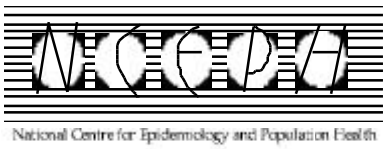
FEASIBILITY RESEARCH INTO THE CONTROLLED AVAILABILITY OF OPIOIDS



IN COLLABORATION WITH

AUSTRALIAN
INSTITUTE OF
CRIMINOLOGY

Feasibility Research into the Controlled Availability of Opioids

Published by the National Centre for Epidemiology and Population Health
The Australian National University
Canberra, Australia

July 1991
Reprinted with corrections September 1991

ISBN 0 7315 1234 0 set
0 7315 1235 9 volume 1
0 7315 1236 7 volume 2

Cover designed by Kathie Griffiths, ANU Graphic Design, Acton, A.C.T. 2601
Publications Officer: Stefanie Pearce, NCEPH, ANU, A.C.T. 2601
Printed by National Capital Printing, Fyshwick, A.C.T. 2609

Printed by National Capital Printing, Fyshwick, A.C.T. 2609

VOLUME 1: REPORT AND RECOMMENDATIONS

TABLE OF CONTENTS

FOREWORD

Illegal drug use is a problem worldwide. Prisons are overcrowded with people whose criminal activity is related to illegal drug use and/or distribution. Yet illegal drug use apparently goes unchecked.

Addiction to opioids is no recent phenomenon. The opium trade is centuries old. The question is increasingly being asked whether the costs of current social and legal policies concerning opioid use outweigh their benefits. Urgency has been given to the issue by the advent of the human immunodeficiency virus and its wildfire spread through shared use of injecting equipment in some drug using communities. Opioid use has become synonymous with criminal activity, 'chaotic lifestyles' and living dangerously.

In April 1991, I was approached by the chairman of the committee appointed to enquire into HIV, Illegal Drugs and Prostitution by the ACT Legislative Assembly, Mr Michael Moore MLA, who asked whether the National Centre for Epidemiology and Population Health (NCEPH) would be willing to explore the possibility of a trial of the controlled availability of opioid drugs in the ACT. My response was that I believed NCEPH would be willing to explore the issue provided it could be done rigorously and that the work offered the possibility of providing firm answers to genuine questions.

Academics and doctoral students at NCEPH were already involved in research into the epidemiology of AIDS in prisons and in drug users, and were carrying out research into community drug use. We convened a reference group of experts from around Australia who met in late April to advise us on the question that Mr Moore had raised.

The conclusion of that reference group was that although controlled availability of opioids has been implemented as a policy in parts of the world in recent years, no rigorous evaluation of this policy has been undertaken, and that there are questions which demand definite answers before major policy changes are contemplated in Australia. There was a feeling in the reference group that a trial of the kind that Mr Moore was proposing would be worthwhile, but that a great deal of preparatory work would be needed. The trial would need to be widely understood and supported by the community if the questions it asked were to be properly answered.

It was agreed that any such trial should be a four stage process and that each stage should be seen as a self contained activity which might, or might not, be followed by a later stage.

Stage 1 (feasibility), which is completed with the submission of the two volumes of this report to the ACT Legislative Assembly Select Committee on HIV, Illegal Drugs and Prostitution, was seen as an exploration of the issues surrounding the principles of such a trial. We estimated that it would take about three months to complete and that it should be carried out on the initiative of an academic team with broad peer group support from reference and advisory groups. NCEPH agreed to undertake this exercise with assistance from the Australian Institute of Criminology. This part of the investigation has been funded from within the core budgets of those two institutions.

Stage 2 (feasibility) would require political and financial commitment by the ACT Legislative Assembly to proceed further with the investigation of feasibility. It would not involve any administration of drugs or change in policy, but would require a more detailed examination of the logistics of the trial and the mechanism by which it might be run. Stage 2 feasibility would conclude with a report which carefully detailed all procedures and mechanisms by which a trial could be run, but would not involve commitment to undertake the trial. Stage 2 would probably take at least eight months to complete and would require a financial commitment by the Legislative Assembly of around $60,000, with approaches to other funding agencies for some of the tasks.

Stage 3 (pilot) would be a piloting of the procedures of the trial and would only begin with firm political commitment by ACT government and the community to undertake the trial and following some legislative changes which would be necessary for it to be carried out. Stage 3 would be a small scale study in which the procedures of the trial are pretested on a limited number of dependent users. This stage would take about six months to complete. It would cost about $250,000, and would require active involvement of the drug and alcohol services in the ACT.

Stage 4 (trial) would be a full scale trial of the proposed approach to controlled availability. It would be designed in a way which could unambiguously answer the questions which led to the trial. It would probably last two years. It would substantially alter the direction of drug services in the ACT and would require their firm cooperation and involvement. An independent evaluation team would be required. Funding would be of the order of millions of dollars, and would need to draw on national and possibly international resources. It would be a world "first". It might either result in the conclusion that controlled availability of opioids had little to offer as an approach to the problem, or pave the way for significant changes in treatment policy.

