is little that can be done about the manipulation of public opinion by those with vested interests.

4. A model for service provision

A model for service provision was proposed during the Stage 1 research and was further developed during Stage 2. The Stage 2 considerations were both philosophical and practical. At the end of this section there is a discussion of the reasons for changes between the Stage 1 and Stage 2 models.

Principles of service provision

A small working group considered principles of service provision which constitute a health development approach (McDonald et al. 1994*; the health development principles arise from a broader program of research by one of the group members, Dr David Legge). Four health development principles are:

- service delivery is undertaken in a respectful collaboration with the people whose health is at issue (at both the clinical and community levels);
- service delivery addresses the immediate needs of sick care and public health in ways that also contribute to redressing problems understood in terms of larger structures and longer time horizons;
- service delivery addresses the technical tasks of sick care and public health in ways that also strengthen our ability to manage existential challenges;
- service delivery conceives the functions of sick care and public health as continuous with the broader domains of living a fulfilling life and contributing to building a better society.

The way these principles would translate in terms of the provision of a service which expands maintenance prescribing to include diacetylmorphine are discussed by McDonald and colleagues (1994*). They include a collaborative approach between staff and participants to dealing with drug use and the problems arising from it, and the fostering of personal and social responsibility.

Practical issues

In terms of practicalities, consideration was given to the location and design of one or more clinic sites; staffing; security; eligibility to participate; day-to-day operation; and pilot or trial termination. These are elaborated in Working Paper E (in preparation) and there are also further details in the budget justification in Part 4.

a) Location and design of the clinic

The clinic site where diacetylmorphine maintenance prescribing is an option should be physically separate from the existing methadone clinics during the pilots and trial. This is to minimise friction between trial participants allocated to the 'choice' group and those allocated to the 'control' group, as well as those unsuccessful in obtaining a place on the pilots and trial. The clinic site for the 'choice' group must have provision for an injection room, where a few participants can administer injectable diacetylmorphine under close supervision. The current Swiss trials provide a number of models for clinic arrangements that maximise efficient flow-through of participants.

Thus there will be a clinic(s) for those receiving methadone maintenance only, which will be attended by those who do not want or are not eligible or are otherwise unsuccessful in obtaining a place on the pilots and trial, as well as trial participants allocated to the 'control' group in pilot 2 and the trial. There will be a different clinic for the expanded maintenance program which will be

attended by all participants from pilot 1 and those allocated to the 'choice' group in pilot 2 and the trial.

It is likely that one site will be able to accommodate the participants of the expanded maintenance group in pilots 1 and 2; a second site may be needed to accommodate the larger number of trial participants in the 'choice' group. Although one clinic site is the cheapest option, and has been the basis for the budget calculations, it does have disadvantages. It may make the site more conspicuous, increase the likelihood for congregation and make it more difficult for participants who want to disassociate themselves from their past lives or who simply want to avoid other participants.

Considerations for choosing a clinic site include: security; inconspicuous location; proximity to public transport; public acceptability; minimisation of opportunity for congregation by participants; and participant preference. Two-thirds of those interviewed for the Stage 2 research reported a preference for a site in Civic (the central area of Canberra; Working Paper B in preparation).

b) The diacetylmorphine

Diacetylmorphine hydrochloride can be purchased through legal commercial channels outside Australia. It is available as a sterile powder. It is not stable in solution in the long term, so that solutions must be mixed daily. The appropriate dose will be drawn up into a syringe in front of the participant at each dosing session.

Diacetylmorphine will only be available in injectable form. Experience in the Swiss trials has shown that no satisfactory smokable form is available. The Swiss are investigating inhalant preparations and slow-release oral tablets and if these are shown to be successful, they should also be included in the Australian trial.

c) Staffing

A combination of medical, nursing and counselling staff is envisaged. There might also be advantages to employing pharmacists to dispense the diacetylmorphine, but this has not been considered here. Staffing details are provided in the budget justification in Part 4. There will be regular medical review of the participants and counselling and social support will be available.

A case work system is proposed, where each nurse and counsellor will be the caseworker for a specific group of participants and will be responsible for initial assessment and review; general support; continuity of care; the participant's file; and liaison with medical and other staff. (To ensure comparability between the 'choice' and 'control' groups, a case worker system should also be introduced in the methadone program. In pilot 1, the diacetylmorphine clinic staff have some 'excess hours' which could be used to establish this system in the methadone clinic.) The casework load for a full-time staff member will be about 10 participants and will be adjusted on a pro-rata basis for part-timers.

Current staff of the ACT Health Alcohol and Drug Service will not be required to work in the clinic where the diacetylmorphine option is provided unless they wish to do so.

d) Security

There must be strict security to prevent theft of drugs by staff, participants or outsiders. For obvious reasons, security measures will not be presented in detail, but will include the usual requirements for storage and transport of drugs of this type and a security guard during clinic opening times.

e) Eligibility to participate

As outlined earlier, to be eligible for a place on the pilots or ACT component of the trial, applicants will have to prove ACT residency since at least 1993. In addition, to be eligible for a place on the pilots, applicants must be or have been on the ACT methadone program. Applicants who have dropped out of the methadone program must be able to prove dependence on heroin, using current guidelines for admission to the methadone program.

For the trial itself, dependent heroin users who have never been in treatment will also be eligible, provided they can meet residency criteria and can prove dependence on heroin, using current guidelines for admission to the methadone program.

The following will not be eligible for a place on the pilots or trial: applicants dependent on prescribed opioids for pain relief; applicants with current or recurrent major psychiatric illness; and applicants aged less than 18 years (see Sibthorpe et al. 1993*). Places on the pilots and trial will not be available as a court referral option. Positive or negative HIV or hepatitis infection status will not affect eligibility.

There is a discussion on the ethics of eligibility criteria in Ostini & Bammer (1991*) and Ostini and colleagues (1993*).

f) Day-to-day running

Participants in the 'choice' group will be able to have injectable diacetylmorphine, oral methadone or a combination. They will be able to have a maximum of three injections of diacetylmorphine per day and the clinic will be open in the early morning, early afternoon and evening to accommodate this. Diacetylmorphine will only be able to be administered at the clinic; there will be no take-away doses. Oral methadone will be available once daily and will be available in take-away doses, regulated according to current guidelines. Experience in the Swiss trials indicates that equivalent doses for these two drugs can be easily calculated and the pilot studies will test ease of changing between different options to determine how flexible the expanded treatment is. Based on the Swiss experience, there will be a maximum dose of diacetylmorphine of 800 mg per day. Current guidelines will regulate the provision of methadone. The aim of dosing will be to achieve stabilised consumption, within a defined therapeutic range, in order to allow participants to function normally. There will be low starting doses and a carefully monitored build-up to the stabilising dose. Doses which produce drowsiness will be allowed, but participants who request these doses must come early in the dosing session, so that they will be in a fit condition to leave the clinic at the end of the dosing session. The dose requested by participants will be an important indicator of stability (see next section).

Time-limited maintenance treatment, which attempts to force participants to achieve a drug-free lifestyle, has not been found to be successful (Ward et al. 1992). Some participants will require long-term maintenance treatment, while others will aim to become drug-free. A full range of psychosocial supports to assist those participants who choose abstinence should be available.