The present report covers stage 1 (feasibility). It has been prepared at NCEPH by Dr Gabriele Bammer who has co-ordinated a multi-disciplinary team drawn both from within and outside the Centre. Our collaboration with the Australian Institute of Criminology on this exercise has been particularly important, and the process has been monitored and modified by an advisory committee and informed by a large reference group of experts, both in Australia and overseas. Responsibility for the report and its recommendations rests with me and the authors. We have carefully considered the advice of all members of the advisory committee and the suggestions of the reference group. Not all of the recommendations in the report are necessarily endorsed by all individuals in either group. The two volume report is being submitted to Mr Moore's committee and being widely disseminated in the ACT community and beyond, to inform and provoke discussion about whether or not to proceed to Stage 2.

The report offers our advice that an ACT trial of controlled availability of opioids is feasible. It argues that such a trial would need to be very carefully structured as a randomised control trial which can provide answers to specific questions. These answers do not exist anywhere in the world at this time. We recognise that there are many uncertainties associated with undertaking such a trial, but conclude that there is a sound basis for proceeding to a Stage 2 feasibility study.

We would emphasize that the Stage 2 feasibility study might well lead to a different recommendation to the one that we have reached as a result of our Stage 1 investigations. As the logistics of the trial are more closely investigated, they may reveal issues which would make it undesirable to proceed to Stages 3 or 4.

We have recognised in all of this that drug policy is an intensely political issue. From here on, the issue is a political one, and we will observe the debate with great interest.

R M Douglas
Director

CO-ORDINATOR
Gabriele Bammer BSc(Hons) BA PhD
Research Fellow, NCEPH, ANU, Canberra

WORKING GROUP MEMBERS
Margaret Burns BA(Hons)
Research Assistant, NCEPH, ANU, Canberra

David Crawford BSc
Research Officer, NCEPH, ANU, Canberra

Phyll Dance RN RM BA(Hons)
Research Assistant, NCEPH, ANU, Canberra

Robert Douglas MBBS MA MD FAFPHM FRACP FRACGP
Director, NCEPH, ANU, Canberra

Beverley Garlick RN
Office Assistant, NCEPH, ANU, Canberra

Matthew Gaughwin BSc(Hons) PhD MBBS FAFPHM
Visiting Research Fellow, Department of Community Medicine, University of Adelaide and Visiting Fellow, NCEPH, ANU, Canberra

Robert Goodin BA IANA DPhil FASSA
Professorial Fellow, Philosophy Program, Research School of Social Sciences, ANU, Canberra

Nicholas Hartland BA(Hons)
Visiting Fellow, NCEPH, ANU, Canberra

J. Michael Lane MD MPH
Visiting Fellow, NCEPH, ANU, Canberra

David Legge MBBS BMedSci MD FAFPHM FRACP
Senior Research Fellow, NCEPH, ANU, Canberra

David McDonald BA DipSocWk MA
Visiting Fellow, NCEPH, ANU, Canberra

Brian Martin BSc PhD
Lecturer, University of Wollongong, Wollongong

Stephen Mugford BSc(Hons) PhD
Senior Lecturer, Sociology, The Faculties, ANU, Canberra

Jennifer Norberry BA(Hons) LLB(Hons) DipLib
Criminologist, Australian Institute of Criminology, Canberra

Remo Ostini BA GradDipSci
Research Assistant, NCEPH, ANU, Canberra

Stefanie Pearce BA(Hons)
Publications Officer, NCEPH, ANU, Canberra

Keith Powell MBBS MPH FRACP FAFPHM
Senior Physician, Royal Canberra Hospital South Alcohol & Drug Service, Canberra

Jennifer Rainforth BSc(Hons) DipEd
Research Assistant, NCEPH, ANU, Canberra

Beverly Sibthorpe RN BA(Hons) PhD
Visiting Fellow, NCEPH, ANU, Canberra

Adele Stevens RN RM BA(Hons)
Research Assistant, NCEPH, ANU, Canberra

ADVISORY COMMITTEE

CHAIR
Robert Douglas MBBS MA MD FAFPHM FRACP FRACGP
Director, NCEPH, ANU, Canberra

MEMBERS
Tony Adams MB BS MPH FRACMA, FAFPHM, FAPHA, FPHA
Chief Medical Advisor, Department of Health, Housing and Community Services, Canberra

Robert Ali MBBS
Director of Treatment Services, Drug and Alcohol Services Council, Adelaide

Ron Cahill* **BA LLB(Hons) CM**
Chief Magistrate, ACT Magistrate's Court, Canberra

Duncan Chappell BA LLB PhD
Director, Australian Institute of Criminology, Canberra

Brian Smith Brinkler#
Detective-Superintendent, Officer-in-Charge ACT Region City Crime Branch, Australian Federal Police, Canberra (Currently Acting Commander ACT Crime Division)

John Dau*
Commander, ACT Crime Division, Australian Federal Police, Canberra

Michael Moore MLA BA DipEd
Chair of the Select Committee on HIV, Illegal Drugs and Prostitution, ACT Legislative Assembly, Canberra

Keith Powell MBBS MPH FRACP FAFPHM
Senior Physician, Royal Canberra Hospital South Alcohol & Drug Service, Canberra

Marion Watson BAppSci(Health Education) RPN
Coordinator of ADDInc (Assisting Drug Dependents Inc), Drug Referral and Information Centre, Canberra

Alex Wodak MBBS FRACP FAFPHM
Director of Alcohol and Drug Services, St Vincent's Hospital, Sydney

---

* joined in June 1991
# replaced John Dau in July 1991

ACKNOWLEDGEMENTS

Useful information and comments were provided by:
Kenn Basham, AIDS Action Council of the ACT Inc
Charlie Blatch, Alcohol and Drug Foundation of the ACT
Dorothy Broom, NCEPH
Paul Broughton
Jeff Brown, Australian Federal Police Association
Michelle Burgermeister, ACT Corrective Services
Jude Byrne, ACTIV League
Claire Caesar, Needle Exchange Program
Peter Chivers, ACT Corrective Services
Geoffrey D'Abbs, Commonwealth Attorney-General's Department
Jennifer Dillon
Richard Downing, Australian Federal Police
Peter Drennan, Australian Federal Police
Cindy Fazey
Edward Foster, Australian Federal Police
Annette Gilmour, ACT Corrective Services
Barry Hindess, Political Science Program, Research School of Social Sciences, ANU
Brian Hodge and Staff of the Hospital Unit, ACT Drug and Alcohol Service
Rosemary Jardine, ACT Drug and Alcohol Service
Erich Kliewer, NCEPH
Chris Lidgaard, ACT Attorney-General's Department
Wendy Loxley, National Centre for Research into the Prevention of Drug Abuse
Ron McGrath, ACT Corrective Services
Bill McKay-Simm, ACT Drug and Alcohol Service
'Roger Mitchum' (pseudonym for an illicit drug using contact) and friends
Michelle Morrison, AIDS Action Council of the ACT Inc
Joy Murdoch, Karralika
Russell Newcombe
Chris Nichols, ACT Corrective Services
Allan Parry, 'The Atlantic Project', Liverpool
Michelle Pyke, Detoxification Centre, ACT Drug and Alcohol Service
Michael Rimmer, ACTIV League
Charles Roberts, AIDS Action Council of the ACT Inc
Barry Rosenberg, NCEPH
Staff of the ACT Drug Referral and Information Centre
Staff of the Drugs of Dependency Branch, Commonwealth Department of Health, Housing and Community Services
Staff of the Methadone Clinic, ACT Drug and Alcohol Service
Colin Stoddart, ACTIV League
John Strang, Drug Dependence Clinical Research and Treatment Unit, The Bethlem Royal Hospital and the Maudsley Hospital, Beckenham, UK
Judith Wilson, Commonwealth Attorney-General's Department
Lloyd Worthy, Australian Federal Police

Valuable assistance and support were provided by NCEPH staff:
Kaye Devlin, Liz Foster, Rodney Malbon, Jenni Miller and Barbara Payne

EXECUTIVE SUMMARY

G. Bammer and R. M. Douglas

The results of a three month exploration of legal, ethical, political, medical and logistic issues lead us to the interim conclusion that it would be feasible to undertake a randomised controlled trial as a test of the policy of expanding the availability of heroin in a controlled fashion for the management of heroin dependent users in the ACT.

There is evidence that the ACT community is willing to consider such a trial, but also that ACT police have significant concerns about its logistics and possible ill effects.

The trial would compare oral methadone treatment with a program of expanded opioid availability, in which dependent individuals would be able to take intravenous, oral or smoked heroin and/or methadone under careful medical supervision.

Volunteers would be subject to strict residential eligibility criteria and would need to agree to extensive medical tests and data collections. They would be randomly assigned either to methadone treatment or to the expanded availability program. The two groups would be carefully followed for at least one year in an effort to discover whether or not the expanded availability program provides benefits for dependent drug users, their families and to society at large which methadone programs cannot provide.

The purpose of the study would be to discover whether or not a policy of controlled heroin availability could ameliorate the massive burden which illegal heroin use currently imposes on Australian and ACT societies.

Our exploration of these matters leads us to recommend to the Select Committee on HIV, Illegal Drugs and Prostitution of the ACT Legislative Assembly that it cautiously proceeds to a second stage exploration of the feasibility of such a study without commitment to the trial until logistic issues are more fully described.

REPORT AND RECOMMENDATIONS

Gabriele Bammer

Introduction

This is a report of a three-month intensive investigation which examined two questions:

- is a trial to provide opioids* in a controlled manner to users feasible in principle, and
- if so, how should such a trial be conducted?

Examination of these questions involved drawing on a range of expertise from the areas of public health, criminology, medicine, law, epidemiology, sociology, political science, psychology, medical anthropology, philosophy, pharmacology, and sociology of science. It also involved bringing together academics, bureaucrats, health service providers, law enforcement agents and illegal drug users.

Most of the research was conducted by working groups which focussed on particular topics. Their reports are published in an accompanying volume of background papers. A range of methodologies was employed: literature reviews, surveys, interviews with key informants, examination of legal arguments, analysis of key documents, brain-storming and discussion.

The research was a team effort, where each member made an essential contribution. The recommendations are based on the results of the reports in Volume 2. Responsibility for the recommendations lies with me as the Co-ordinator of the project and with the Chair of the Advisory Committee, Professor Robert Douglas.