By and large, these conditions are congruent with those that interviewees and the reference group thought would be appropriate and feasible (Working Paper B in preparation). Most interviewees wanted to inject three times a day or less often and this was consistent with their current patterns. Seventy percent of those interviewed wanted an upper limit on the amount of diacetylmorphine available. A few indicated that access to diacetylmorphine would help them to stop using methadone and become drug-free. Having to inject on site and not being able to use when and where they wanted would be a disadvantage for some, as would the inconvenience of having to go to the site for every injection. However most also recognised advantages in not having to worry about theft or being pressured or tempted to sell the diacetylmorphine. For some having a site at which to inject was an advantage. In general, longer opening hours would be needed to accommodate all preferences, but this would be much more expensive and the Swiss experience indicates it may be unnecessary.

The Swiss experience shows that participants do not arrive in a steady stream throughout the dispensing period, but that there are peak times particularly at the beginning of the session. To cope with this, a second dispensing area at the clinic is proposed. This

is analagous to the regulation of customer service in banks, where the number of tellers available is tied to the number of customers.

The following will be grounds for removing participants from the pilots or trial and transferring them to another treatment: diversion of diacetylmorphine (ie smuggling the drug out of the clinic); bringing illegal drugs or alcohol into the clinic; breach of confidentiality of other participants; and disregard for their own health and that of others through unsafe injecting, regularly coming to the clinic intoxicated with other depressant drugs, disregard of infection controls, and violence.

Participants who leave the pilots or trial will not be replaced. Thus it will not be possible for those unsuccessful in gaining a place on a trial to replace participants.

Payment to participate in the pilots or trial will not be required. First, it is not usual to ask people to pay to participate in a trial. Second, enforcing payment is likely to confound measurement of trial outcomes and would counteract the ability of the pilots and trial to produce clear answers to the research questions. However, if diacetylmorphine maintenance prescription is found to be a successful and viable option, in the long term it should be paid for like any other treatment option.

An issue which is not yet fully resolved is that of smoking policy. There will be no smoking in the injecting room, but it will probably be necessary to allow participants to smoke in the waiting room. This may have implications for the employment of clinic staff.

Children will not be allowed in the clinic; instead there will be a children's program which trial participants can use. The ACT Intravenous Drug Users League (ACTIV) should be invited to expand its playgroup into a children's program. Parents are encouraged to participate in the playgroup, which has a high level of support and supervision. Community health nurses regularly attend to ensure that the health needs of the children are met and to provide information and education to the parents.

g) Pilot or trial termination

As part of the informed consent process, participants must understand that continued availability of diacetylmorphine maintenance prescription cannot be guaranteed and must be made aware of the conditions under which the pilots or trial might be terminated. If either of the pilots was shown not to be successful under the conditions specified in Part 1 (Recommendations 4 and 6), diacetylmorphine maintenance prescribing would terminate. This would occur under the recommendation of a committee established to oversee the running of the pilot studies and the ACT component of the trial (Recommendation 8). This committee would also have the power to recommend that the diacetylmorphine maintenance program should be stopped at any time.

At the end of the first year of the trial, if the results show that there is no additional advantage to prescribing injectable diacetylmorphine over the prescription of oral methadone alone, or that expanding maintenance treatment by prescription of injectable diacetylmorphine has value for only a subgroup of dependent heroin users, the second year should be used to limit or wind down the prescribing of injectable diacetylmorphine and to gradually return those in the 'choice' group to other treatment options.

To avoid undue politically-motivated interference, the committee should agree at the outset on reasons for terminating or modifying the pilots or trial (Ostini & Bammer 1991*; Ostini et al. 1993*).

How and why the Stage 2 model is different from that proposed in Stage 1

There are two main differences between the model proposed at the end of the Stage 1 research in 1991 and the Stage 2 model proposed here. The Stage 2 model has restricted the choices available to three (injectable diacetylmorphine only, injectable diacetylmorphine plus oral methadone and oral methadone only) compared with any combination of diacetylmorphine and methadone in injectable, smokable or oral forms in the Stage 1 model. The other is that the Stage 2 model proposes a restricted numbers of places for the trial, whereas the Stage 1 model proposed unlimited numbers. There are also some minor changes which bring the service more in line with current methadone treatment.

Practically, the restriction in options eliminates two likely choices—smokable diacetylmorphine and injectable methadone.

As outlined earlier, the provision of smokable diacetylmorphine was not successful in the Swiss trials, although it has been reported to have been used successfully in the United Kingdom (Working Paper A in preparation; Bammer et al. 1991*). It is anticipated that investigation of routes of administration for diacetylmorphine other than through injection will continue, and if successful routes are found, they may be introduced as one of the options for the pilots and trial. (The development of other routes is important, because injection, particularly intravenous injection, is the most hazardous to health.)

While injectable methadone may be preferred by some participants over oral methadone, only one of the interviewees in the Stage 2 research reported they would prefer it over injectable diacetylmorphine (Working Paper B in preparation) and it has not been found to be a popular choice in the Swiss trials. The real debate, as has been discussed earlier, is about the addition of the option of diacetylmorphine to maintenance treatment, hence the Stage 2 model has focussed on this.

There are two reasons for the restriction in numbers of places on a trial. One is that both the reality and perception that there are limited places will reduce the likelihood that dependent users from elsewhere in Australia will move to the ACT. The second is that it allows a more realistic budget to be developed.

5. Trial evaluation

There was extensive discussion in Stage 1 about the ethics of conducting a trial, compared with simply introducing a new policy option (Ostini & Bammer 1991*; Ostni et al. 1993*). The real uncertainties which exist argue for a trial and this proposal will substantially contribute to resolving those uncertainties.

The ultimate aim of the trial is to determine the effectiveness and cost-effectiveness of expanding standard oral methadone maintenance treatment to include the options of maintenance with injectable diacetylmorphine or the combination of injectable diacetylmorphine and oral methadone. Both individual and social effects will be assessed.

Preliminary questions which will be tackled in the pilot studies are:

- can a substantial proportion of participants be stabilised on injectable diacetylmorphine or the combination of injectable diacetylmorphine plus oral methadone?

and

- can injectable diacetylmorphine maintenance treatment be successfully integrated with oral methadone maintenance treatment to provide a flexible range of options?

There are three components to measuring effectiveness and cost-effectiveness:

- the ability of these new options to attract and retain people in treatment
- the ability of these new options to improve treatment outcomes, measured at both individual and social levels
- measurement or estimation of dollar costs associated with the positive and negative effects of introducing these new options.

Some components of the evaluation are straightforward and use well-established methodologies, others will require extensive developmental work. A distinction is also made between the minimum amount of evaluation which must be conducted and which must be budgeted for in the costs of the pilots and trial and highly desirable elements of evaluation which can be funded separately. A full discussion of the research protocol is presented in Working Paper F (in preparation).

Can a substantial proportion of participants be stabilised on injectable diacetylmorphine or the combination of diacetylmorphine plus oral methadone?

This preliminary question will be tested in pilots 1 and 2. Clearly if a substantial proportion of participants who prefer these options cannot be stabilised, there is no point in proceeding further. The key measures of stabilisation are use of illicit heroin; concurrent use of benzodiazepines and/or alcohol with the trial drugs; withdrawal symptoms; and the participants' requested doses. Participants would be deemed to be stabilised if:

- they are no longer using illicit heroin;

- they are not presenting at the clinic under the influence of benzodiazepines and/or alcohol;
- they are exhibiting and reporting no or only mild withdrawal signs and symptoms when they present at the clinic; and
- once the initial adjustment of doses has been made, there is no or only minimal increase in doses and, secondly, participants are not requesting doses which would make them drowsy when they leave the clinic. (As discussed above, participants can be given doses which induce drowsiness, provided the doses and timing of administration are such that the drowsiness will wear off before the participants leave the clinic.)