A large reference group and numerous other individuals provided information and commented on draft reports. The process was guided by an Advisory Committee. None of these individuals, however, bear responsibility for, or necessarily agree with all of the recommendations.

This report and the accompanying recommendations are distilled from the background papers. A trial has been found to be feasible in principle and a model for its conduct is proposed.

The next step should be a careful examination of the logistics of the proposed trial. This would include extensive consultation with the Canberra community, the police, drug treatment service providers and illegal drug users. Only after that should consideration be given to implementing a small pilot study. The trial itself should only go ahead if both logistical considerations and a pilot study are favourable.

Stage 1 in the process has therefore been completed.

---

* Throughout this document the discussion is of opioids (a term covering a range of drugs, naturally or synthetically derived from opium, and including heroin) rather than restricted to just heroin. This reflects the broad range of considerations which underpinned this stage of the feasibility study.

Stage 2 would involve examination of the logistics of a trial and the mechanism by which it might run. It would not involve any administration of drugs or change in policy.
Stage 3 would pilot the procedures of a trial, and
Stage 4 would be a full-scale trial.

This report has four sections:
- a recommendation concerning the in principle feasibility of conducting a trial to provide opioids to users in a controlled manner and the reasons for that recommendation,
- recommendations for a model for conducting a trial and the reasons underlying them,
- a list of particular issues which must be examined in Stage 2. These are divided into research issues, issues relevant to the day-to-day running of a trial and administrative issues, and
- conclusions.

IS A TRIAL FEASIBLE IN PRINCIPLE?

The detailed investigations conducted to date have found that a trial to provide opioids to users in Canberra in a controlled manner is feasible in principle.

Recommendation

The investigation of the feasibility of a trial to provide opioids, including heroin, in a controlled manner should proceed to Stage 2, namely an investigation of the logistics of conducting a trial.

Rationale

This recommendation is informed by three considerations:

- a trial, if successful, has the potential to produce significant benefits for both illegal drug users and the community,
- there are no significant legal or political barriers to the conduct of a trial, and
- there is support for a trial in the general community, among service providers in drug treatment agencies and among illegal drug users.

It should be noted that there was only minority support for a trial among the police.

Potential Benefits of a Trial

There is a broad consensus of opinion that prohibition as it is currently enforced is not effective, that changes in drug policy are urgently needed to prevent the spread of HIV infection amongst injecting drug users and the general community, and that changes are needed to reduce crime (both individual and organised) associated with illegal drug use.

There is no consensus, however, on what form changes should take. The case for increasing the controlled availability of opioids, including heroin, seems to be stronger than the case against. The likely potential benefits of such a change are thought to include reduced crime, reduced corruption, and improvements in health and lifestyle for users, as well as preventing the spread of HIV infection.

To date there are indications that such benefits would indeed result from a change in controlled availability. However, they are based on a small number of relatively inconclusive studies. A trial such as the one proposed here would shed significant light on the veracity of the claims which have been made.

These issues are discussed in more detail in Volume 2 (Chapter 2: Literature Review: Arguments For and Against Changing the Controlled Availability of Opioids).

Legal Issues

The legal position of a trial where heroin was provided in a controlled manner involves consideration of international treaties, Commonwealth legislation, and State and Territory legislation.

A trial involving the controlled availability of opioids, including heroin, that was conducted for a medical or scientific purpose would not place Australia in breach of international treaty obligations.

The Commonwealth controls the importation and manufacture of narcotic goods and has extensive powers in relation to therapeutic goods. Under current legislation, those associated with a trial would commit a number of offenses if heroin or other narcotic drugs were to be imported, possessed or manufactured. However a trial could proceed legally if a number of Commonwealth licences and permissions were obtained and if the Commonwealth agreed to notify estimates for heroin importation to the International Narcotics Control Board.

Under current ACT legislation, a trial to provide opioids, including 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 between 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.

It is likely that New South Wales and Victorian legislation are also relevant to whether or not a trial can proceed. New South Wales legislation is potentially important for the movement of trial drugs to the ACT from the point of manufacture and for trial participants who may, for various reasons, cross the border into that state. If heroin to be used in a trial is manufactured within Australia, Victoria is the most likely source of licit supply. A Victorian manufacturer would need the appropriate Commonwealth licences and permissions as well as appropriate approvals under Victorian Legislation.

These issues are discussed in more detail in Volume 2 (Chapter 5: Legal Issues).

Political Considerations

Consideration of the political context in which a trial would occur provides no major barriers and gives some support for the conduct of a trial. Four aspects of political context were examined: party political considerations; the reports of various committees, Royal Commissions and inquiries into drug use; the National Campaign Against Drug Abuse; and the non-government sector.

Party political considerations show that within both the Liberal and Labor parties there is a diversity of positions and policies relevant to problems arising from the use of opioids. While both major parties have at least some stated positions on decriminalisation and legalisation (generally opposing them), neither has a stated position on controlled availability. In contrast, the Democrats support controlled availability in the context of treatment and the ACT Division has supported the notion of an ACT based trial.