The minimum level of assessment budgeted for involves analysis of self-report measures and of staff and independent researcher assessments; urinalysis; minimal pharmacokinetic analysis and some psychopharmacological test battery analysis (Working Paper F in preparation). It would be desirable to have more extensive pharmacokinetic and psychopharmacological analysis to examine the relationship between blood levels of the drug and physiological and behavioural effects, including a full analysis of effects on driving.

Can injectable diacetylmorphine maintenance treatment be successfully integrated with oral methadone maintenance treatment to provide a flexible range of options?

It is fundamental to the proposal that maintenance treatment provides three options—injectable diacetylmorphine alone, injectable diacetylmorphine plus oral methadone, and oral methadone alone—and that participants have flexibility in moving between these options. For example, only oral methadone will be available to be taken away from the clinic (under current guidelines), so that if participants are unable to attend the clinic they must be able to move easily from the other options to oral methadone alone (and back again).

The flexibility of movement between options has both pharmacological and service provision components. Experience from the Swiss trials suggests that there is no problem calculating equivalent doses for diacetylmorphine and methadone, but there is as yet no evidence about the ease of movement between options.

From the point of view of service provision, integration would be achieved if participants and staff made appropriate use of the range of options; were satisfied with them; and if the availability of the range of options did not affect the ability to provide oral methadone maintenance treatment to those who want only that option.

The minimal level of assessment budgeted for includes analysis of prescribing records; surveys of trial participants and staff; and some pharmacokinetic and psychopharmacological analysis. Again it would be highly desirable to undertake more extensive pharmacokinetic and psychopharmacological analysis.

Does expanding maintenance treatment to include diacetylmorphine attract dependent heroin users into treatment and does it improve retention?

There are two target groups for the first part of this question—dependent heroin users who have dropped out of treatment and dependent heroin users who have never been in treatment. The second part of the question concerning retention is also relevant to participants from methadone treatment who prefer an expanded range of options. Answering these questions will require examining pre-trial data about movement into and out of treatment. This can be strongly influenced by, for example, changes in policy which can affect the number of places available, criteria for expulsion and so on. Providing a valid and reliable answer is therefore statistically complicated and will require developmental work.

The budget allows for the employment of a statistician to undertake this developmental work in pilot 2. A statistician will also need to be employed to analyse the data from the trial.

Does expanding maintenance treatment to include diacetylmorphine improve treatment outcomes, measured at both individual and social levels

The value of attracting and retaining people in treatment hinges on the success of the treatment, therefore this question is central to the evaluation.

a) Outcomes for trial participants

A randomised controlled trial is the most effective method of assessment at the individual level. Participants who volunteer for and are eligible for a place on the trial will be randomly allocated to either the 'choice' group, which provides the expanded treatment option, or to the 'control' group, which provides only oral methadone. The outcomes to be assessed are health, including HIV/AIDS and hepatitis risk behaviours and licit drug use; criminal behaviour, including illicit drug use; and social functioning. There are standard instruments for measuring these outcomes, such as the Opiate Treatment Index, but instruments which ask a broader range of questions will also be developed (Working Paper F in preparation).

However randomised controlled trials do not work if participants in the control group feel particularly disadvantaged. In recent years there has been growing resistance by participants and, often, service providers to randomised controlled trials.

While there is a strong case for running a randomised controlled trial to assess the effects of addition of diacetylmorphine to maintenance treatment, it may be difficult to convince participants, in particular, that this is the case. Pilot 2 will assess whether or not a randomised controlled trial is likely to succeed. One possible way to encourage those allocated to the 'control' group to participate is to guarantee them a place in the 'choice' group for the second year of the trial. Other incentives may also be needed for people in this group and it can be argued that this is a matter of justice, as it is unfair to ask people to participate unless there is some benefit to them (Ostini and Bammer 1991*; Ostini et al. 1993*). With current uncertainty about future changes to the methadone program, it is not possible at this stage to determine what appropriate incentives may be. Care must also be

taken that people who want only oral methadone are not significantly disadvantaged.

If a standard randomised controlled trial is not workable, Jarrett and Solomon (1994*) have proposed a modification which could be investigated further.

Attewell and Wilson (1994*) have investigated statistical issues involved with conducting a standard randomised controlled trial, particularly power and sample size considerations. They constructed a table with a comprehensive range of values for determining whether the study population likely to be available would be adequate for the levels of effect of interest. If the sample size were to be 100 in each of the 'choice' and 'control' groups, then 80 per cent of the time one would detect improvements as small as about eight per cent for outcome measures having frequencies around ten per cent (or 90%) in the 'control' group and this increases (decreases) to about 18 per cent for outcome measures having frequencies around 50 per cent in the 'control' group. The sample sizes proposed will be adequate to measure the effects of interest, provided the drop-out rate is not too large. Pilot 2 is therefore crucial to determining whether a randomised controlled trial is workable.

There are both scientific and political advantages to conducting the randomised controlled trial in more than one city. Scientifically, the results will be more able to be generalised. The illicit drug 'scene' varies from city to city, as does the provision of maintenance treatment and a multi-centre trial would encompass these variations. However, the delivery of the trial service and evaluation of results must be strictly comparable between cities.

The investigation would only move to a randomised controlled trial if the pilots indicated that at least some beneficial outcomes were likely. Both pilot studies would use participants as their own controls and would measure effects before and after expanded maintenance treatment became available. The piloting of the randomised controlled trial in pilot 2, could also allow an indication to be gained of whether beneficial outcomes are likely in the main trial.

Information about outcomes should be obtained both from interviews with participants and from independent sources, including police records; medical examinations; random urine tests; and interviews with relatives.

b) Outcomes for society

Whereas outcome measures for effects on individuals are reasonably well developed, outcome measures for social effects are not. These will monitor both the potential benefits of a trial and the potential risks.

Pilot 1 will investigate the development of a package of indicators to monitor a number of social effects. Those of interest include effects on: crime levels and patterns and public perceptions of crime; illicit drug markets, including leakage of trial drugs onto the illicit market; drug use patterns, especially among young people; heroin users moving to the ACT; offensive public behaviour

by illicit drug users, including the discarding of injecting equipment in public places; effects on public health and safety, including numbers of overdoses and drug-related motor vehicle crashes; and effects on other treatment services, law enforcement and the ambulance service.

The Stage 2 feasibility research pointed to a number of potentially useful ways of developing indicators, including the reintroduction of a modified version of the ACT Drug Indicators Project (Bammer et al. 1994a*; Bammer & Sengoz 1994); improving the availability and quality of drug-related crime data (Working Paper F in preparation); regular monitoring of ambulance service data; and monitoring the illicit drug market through periodic interviews with illicit drug users (Bammer & Sengoz 1994*).

Measurement or estimation of dollar costs associated with the positive and negative effects of introducing these new options.

There should be evaluation of cost-effectiveness as well as effectiveness. This is relatively new in the drug treatment field and relies on good measures of effectiveness as well as reliable indicators of costs for people not in treatment or before they entered treatment. A health economist should be employed for this evaluation.

Informed consent and other ethical issues

The exploration of the criminal and civil liability issues associated with a trial, as well as the ethical issues, have highlighted the importance of informed consent (Bronitt 1995*; Cica 1994*; Ostini & Bammer 1991*; Ostini et al. 1993*).

It is also crucial that researchers evaluating the outcomes of the trial do not have restrictions placed on their ability to freely publish the results of their investigations. In addition, any empirical data collected should be made publicly available after a reasonable period, with appropriate protection to prevent identification of individual participants (Ostini & Bammer 1991*; Ostini et al. 1993*).

Part 4: Budget for the pilot studies and budget justification

Preparatory phase and pilot 1

Clinic staff

Position	Cost per annum	Preparatory phase & pilot 1 cost
Senior specialist (one position)	155,298	110,500
Service manager (one position)	70,079	79,512
Nursing staff (six positions)		
one level 2-full-time	53,438	35,968
one level 1-full-time	47,598	32,037
two level 1-70%	67,036	45,120
two level 1-50%	47,598	32,037
Administrative staff		
one SOGC-full-time	61,714	70,021
one ASO2-50%	16,854	11,993
Cleaning staff (casual)		7,392
Security staff (@ \$500 per week)		16,500
Total clinic staff costs		441,080

Other service provision costs

Item	Cost for pilot 1
Site modifications and furnishing	125,000
Clinic running costs	50,000
Total other service provision costs	175,000
Total service provision costs	616,080

Research staff

Position	Cost per annum	Preparatory phase & pilot 1 cost	
Research director (one position)	88,279	62,814	
Criminologist (one position)	78,914	50,080	
Senior research officer (one position)	67,303	42,711	
Total research staff costs			155,605

Other research costs

Item	Cost for pilot 1	
Research overheads, pharmacokinetic analyses, computing support	50,000	
Total other research costs		50,000
Total research costs		205,605

**TOTAL PREPARATORY PHASE AND
PILOT 1 COST**

\$821,685

Pilot 2**Clinic staff**

Position	Cost per annum	Pilot 2 cost
Senior specialist	155,298	134,393
Community Medical Officer level 2-(0.75 positions)	56,299	50,886
Service manager (one position)	70,079	60,645
Nursing staff (twelve positions)		
two level 2-full-time	106,876	9,489
three level-1 full-time	142,793	123,571
one level 1-70%	33,518	29,006
one level 1-60%	28,659	24,801
three level 1-50%	71,396	61,785
one level 1-40%	18,939	16,390
one level 1-20%	9,720	8,412
Counselling staff (six positions)		
one ASO6-full-time	58,399	52,783
one ASO5-full-time	49,648	44,874
one ASO5-80%	40,018	36,170
one ASO5-50%	24,824	22,437
one ASO4-50%	22,949	20,742
one ASO4-40%	18,760	16,956
Administrative staff		
one SOGC-full-time	61,714	53,406
one ASO2-full-time	33,709	29,171
Cleaning staff (casual)		20,160
Security staff @ \$1,000 per week		45,000
Total clinic staff costs		861,077
Other service provision costs		
Item	Cost for pilot 2	
Clinical running costs	175,000	
Children's program costs	104,806	
Total other service provision costs	279,806	
Total service provision costs	1,140,883	

Research staff

Position	Cost per annum	Cost of pilot 2
Research director (one position)	88,279	76,397
Criminologist (one position)	78,914	68,291
Senior research officer (one position)	67,303	58,243
Statistician (one position for six months)		37,253
Research assistant (one position)	45,631	39,489
Total research staff costs		279,673

Other research costs

Item	Cost for pilot 2
Research overheads, pharmacokinetic analyses, computing support	85,000
Total other research costs	85,000
Total research costs	364,673

TOTAL PILOT 2 COST

\$1,505,556

Justification of the budget

Only budgets for the pilot studies have been prepared at this stage. It will be possible to prepare a realistic budget for the trial once results from the pilot studies are to hand.

There are a number of considerations which affect several budgetary items, including the clinical structure and its relationship to the research, the duration of the pilots, the total number of clients on the methadone program and the expanded maintenance options experiment, clinic hours, and pilot termination.

There has been no adjustment in the budget for salary rises, but all salaries are calculated at the top of the range to allow some flexibility in hiring, coverage for leave and some salary increases.

The clinical structure and its relationship to the research

For the purposes of these budgetary calculations, the maintenance program which includes diacetylmorphine is considered to be separate from the methadone maintenance program and to be separately staffed. It is intended however, that there will be considerable cross-over between the two groups of staff, although current methadone program staff who do not wish to work on the diacetylmorphine maintenance prescribing program will not be required to do so. Policy and administration for the pilots will be integrated into the existing Alcohol and Drug Service of ACT Health. The maintenance clinic which includes diacetylmorphine prescription will be located at a physically separate site from the existing methadone clinics.

Pilot 2 participants allocated to the 'control' group will attend the methadone program. There should be continuation of referral of participants to non-government and other services as appropriate.

The evaluation team must be independent of the service provision and will therefore have no role in the day-to-day running of the service. The evaluation team will be responsible for recruiting pilot participants, for randomly allocating them to the 'choice' and 'control' groups (where appropriate) and for measuring the outcomes of the pilots (and trial). Although the evaluation team is separate, evaluation is an essential component of the pilots and must be included in the budgets for the pilots.

Duration of the pilots

Preparatory phase	6 months (minimum)
Pilot 1	7.75 months
Pilot 2	10.25 months

Preparatory phase (Pre-Pilot 1)

After a decision is made to proceed with the pilot studies and resources are committed, there must be legislative change and the Commonwealth must grant licences and give permissions (see Part 3, The legal aspects of a trial). A new clinic must be established and it will take time to find and refurbish a suitable site. Staff must

be hired and trained and agreed policy and procedures developed. It is estimated that this preparatory phase will take six months or more.

Pilot 1

Clinical timetable

Pilot 1 will begin gradually with ten new participants commencing on the pilot each week.

Weeks 1-4	10 new participants start each week
Weeks 5-26	40 participants in pilot 1
Weeks 27-30	10 participants have completed six months in pilot 1 each week (all participants will be maintained in the pilot until a determination of success is made in Week 33)
Week 33	end of pilot 1

Research timetable

Pre-pilot (four weeks)	Recruit participants, collect pre-pilot data
Weeks 1-30	Analyse dosing records, clinical records and test battery records on weekly basis
Weeks 1-30	Examination of possible measures of social impact
Weeks 14-17	Three month interviews with participants and staff (10 participants per week)
Weeks 27-30	Six month interviews with participants and staff (10 participants per week)
Weeks 31-32	Collation of analyses and preparation of final report
Week 33	Decision on whether or not to proceed to pilot 2.

Duration of pilot 1 is 33 weeks (7.75 months).

Pilot 2

Clinical timetable

If the decision is that pilot 1 was a success and therefore that pilot 2 should proceed, transfer of participants from pilots 1 to 2 and commencement of new participants would begin in Week 34. Twenty participants would begin on pilot 2 each week.

To minimise the gap between the pilots, staff and participants for pilot 2 will be recruited in advance of the decision about whether or not pilot 1 is success, but with clear understanding that their recruitment is provisional until that decision is made.