In the last 20 years there has been a series of reports on drugs and drug dependency produced by various committees, Royal Commissions and inquiries. In essence, the reports have reiterated important points with a good deal of consensus on the nature of the problem and appropriate ways of dealing with it; the recommendations focus on education, treatment and law enforcement. Since 1977 the reports have argued for harm minimisation rather than the elimination of drug use. Despite this, the reports which considered heroin maintenance for dependent individuals have argued against it, with one calling for research using a limited trial. It should be noted, however, that the context in which these deliberations took place was rather different from that existing now. Other ways of providing heroin in a controlled manner have not been considered. Every report has lamented the lack of empirical information on which to base decisions and has called for informed public debate and more research.

The National Campaign Against Drug Abuse (NCADA) was launched in 1985, with the central aim being to minimise the harmful effects of drugs on Australian society. A

trial which would make opioids available to users in a controlled manner is positioned ambiguously in relation to NCADA. A trial encompassing one or more of treatment, education or enforcement would be compatible with the established NCADA framework. However, a trial does not, at least at first glance, fit easily with the deeper assumptions which generated the approach of governments to drugs because it does not primarily address the causes of drug use. The trial does however fit comfortably with the objective of harm minimisation as it has evolved. It is also worth noting here that the current NCADA research priorities include "the need to conduct research on the effects of changes in the supply of illicit drugs, for example the supply of injectable methadone, the decriminalisation of personal possession of marijuana and the effect of present government policies".

Non-government organisations, as represented by the Australian Council of Alcohol and Other Drug Associations, advocate change in the legal status of heroin, but do not seem to have a formal position on controlled availability.

These issues are discussed in more detail in Volume 2 (Chapter 3: Political Issues).

Attitudes to A Trial

As part of stage 1 of the feasibility study, surveys were conducted of the general community, the police, service providers in drug treatment agencies and illegal drug users and ex-users. Comment was also invited from the community and from key community groups. It must be noted that there was no specific proposal put to any of these groups. Survey respondents were asked to comment on potential advantages and disadvantages of a trial and on a range of potentially difficult issues. A key question was:

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 the 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 that a trial should go ahead or that a trial should not go ahead?

The responses were:

	%General Community (n = 516)	% Police (n = 446)	% Service Providers (n= 93)	% Drug Users/ Ex-Users (n= 133)
Should go ahead	*66*	*31*	*71*	*76*
Should not go ahead	*27*	*63*	*19*	*14*
Don't know	*7*	*7*	*9*	*10*

Of those approached to complete the surveys, responses were received from: 77% of the general community, 40% of the police, 38% of service providers and 25% of drug users/ex-users. Further information about these surveys is given in Volume 2 (Chapter 8: Attitudes to A Trial).

Thus there was strong support for a trial from the general community, service providers and users. There was only minority support from the police.

Now that a specific proposal has been developed, it is essential that there is further and adequate consultation with key community groups, the police, relevant service providers and illegal drug users.

HOW SHOULD A TRIAL BE STRUCTURED?

The model presented here was developed once the trial was found to be feasible in principle. It is intended to form the basis for further discussion and research. It was clear from the work done in Stage 1 that there is an urgent need for a trial which will address key questions, which has clear measures of outcomes and which is rigorously conducted. Legal (particularly Australia's obligations under international treaties), ethical and political considerations place significant constraints on the design of a trial and these have been taken into consideration. There will also be logistic constraints and these will be considered and resolved in Stage 2. A set of recommendations follows with an accompanying rationale for each of them.

Recommendations

Aims and Evaluation

1. The overall aim of the trial should be to compare outcomes for opioid users who have a choice of drugs and routes of administration in their treatment options with those who have oral methadone only available to them. The choice of drugs involves a choice of heroin or methadone or both, in injectable, smokable or oral forms. The outcomes to be examined are changes in health and social behaviours, including criminal behaviour.

2. The trial should run over two years.

3. The trial should be structured to allow rigorous and unequivocal evaluation of outcomes. The core of the evaluation should be a carefully conducted randomised controlled trial.

4. Applicants for the trial who meet the selection criteria will be randomly allocated to one of two groups. Those in the first, 'opioids', group will have available to them heroin and/or methadone, in injectable, oral and smokable forms. Those in the second, 'control', group will have oral methadone only available. Other conditions for the two groups will be identical.

5. The randomised controlled trial should address the following key questions (by comparing the two groups):

   Can a treatment program which offers heroin (as well as methadone) and injectable and smokable routes of administration (as well as oral) increase the likelihood that participants will be able to:
   a. lead a more stable lifestyle in terms of employment, relationships and day-to-day activity,
   b. reduce their criminal activity,
   c. reduce behaviours which place them at risk of contracting HIV and hepatitis B and C,
   d. increase behaviours important in the maintenance of health and well-being?

6. Other important questions which a trial should address are:

   Can such a treatment program bring into treatment illicit opioid users who have not sought treatment before and can it maintain clients in treatment for a longer time than currently available programs? How satisfied are participants and workers with the program?

   Can such a treatment program have measurable benefits to society at large, in terms of reducing the level of drug-related problems and the social and economic costs of drug use?

   Would such a treatment program be cost-effective?

   Can such a treatment program improve relationships and lifestyle from the point of view of family members and others close to trial participants?

   Would such a treatment program have major impact on existing drug treatment services and on law enforcement?

7. The evaluation should be conducted by researchers who are independent from the running of the trial. No restrictions should be placed on their ability to publish freely the results of their investigations.