Weeks 34-37	10 participants transfer from pilot 1 and 10 new participants start each week
Weeks 38-46	20 new participants start each week (only 10 in the last week)
Weeks 47-59	250 participants in pilot 2; 125 in each of the 'choice' and 'control' groups
Weeks 60-72	20 participants have completed six months in pilot 2 each week (all participants will be

maintained in the pilot until a determination of success is made in Week 78)
 Week 78 end of pilot 2

Research timetable

Weeks 34-46	Interviews with new participants to collect pre-pilot data
Weeks 34-72	Analyse dosing records, clinical records and test battery records on weekly basis
Weeks 34-72	Analysis of attraction and retention data
Weeks 34-72	Collection and analysis of social impact data
Weeks 47-59	Three month interviews with participants and staff (20 participants per week)
Weeks 60-72	Six month interviews with participants and staff (20 participants per week)
Week 73-77	Collation of analyses and preparation of final report
Week 78	Decision on whether or not to proceed to trial.

Duration of pilot 2 is 45 weeks (10.25 months)

Duration of pilots 1 and 2 is 78 weeks (1.5 years)

Total number of clients on the methadone program and the expanded maintenance program which includes diacetylmorphine prescribing

These budgetary calculations assume that there will be no major changes to the existing ACT methadone program. It is, however, likely that there will be an increase in private methadone prescribers and in pharmacy distribution of methadone, although the speed of introduction of these changes and their magnitude cannot be estimated at this stage. A consequent 'freeing up' of current methadone program staff could be used to cut pilot staffing costs, but this is not factored in here. As outlined above, for these budgetary calculations, the expanded maintenance program which provides diacetylmorphine is considered to be separate from the methadone maintenance program and to be separately staffed.

Assuming the methadone program has reached a 'steady-state' at 350 participants, the likely number of participants in each of the methadone and expanded maintenance programs are as follows:

In pilot 1, 20 participants will be recruited from the methadone program and 20 from outside the program, leaving 330 people on the methadone program.

In pilot 2, an additional 130 people will be recruited from the methadone program, the 20 recruited from the methadone program for pilot 1 will be transferred to pilot 2, leaving 200 people on the methadone program. These 150 participants plus the 100 participants recruited from outside the methadone program (20 in pilot 1 and 80 in pilot 2) will be randomly assigned to 'choice' and 'control' groups on a 1:1 basis. Thus the 125 people allocated to the 'control' group will be returned to the methadone program, so that there will be 325 people on the methadone program.

The number of participants in the expanded maintenance program which includes diacetylmorphine will be 40 in pilot 1 and 125 in pilot 2.

No adjustment has been made to allow for people leaving (either voluntarily or being expelled from) the expanded maintenance program which includes diacetylmorphine. Experience with the Swiss trials has shown a high retention rate⁷ (Swiss Federal Office of Public Health, 1995).

Clinic hours

To accommodate those participants who choose to inject diacetylmorphine three times per day (the maximum permitted), there will need to be three dispensing times. For pilot 1 the dispensing times will be 0700 to 0800, 1300 to 1400, 1900-2000. For pilot 2 the dispensing times will be 0700 to 0900, 1230 to 1430, 1800-2000.

These dispensing times are based on those used in the Swiss trials, where they have been found to work well. Some participants

⁷ It is difficult to calculate a precise retention rate because the trials in different Swiss cities began at different times. In January 1995, when some trials had been running for 12 months and others for six or so, the overall retention rate was 81 per cent.

who request diacetylmorphine only may experience withdrawal symptoms overnight and they will be offered a low dose of methadone to alleviate these symptoms.

For pilot 1, in addition to the dispensing times, the clinic will be staffed for three hours per day, seven days per week. These additional three hours per day will be used for client case work; administration; setting up and cleaning up; hand-over between shifts; and regular staff meetings.

With the additional participant numbers in pilot 2, the clinic will be staffed from 0630 to 2030.

For both pilots 1 and 2 there will be two rostered shifts. During pilot 1, excess hours have been budgeted for to give staff, in conjunction with participants, the necessary flexibility to develop the best possible clinic operation for Australian conditions. The excess hours can also be used to assist in the development of a case work system in the methadone program.

Further details on the day-to-day operation of the clinic are presented in Working Paper E (in preparation).

Pilot termination

If a decision to terminate is made during the operation of the pilots, this is unlikely to result in financial problems because money will already have been committed for the expected original duration of the pilot.

If the decision at the end of pilot 1 or pilot 2 is that the pilot was not a success and therefore that there should not be a progression to a further stage, this will have financial implications. Staff contracts should be written with this in mind.

Additional funding should be made available for one month at the end of pilot 1 and for two months at the end of pilot 2 to allow participants to be transferred to other treatment programs and staff to find new employment.

This could cost around \$50,000 for pilot 1 and \$200,000 for pilot 2.

Clinic staff costs

Senior specialist

Because the pilots are innovative, high profile and highly political, the head of the clinical service should be a senior specialist with an established reputation in the illicit drug treatment field. This person will have a half clinical load and, in addition will be responsible for the clinical service budget; the smooth running of the clinical service; liaison with the researchers; and dealing with visitors to the program and the media.

The senior specialist will be the only medical practitioner employed in pilot 1. The period of employment should begin one month before the commencement of the pilot. Hence the period of employment will be 37 weeks in pilot 1 and 45 weeks in pilot 2.

The annual salary for a senior specialist is \$95,470.

Allowances are \$2,737 for administrator in charge; 16 per cent (\$15,275) in lieu of private practice; \$16,612 special allowance (in lieu of on-call payments); and \$1,336 office allowance.

On costs, calculated at 25 per cent of the annual salary, are \$23, 868.

Other medically qualified staff-Community Medical Officers

Additional medically qualified staff will be needed in pilot 2. A ratio of one doctor to 100 participants has been allowed. Given that the senior specialist has a half clinical load (50 participants), a 0.75 position will be needed for pilot 2.

The role of the medically qualified staff will include participant assessment, establishment of a stabilising dose, dose adjustments (if necessary), and advising on and monitoring transitions between the various available pharmaceutical options (diacetylmorphine alone, diacetylmorphine plus methadone and methadone alone). Staff should have training in the alcohol and other drug field and experience in, at least, methadone maintenance treatment of illicit drug users.

These staff have been budgeted at Community Medical Officer (CMO) level 2 at an annual salary of \$60,052. Allowance has been made for the doctor(s) in this position to begin work two weeks before pilot 2. On-costs are calculated at 25 per cent.

Service manager

The service manager will have responsibility for the preparatory phase (pre-pilot 1) and will, under direction of the senior specialist, be responsible for the smooth running of the clinical service for the pilots.

In the preparatory phase, the duties of the service manager will include finding a suitable location for the new clinic; organising refurbishment; hiring and training non-medical staff; and establishing policy and procedures for the service delivery (in consultation with the senior specialist). During the pilots the service manager will be responsible for liaising with the researchers in the recruitment of participants; the process of obtaining informed consent from the participants for the clinical aspects of the pilots; implementing and ensuring the smooth functioning of a case management system; and liaising with adjunct services and other treatment services.

The service manager should have training in the alcohol and other drug field, experience in providing services to illicit drug users and management and training skills. The service manager should also have appropriate skills to have a half load in the service provision (this would cover annual leave for the other staff).

This position has been budgeted at Senior Officer Grade B level with an annual salary of \$56,063, with on-costs at 25 per cent. This person will be employed for the six months preceding pilot 1, as well as for pilot 2.

Nursing staff

Nursing staff will have responsibility for dispensing the prescribed drugs and will, along with counselling staff, be part of the casework system. Each nurse will be the caseworker for a specific group of participants and will be responsible for initial assessment and review; general support; continuity of care; the participant's file; and liaison with medical and other staff.

Nurses will work in two shifts (0630 to 1430 and 1230 to 2030) and, as well as dispensing and case work duties, will have administrative duties and be responsible for setting up and cleaning up at each dispensing session.

Six nurses should be employed to work on pilot 1; two full-time, two at 70 per cent of full-time and two at 50 per cent of full-time (see Working Paper E in preparation for examples of rosters). One (full-time) nurse should be employed at level 2, the others at level 1. The salary for level 2 is \$38,750 and for level 1 34,878; on-costs are calculated at 25 per cent. Penalty rates are calculated at \$5,000 per annum for the level 2 nurse; \$4,000 per annum for the full-time level 1 nurse; \$3,000 for the 70 per cent nurses and \$2,000 for the half-time nurses. The nurses should be employed two weeks before the commencement of pilot 1.

No counselling staff will be employed in pilot 1. The casework load per full-time equivalent staff member will be 9.

Twelve nurses should be employed to work on pilot 2; five full-time, one at 70 per cent; one at 60 per cent; three at 50 per cent;

one at 40 per cent and one at 20 per cent. On-costs and penalty rates are calculated in the same way. Some new nurses will be employed before the commencement of pilot 2, others will be phased in as the number of participants increases (for the budget all calculations are from the beginning of pilot 2). Four nurses must be available for dispensing at peak demand times. An example of a roster for pilot 2 is presented in Working Paper E (in preparation).

There will be a total of 4.2 counselling positions (see below), bringing the casework load per full-time equivalent staff member to 10.

Counsellors

As well as providing counselling, social support and being case workers, the counsellors (Administrative Service Officers) could play an important role by being responsible for the smooth running of the waiting room. They could undertake a preliminary check of participants to ensure that they are not intoxicated with other drugs and therefore unsuitable to be dosed. Final responsibility for assessing participants for fitness to be dosed rests with the dispensing staff, but the counsellors could ease the workload of the dispensing staff by dealing with obviously intoxicated participants. The counsellors could also be responsible for assessing the participants' fitness to leave. However agreement would need to be reached with the relevant unions for counselling staff to work in the extended clinic hours and to undertake these new duties.

Six counsellors should be employed to work on pilot 2; two full-time, one at 80 per cent; two at 50 per cent; and one at 40 per cent. The annual salaries for different levels are as follows: ASO6 \$42,719; ASO5 \$36,518; ASO4 \$33,519. On-costs and penalty rates are calculated as for nurses. The counsellors should be employed two weeks before the commencement of pilot 2. The casework load per full-time equivalent staff member will be 10 (see discussion for nurses above).

Administrative staff

A half-time administrative position will be needed at the clinic in pilot 1 and a full-time position in pilot 2. The person in this position should be employed one month before the commencement of pilot 1. This position has been budgetted at ASO2 with an annual salary of \$26,967.

The Swiss experience is that the introduction of diacetylmorphine prescribing also significantly increases the workload of 'central office' staff because of outside interest and enquiries. An additional full-time position has been budgetted for from the beginning of the preparatory phase. This salary has been budgetted as Senior Officer Grade C at an annual salary of \$48,531, with a \$1,050 senior officer allowance.

On costs are calculated at 25 per cent.

Cleaning staff

\$16 per hour has been allowed for two hours per day for pilot 1 and four hours per day for pilot 2.

The Swiss have successfully employed trial participants to undertake cleaning. This could be tried under the supervision of the service manager.

Security staff

A uniformed security officer will be on the premises during the clinic opening times. The cost provided by a security firm for three sessions of two hours duration per day, seven days per week is around \$1,000 per week.

Other service provision costs

Site modifications and furnishing

This includes internal alterations; on-off security costs; and furniture and equipment. Some modifications and furniture and equipment purchases may be delayed until pilot 2. A more detailed proposal is presented in Working Paper E (in preparation).

Clinic running costs

This includes the cost of the diacetylmorphine and methadone, injecting equipment, urinalysis, on-going security costs and overheads.

The children's program

The ACT Intravenous Drug Users League should be invited to expand its playgroup to accommodate a children's program which pilot participants will be able to use. This program relies on a combination of paid workers, parent participation and input from community nurses.

The children's program should be open from 0700 to 2030, seven days per week. There will always be one paid staff member on duty. The salary has been calculated at the equivalent of three full-time staff employed at AS05 level (\$36,518 per annum).

\$1,000 per month has been allowed to cover other costs, including insurance, furnishings, food, activities and toys.

This item has been budgetted for pilot 2.

Research staff costs***Research Director***

The research director will be responsible for the overall conduct of the evaluation and for the collation of the analyses and preparation of the final reports at the end of pilots 1 and 2.

The research director will collect and analyse data on stabilisation, integration of treatments and individual outcomes. Because of the larger number of participants, research assistance will be needed for pilot 2.

The research director will be appointed at the Level D Senior Fellow with an annual salary of \$70,623. On-costs are calculated at 25 per cent. The research director will need to be appointed one month before pilot 2, to recruit and collect data on participants.

Criminologist

The criminologist will work with the senior research officer to develop a package of indicators to measure the social impact of adding injectable diacetylmorphine to maintenance treatment in pilot 1 and to collect and analyse data in order to monitor social impact in pilot 2.

The criminologist will be appointed at Academic Level 3 with an annual salary of \$57,184. On-costs are calculated at 38 per cent.

Senior research officer

The senior research officer will work with the criminologist to develop a package of indicators to measure the social impact of adding injectable diacetylmorphine to maintenance treatment in pilot 1 and to collect and analyse data in order to monitor social impact in pilot 2.

The senior research officer will be appointed at Academic Level 2 with an annual salary of \$48,770. On-costs are calculated at 38 per cent.

Statistician

A statistician will be employed for six months full-time in pilot 2 to develop methods to analyse data on attraction and retention rates.

The statistician will be employed at Level C Fellow at an annual salary of \$59,605, with on-costs calculated at 25 per cent.

Research assistants

The research director will require research assistance during pilot 2 to collect and analyse data on stabilisation, integration of treatments and individual outcomes.

One full-time research assistant will be employed at ANU Officer 6 levels with an annual salary of \$36,505. On-costs are calculated at 25 per cent.

Other research costs

An allowance was made for overheads, computing support and limited pharmacokinetic analysis.