Routine Procedure

8. The number of administrations per day for the 'opioids' group will depend on pharmacological evidence about the drug, route of administration and dose. However, no more than three administrations of opioids per day should be provided. The control group should receive one administration per day (of methadone orally).

9. For the 'opioids' group initial determination of drug, dose and route of administration should be a matter of negotiation between service provider and user. For the control group similar negotiations will revolve only around dose. Safety will also be a prime consideration, so that initial doses will have to be low with a build up to a holding dose.

10. For the 'opioids' group, there should be regular review of drugs taken, routes of administration and dose and, where applicable, encouragement should be given to users to move from heroin to methadone, to move away from injecting routes of administration and to decrease the dose and the frequency of drug administration. There should be a similar regular review for the control group, with encouragement to decrease the dose and frequency of methadone administration.

Criteria for Inclusion of Users

11. The trial should be open to dependent users of heroin, with screening based on the presence of drug metabolites in urine or hair, other physical evidence of use (e.g. evidence of injection, so-called 'track marks') and drug-taking history.

12. The following categories of people should be excluded from the trial: non-ACT residents, people dependent on prescribed opioids for pain relief, and dependent people with current or recent major psychiatric illness.

13. The trial should be designed with the ability to allow all dependent users who meet the selection criteria to participate. However in Stage 2 further detailed consideration should be given to whether or not the following groups should be eligible for the trial: pregnant women, people who are HIV positive, people under the age of 18 and people who would be referred to the trial from the courts. Applicants for the trial who do not meet the selection criteria should have a different (i.e. outside the randomised controlled trial) oral methadone program available to them.

Distribution Points

14. All drugs should be administered at the distribution points. After participants have been on the trial for 3 months, consideration should be given to allowing those taking oral methadone (in either the 'opioids' or 'control' groups) to administer at home.

15. In Stage 2, consideration should be given to the number of distribution points and hours of opening which are feasible, particularly in terms of resources. Ideally, there should be three distribution points with extended hours of operation. While it should not be necessary for each point to be open for 24 hours per day, consideration should be given to at least one distribution site being open at any one time. There should be one principle site, where medical and social assessments are also conducted.

16. Distribution points should be inconspicuous and should be located in busy public places, close to public transport and to medical facilities.

17. The distribution sites and the procedures used will have to be adequately secure to prevent theft of drugs.

18. Each distribution point should have a special 'fixing room' where injectable drugs are administered under supervision.

19. The distribution sites should be staffed by a mixture of medical and non-medical personnel.

Recruitment

20. Recruitment should not be through widespread public advertisement, rather it should be through low-key methods like word of mouth.

Payment for Trial Drugs

21. No payment should be required for participation in the trial.

Data Collection and Registration of Users

22. Data collection is fundamental to a trial and the provision of information will be a requirement for trial participation. There are also three other fundamental principles which govern data collection: informed consent, confidentiality, and protection of privacy. Trial participants and researchers should be protected by the Epidemiological Studies (Confidentiality) Act 1981 and/or an ACT equivalent drafted especially for the trial.

23. There should be a register and identification system for trial participants.

24. There should be appropriate legal protections for trial participants.

Continued Use of Illegal Drugs

25. The legal protections which will need to be instituted for the use of trial drugs should not be extended to non-trial drugs. In other words use of 'street' drugs should continue to be a criminal offence.

26. Use of illegal drugs should not bar people from receiving trial drugs, except when this might lead to a risk of overdose.

Standards of Behaviour for Trial Participants

27. At the distribution site, there should be certain behavioural standards which trial participants will be required to meet, including non-violence and courtesy.

28. Diversion (i.e. selling) of trial drugs should be strictly forbidden.

29. There should be sanctions for not meeting behavioural standards and for diversion of trial drugs. Consideration of effective standards should be undertaken in Stage 2. In addition, if people are found to be selling rather than using trial drugs there should be a review of the drugs they are taking and of the doses and frequency of administration. The procedure for imposing sanctions should be clearly laid down and should not be at staff discretion.

30. There should be no other requirements for behavioural standards.

Counselling, Other Treatment and Service Provision

31. There should be no compulsion on trial participants to undertake counselling or other treatment, although these should be freely available and trial participants should be encouraged to use them.

32. Trial participants in both the 'opioids' and control groups should be regularly assessed with regard to their social functioning and referred to appropriate services (legal aid, housing assistance etc) as necessary.

Staffing Issues

33. There should be no compulsion on medical or non-medical staff to work on the trial.

34. Stage 2 of the feasibility study should explore ways to facilitate rotation of trial staff to positions away from the trial, if and when staff request a transfer.

35. There should be appropriate legal and safety protections for trial staff.

Termination of the Trial

36. At the conclusion of the trial all participants should have oral methadone available to them. At the commencement of the trial, participants need to understand that there is no guarantee that provision of heroin (or methadone through other than oral routes of administration) will continue after the trial has concluded.

37. If in practical terms the methadone program instituted for the control group runs successfully, it should be continued after the trial is terminated.

Rationale

Recommendation 1. The overall aim of the trial should be to compare outcomes for opioid users who have a choice of drugs and routes of administration in their treatment options with those who have oral methadone only available to them. The choice of drugs involves a choice of heroin or methadone or both, in injectable, smokable or oral forms. The outcomes to be examined are changes in health and social behaviours, including criminal behaviour.