Grant support

1991	\$445,000 over 5 years	The Australian National University's Strategic Development Fund <i>A Randomised Controlled Trial of New Treatment Options for Heroin Dependent People</i> (to G. Bammer and R.M. Douglas)
1991	\$5,040	Criminology Research Council <i>An Estimation of the Number of Heroin Users in the ACT</i> (to G. Bammer)
1992	\$8,028	Youth Organisations Research and Development Grant for collaboration with the Youth Affairs Network ACT on <i>Alcohol and Other Drug Use among Homeless Youth in the ACT</i> (to G. Bammer)
1993	\$16,548	Australian Institute of Aboriginal and Torres Strait Islander Studies Grant for collaboration with Winnunga Nimmityjah (Aboriginal Health Clinic) on <i>HIV Risk for Aboriginal Heroin Users in the ACT</i> (to G. Bammer, O. Brown, D. McDonald and B. Sibthorpe)
1993	\$56,146	Research Into Drug Abuse Grant for <i>Illicit Drug Users' Unmet Treatment Needs—What Can We learn from Treatment Drop-outs?</i> (to G. Bammer, B. Sibthorpe and D. McDonald)
1994	\$29,343	National Drug Crime Prevention Fund Grant for <i>Narcotic Treatment and Road Safety</i> (to G. Starmer, A.F. Moynham, J. Perl and G. Bammer)

The Advisory Committee

Co-chairmen

Professor Bob Douglas	NCEPH
Professor Duncan Chappell	AIC, to April 1994
Dr Grant Wardlaw	AIC, April-November 1994
Dr Adam Graycar	AIC, from November 1994

Members

Dr Tony Adams	Commonwealth Department of Human Services and Health
Dr Robert Ali	Drug and Alcohol Services Council, SA
Mr Michael Brown	Commonwealth Attorney-General's Department (August 1993 to April 1994; observer)
Dr Andy Butlin	Alcohol and Drug Service, ACT Health (to November 1992)
Chief Magistrate Ron Cahill	Magistrates' Court, ACT
Ms Amanda Corkery	Dependency Care Foundation Inc., ACT (from April 1994)
Professor Terry Carney	Faculty of Law, University of Sydney, NSW
Assistant Commissioner Peter Dawson	Australian Federal Police, ACT Region
Professor Wayne Hall	National Drug and Alcohol Research Centre, NSW
Associate Professor Margaret Hamilton	Turning Point, Alcohol and Drug Centre Inc., Victoria
Superintendent Frank Hansen	Drug Enforcement Agency, NSW
Professor David Hawks	National Centre for Research into the Prevention of Drug Abuse, WA
Dr Michael MacAvoy	Directorate of the Drug Offensive, NSW Department of Health and Chair, National Drug Strategy Committee (October 1992 to April 1994)
Deputy Commissioner Richard McCreadie	Tasmanian Police and Chair, National Drug Strategy Committee (from June 1994)
Mr Kerry McDermott	Commonwealth Law Enforcement Board (to August 1993 and from February 1995; observer)
Ms Tarquin McPartlan	ACT Intravenous Drug Users League (from April 1994)
Mr Michael Moore (MLA)	Legislative Assembly for the ACT
Mr Keith Simpson	ACT Attorney General's Department (from June 1992)
Mr Maarten van der Kleij	Alcohol and Drug Service, ACT Health (from August 1993)
Ms Marion Watson	Assisting Drug Dependents Inc., ACT
Dr Don Weatherburn	NSW Bureau of Crime Statistics and Research, NSW Attorney General's

Dr Alex Wodak

Department
Alcohol and Drug Service, St
Vincent's Hospital, NSW

The Advisory Committee met on 17 February, 1992; 17 June, 1992; 26
October 1992;
12 August 1993; 6 April 1994; and 20 February 1995.

The Stage 2 Research Team

Dr Gabriele Bammer	Fellow, NCEPH; Feasibility Research Director
Mr Iain Anderson	Research Assistant, NCEPH (studies with dependent heroin users in and out of treatment)
Ms Robyn Attewell	Consultant, NCEPH (statistical issues for a randomised controlled trial)
Ms Francesca Baas Becking	Research Assistant, NCEPH (Aboriginal Community AIDS Project)
Mr Simon Bronitt	Lecturer, Faculty of Law, ANU (criminal liability)
Dr Jim Butler	Senior Fellow, NCEPH (economics of drug markets)
Dr Andy Butlin	Visiting Fellow, NCEPH (ACT and national surveys of community attitudes)
Ms Jennifer Chadwick-Masters	Research Assistant, NCEPH (migration of illicit drug users to the ACT)
Ms Natasha Cica	Consultant, AIC (civil liability)
Ms Kate Elliot	ANU Officer 9, NCEPH (preparation of grant applications)
Ms Deborah Felton	Research Assistant, NCEPH (design of the service provision component of the pilots and trial)
Ms Amanda Goodban	ANU Officer 3, NCEPH (general assistance)
Ms Miriam Hazel	Research Assistant, NCEPH (general assistance)
Ms Glenda Humes	Research Assistant, NCEPH (Aboriginal Community AIDS Project)
Ms Nova Inkpen	Research Officer, AIC (Outcome measures for a trial)
Professor Richard Jarrett	University of Adelaide (trial design—statistical issues)
Dr Jonathan Kelley	Research School of Social Sciences, ANU (ACT and national surveys of community attitudes)
Dr Ann Larson	Lecturer, University of Queensland (estimating numbers of heroin users)
Ms Corinna Lee	Research Assistant, NCEPH (studies with dependent heroin users in and out of treatment)
Dr David Legge	Fellow, NCEPH (philosophy of

	service provision)
Mr David Mascord	Research Assistant, University of Sydney (heroin and driving)
Mr David McDonald	Senior Criminologist, AIC (various projects)
Mr Timothy McGregor	Research Assistant, NCEPH (contribution of childhood sexual abuse to alcohol, heroin, and other drug problems workshop)
Ms Michele Moloney	Research Assistant, NCEPH (Aboriginal Community AIDS Project)
Mr Greg Morris	Research Assistant, NCEPH (analysis of studies with dependent heroin users in and out of treatment)
Dr Tony Moynham	Clinical Forensic Medicine Unit, New South Wales Police Service (heroin and driving)
Ms Amanda Neil	Research Assistant, NCEPH (economics of drug markets)
Ms Jennifer Norberry	Criminologist, AIC (legal issues)
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Ms Helen-May Timiney	Research Assistant, NCEPH (preparation of grant applications)
Ms Deborah Tunnicliff	Research Assistant, NCEPH (various projects)
Ms Sue Weekes	Research Assistant, NCEPH (ex-users study)
Professor Sue Wilson	Centre for Mathematics and Its Applications, ANU (statistical

issues for a randomised
controlled trial)

Collaborations

Winnunga Nimmityjah (Aboriginal Health Clinic) Aboriginal Community AIDS Project.

Youth Affairs Network of the ACT (YANACT) in a study of alcohol and other drug use among young people who are homeless or at risk of being homeless.

Reference Group

Ms Jude Byrne

Ms Phyll Dance

Mr Glenn James

Mr Timothy McGregor

Ms Tarquin McPartlan

Mr Anthony Roben

Ms Margaret Shanahan

Ms Marion Watson

Workshop participants

The participants in the workshops on Australian drug markets research: the contribution of childhood sexual abuse to alcohol, heroin, and other drug problems; and the design and evaluation of a trial are listed in Working Papers 2, 5, and 8, respectively.