The debate about changing the availability of opioids has ranged over a number of areas, including questioning the effectiveness of prohibition, the consequences of illegality, the likely relationship between drug availability and the spread of HIV infection, and the costs and benefits of legal availability of opioids (see Volume 2, Chapter 2: Literature Review: Arguments For and Against Changing the Availability of Opioids). There is a dearth of evidence to inform debate in any of these areas, but all of them cannot be tackled in any one study. A major area of concern is the ability to improve treatment of people dependent on opioids, especially heroin. The trial aims to address a central question in this area. It will compare a new range of treatment options with a standard form of treatment. The outcome measures will encompass changes in a range of health and social behaviours. This is discussed in greater depth in Volume 2, Chapter 9: Evaluation by a Randomised Controlled Trial.

Recommendation 2. The trial should run over two years.

Trial participants must be followed for a minimum of 12 months to allow realistic evaluation of outcomes. It is likely that recruitment onto the trial will be episodic and stretch over 6 months. There must also be an adequate wind-down phase to allow participants to be moved onto oral methadone (see Recommendation 35). Thus two years is a minimum period over which a trial should run. Once the important outcome measures have been determined, further careful consideration will need to be given to whether or not this time frame is adequate for measuring them.

Recommendations 3 to 6

Recommendation 3. The trial should be structured to allow rigorous and unequivocal evaluation of outcomes. The core of the evaluation should be a carefully conducted randomised controlled trial.

Recommendation 4. Applicants for the trial who meet the selection criteria will be randomly allocated to one of two groups. Those in the first, 'opioids', group will have available to them heroin and/or methadone, in injectable, oral and smokable forms. Those in the second, 'control', group will have oral methadone only available. Other conditions for the two groups will be identical.

Recommendation 5. The randomised controlled trial should address the following key questions (by comparing the two groups):

Can a treatment program which offers heroin (as well as methadone) and injectable and smokable routes of administration (as well as oral) increase the likelihood that participants will be able to:

a. lead a more stable lifestyle in terms of employment, relationships and day-to-day activity,

b. reduce their criminal activity,

c. reduce behaviours which place them at risk of contracting HIV and hepatitis B and C,

d. increase behaviours important in the maintenance of health and well-being?

Recommendation 6. Other important questions which a trial should address are:

Can such a treatment program bring into treatment illicit opioid users who have not sought treatment before and can it maintain clients in treatment for a longer time than currently available programs? How satisfied are participants and workers with the program?

Can such a treatment program have measurable benefits to society at large, in terms of reducing the level of drug-related problems and the social and economic costs of drug use?

Would such a treatment program be cost-effective?

Can such a treatment program improve relationships and lifestyle from the point of view of family members and others close to trial participants?

Would such a treatment program have major impact on existing drug treatment services and on law enforcement?

As indicated above, debate about changing the availability of opioids has been hampered by a lack of empirical evidence. It is important, therefore, that a trial is rigorously conducted and provides unequivocal findings. The conventional way to evaluate new treatments is by a carefully conducted randomised controlled trial (with the best conventional form of treatment used as the comparison). This is also the most rigorous form of evaluation offering the greatest ability to control for potential confounders such as demographic and selection variables, and changes over time in the trial population or trial procedures.

It is also unethical to use people as 'subjects' for scientific research unless it is clear that the results of a trial can be adequately evaluated and that they will have a meaningful bearing on later policy considerations. These ethical issues are discussed in more detail in Volume 2 (Chapter 7: Ethical Issues).

All evaluations, including randomised controlled trials, have limitations. The process of randomisation is itself a mitigating factor against success as outcomes are better if people have a choice of treatment options. Nevertheless, the potential of a randomised controlled trial to produce unequivocal results is far greater than that offered by any other form of evaluation.

All forms of evaluation are also limited in the types of questions they can properly address. A randomised controlled trial is appropriate for the questions listed in Recommendation 5. The questions listed in Recommendation 6 will mostly require other types of evaluation which should be further explored in Stage 2.

As noted in the rationale under Recommendation 1, a trial such as the one proposed here only provides information concerning some aspects of the debate about changing the availability of opioids. Further research would be needed to address other aspects. In addition, the debate about changing the availability of opioids is only part of a larger debate about changing the availability of all illegal drugs. Restriction of trial drugs to heroin and methadone will only impact on part of the drug using population and will not resolve questions about other illegal drugs.

The evaluation of the trial must also be sensitive to unintended negative (and positive) effects. Further examination of how this could be achieved should occur in Stage 2.

These points are all discussed in more depth in Volume 2, Chapter 9: Evaluation by a Randomised Controlled Trial.

Recommendation 4. Applicants for the trial who meet the selection criteria will be randomly allocated to one of two groups. Those in the first, 'opioids', group will have available to them heroin and/or methadone, in injectable, oral and smokable forms. Those in the second, 'control', group will have oral methadone only available. Other conditions for the two groups will be identical.