Workshop on Policing Issues, May 30, 1994

Detective Sergeant Don Bailey, ACT Police
Dr Gabriele Bammer, NCEPH
Inspector Tim Fenlon, Queensland Police
Detective Sergeant Tim Fisher, ACT Police
Detective-Superintendent Ted Foster (Co-organiser), ACT Drug Squad
Sergeant Bob Gresham, Australian Federal Police Association
Superintendent Frank Hansen (Chair and co-organiser), Drug Enforcement Agency, NSW
Intelligence Officer Paddy Mahony, Australian Bureau of Criminal Intelligence
Deputy Commissioner Richard McCreadie, Tasmanian Police
Superintendent Dennis McDermott, ACT Police
Superintendent Peter McDonald, ACT Police
Commander Rick Ninness, ACT Police
Inspector Steven Vaughn, Victorian Police
Sergeant Rob Wheeler, ACT Legal Services Branch
Dr Grant Wardlaw, AIC

Apologies: SA Police

Workshop on Cost Considerations for Service Provision for a 'heroin trial', February 23, 1995

Ms Lia Battinson
Ms Jude Byrne
Ms Phyll Dance
Ms Deborah Felton
Dr Jo Mazengarb
Mr Timothy McGregor
Ms Tarquin McPartlan
Ms Julie Perrin
Ms Margaret Shanahan
Ms Marion Watson
Ms Cheryl Wilson

Workshop on Medical Issues Involved in Prescribing Heroin to Dependent Users, February 28, 1995

Dr Robert Ali, Drug and Alcohol Services Council, SA
Dr Gabriele Bammer, NCEPH
Professor Peter Baume, School of Community Medicine, University of New South Wales
Dr James Bell, Drug and Alcohol Services, Prince of Wales Hospital, NSW
Dr Jack Best, Australasian Faculty of Public Health Medicine
Dr Nick Cummings, Alcohol and Drug Service, Launceston
Dr Margaret Deane, Department of Human Services and Health
Professor Bob Douglas, NCEPH
Dr Janelle Hamilton, ACT Division of General Practice
Dr Nick Lintzeris, Turning Point Alcohol and Drug Centre, Victoria
Dr Jo Mazengarb, Alcohol and Drug Service, ACT Health
Dr Sue Morey, Morey Australia Pty Ltd
Dr Rene Pols, Royal Australian and New Zealand College of Psychiatrists
Dr Keith Powell, ex-Physician, Alcohol and Drug Service, ACT Health
Dr Adrian Reynolds, Community Drug and Alcohol Service, Brisbane North
Dr Stephen Rosenman, Drugs Advisory Committee, ACT Health
Dr Michael Tedeschi, Royal Australian College of General Practitioners
Professor Ian Webster, Drug and Alcohol Services, Liverpool, NSW
Dr Alex Wodak, Alcohol and Drug Service, St Vincent's Hospital, NSW

Apologies: Dr Bob Allan, AMA, ACT Branch

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Part 4: Budget for the pilot studies and budget justification

List of feasibility study publications

Peer-reviewed papers

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- Ostini, R.; Bammer, G.; Dance, P.; Goodin, R. 1993 'The ethics of experimental heroin maintenance'. *Journal of Medical Ethics*, 19, 175-182.
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- Bammer, G. 1993a 'Should the controlled provision of heroin be a treatment option? Australian feasibility considerations'. *Addiction*, 88, 467-475.
- Larson, A.; Stevens, A.; Wardlaw, G. 1994 'Indirect estimates of 'hidden' populations: capture-recapture methods to estimate the numbers of heroin users in the Australian Capital Territory'. *Social Science and Medicine*, 6, 823-831.
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Reprinted in Legislative Assembly for the Australian Capital Territory, Select Committee on HIV, Illegal Drugs and Prostitution, Second Interim Report, 'A Feasibility Study on the Controlled Availability of Opioids'.
- Volume 2 of Feasibility Research into the Controlled Availability of Opioids*. National Centre for Epidemiology and Population Health, Australian National University, Canberra, 1991.
- Chapters are:
- Stevens, A.; Dance, P.; Bammer, G. 'Illegal drug use in Canberra', 1-18.
- Rainforth, J. 'Literature review: arguments for and against changing the availability of opioids', 19-52.
- Hartland, N. 'The political context', 53-82.
- Martin, B. 'Interest groups and social controversies', 83-86.
- Norberry, J. 'Legal issues', 87-115.
- Bammer, G.; Rainforth, J.; Sibthorpe, B. 'Possible options for a trial', 117-176.
- Ostini, R.; Bammer, G. 'Ethical issues', 177-186.
- Crawford, D.; Bammer, G. 'Attitudes to a trial', 187-278.

- Bammer, G.; Douglas, R.M.; Dance, P. 'Evaluation by a randomised controlled trial', 279-286.
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the Controlled Availability of Opioids Stage 2 Working Papers Number 8.

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Jarrett, RG.; Solomon, PJ. 'An evaluation of possible designs for a heroin trial (draft)', 11-30.

McDonald, D.; Bammer, G.; Legge, DG.; Sibthorpe, BM. 'Service provision considerations for the evaluation of a 'heroin trial'. A discussion paper', 31-34.

Bammer, G.; Tunnicliff, D.; Chadwick-Masters, J. 1994a How could an influx of users be prevented if Canberra introduces a trial of controlled availability of heroin? *Feasibility Research into the Controlled Availability of Opioids Stage 2 Working Papers Number 9.*

Bammer, G.; Sengoz, A. (with assistance from Stowe, A.; Anderson, I.; Lee, C.; Tunnicliff, D.; Ostini, R.) 1994 How would the controlled availability of heroin affect the illicit market in the Australian Capital Territory? An examination of the structure of the illicit heroin market and methods to measure changes in price, purity and availability, including heroin-related overdoses. *Feasibility Research into the Controlled Availability of Opioids Stage 2 Working Papers Number 10.*

Cica, N. 1994 Civil liability issues associated with a "heroin trial". *Feasibility Research into the Controlled Availability of Opioids Stage 2 Working Papers Number 11.*

Attewell, RG.; Wilson, SR. 1994 Statistical issues in planning a randomised controlled 'heroin trial'. *Feasibility Research into the Controlled Availability of Opioids Stage 2 Working Papers Number 12.*

with

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Bronitt, S. 1995 Criminal liability issues associated with a "heroin trial". *Feasibility Research into the Controlled Availability of Opioids Stage 2 Working Papers Number 13.*

Working papers in preparation (contributors listed in alphabetical order)

A. Examination of historical and current international evidence about the efficacy of treatment of dependent users with short-acting psychoactive drugs (Bammer).

B. A study of ACT methadone clients and dependent heroin users who have never been in treatment or who have dropped out of treatment to investigate unmet needs for treatment, views about expanding maintenance treatment to include diacetylmorphine prescription and behaviours relevant to measuring trial outcomes. Study participants also participated in the use of a nomination technique to estimate

- numbers of dependent heroin users (Anderson, Bammer, Larson, Lee, McDonald, Sibthorpe, Stowe, Tunnicliff).
- C. Results of surveys of the ACT and Australian populations concerning opinions of drug use, drug users, treatment, attitudes to various drug policy options and their own drug using behaviours. The ACT survey also asked a range of more general attitudinal questions (Bammer, Butlin, Kelley).
- D. Analysis of evidence about the effects of diacetylmorphine on driving skills. Includes analysis of New South Wales police records of people charged with driving under the influence of a drug; literatures reviews of the basic pharmacological and physiological effects of diacetylmorphine and effects of diacetylmorphine on psychomotor performance and driving; and a description and evaluation of various psychomotor tests used to assess the effects of drugs on driving ability (Bammer, Mascord, Moynham, Perl, Starmer).
- E. A detailed proposal for the service provision component of the pilots and trial, including a draft policy and procedures manual and examples of staff rosters (Bammer, Felton).
- F. A detailed proposal for evaluation of the pilots and trial (Anderson, Bammer, Inkpen, Lee, McDonald, Stowe).

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