It was decided to restrict the trial opioids to heroin and methadone. Heroin is the most widely used illegal opioid. Illegal use of other opioids is much less common (see, for example, Volume 2, Chapter 8: Attitudes to A Trial, Table 2.41). Oral methadone is a standard treatment for people with problems resulting from illegal opioid, especially heroin, use. It should be possible for people in the 'opioids' group to use a combination of these two drugs if they wish, as this may be the way they find most acceptable for reducing heroin use. For example, of the users we surveyed who were interested in participating in a trial, 71% indicated that they would be interested in volunteering if the standard option was oral methadone plus two injections of heroin/opiates per day (Volume 2, Chapter 8: Attitudes to A Trial, Table 5.10).

It also needs to be noted that opioids "in pure form and administered cleanly, are non-toxic to body tissue" (The Drug Offensive Information Brochure on Heroin and other Narcotic Analgesics, reprinted as Appendix A in Volume 2).

One of the hypotheses to be tested by the trial is that injectable heroin will attract to the trial people who have not previously been attracted to treatment. Given that injection is the most hazardous route of adminstration, other routes should also be available and users encouraged to try them and move to them. Heroin administration by smoking can produce a 'high' similar to that produced by injection, whereas this cannot be obtained by oral administration. There is some evidence from the Marks/Parry program in Liverpool that users will switch from oral to smokable routes of administration (see Volume 2, Chapter 5: Options for A Trial). Smokable heroin can be provided in either tobacco or herbal cigarettes or in 'bongs'. While there are well-documented health hazards associated with smoking tobacco, it should also be noted that the majority of people dependent on illicit drugs already smoke tobacco.

It should be possible for people to use a combination of routes of administration, as this may be the way they find most acceptable for reducing the frequency of injection.

It needs to be recognised that restriction of trial drugs to heroin and methadone will only impact on part of the drug using population. There is widespread agreement that there is a group of users for whom heroin is the preferred drug, but there are other users who prefer drugs such as cannabis and/or stimulants such as amphetamines and cocaine. There is a third group who prefer to use a variety of illicit drugs. A trial such as that proposed will only impact on the first group. It needs to be noted that people who use amphetamines and cocaine also commonly inject (see Volume 2, Chapter 1: Illegal Drug Use in Canberra and Chapter 8: Attitudes to A Trial, Table 2.42) so that a trial such as this does not impact on the whole illegal drug using population for factors such as HIV risk, for example.

Recommendation 7. The evaluation should be conducted by researchers who are independent from the running of the trial. No restrictions should be placed on their ability to publish freely the results of their investigations.

Because of the highly political context in which such a trial would take place, the people running the evaluation must be independent and have no vested interest in the outcome of the evaluation. Further, the results must be freely available and pressures should not be brought to bear on researchers to restrict the publication of their findings (see also Volume 2, Chapter 4: Interest Groups and Social Controversies and Chapter 7: Ethical Issues).

The information for the recommendations which follow has largely been taken from Volume 2, Chapter 6: Options for A Trial.

Recommendation 8. The number of administrations per day for the 'opioids' group will depend on pharmacological evidence about the drug, route of administration and dose. However, no more than three administrations of opioids per day should be provided. The control group should receive one administration per day (of methadone orally).

There is some evidence that many users of illegal heroin inject only two or three times per day (see also Volume 2, Chapter 8: Attitudes to A Trial, Table 2.43). A restriction in the number of administrations is also necessary to make it feasible for drugs to be administered at the distribution site (see Recommendation 13). It may be possible to encourage users to combine methadone and heroin: methadone to minimise withdrawal symptoms and heroin to provide a "buzz" (see also Recommendation 4).

However, such a restriction may encourage users to 'top up' with illegal drugs. Withdrawal effects (such as uneasiness, diarrhoea and abdominal cramps) may occur within a few hours (see Volume 2, Appendix A). Further, there is evidence that some users may inject 5 or more times per day (see Volume 2, Chapter 8: Attitudes to A Trial, Table 2.43). This has important implications not only for law enforcement and the relationship of the police with the trial but also for the likely success of the trial. These potential effects should be considered further in Stage 2.

Recommendations 9 & 10

Recommendation 9. For the 'opioids' group initial determination of drug, dose and route of administration should be a matter of negotiation between service provider and user. For the control group similar negotiations will revolve only around dose. Safety will also be a prime consideration, so that initial doses will have to be low with a build up to a holding dose.

Recommendation 10. For the 'opioids' group, there should be regular review of drugs taken, routes of administration and dose and, where applicable, encouragement should be given to users to move from heroin to methadone, to move away from injecting routes of administration and to decrease the dose and the frequency of drug administration. There should be a similar regular review for the control group, with encouragement to decrease the dose and frequency of methadone administration.

The exact nature of the initial and continuing negotiation processes on type of drug, dose and route of administration must be clearly defined so that comparability between trial participants and between people in 'opioids' and control groups can be maintained. It is envisaged that the process would be analagous to the negotiations between doctor and patient over the prescription of ordinary pharmaceuticals.

A particular issue which needs further consideration is whether or not maximum dose limits should be set and, if so, how they should be determined.

Recommendation 11. The trial should be open to dependent users of heroin, with screening based on the presence of drug metabolites in urine or hair, other physical evidence of use (e.g. evidence of injection, so-called 'track marks') and drug-taking history.

The combination of screening criteria chosen means that there is a high degree of certainty that those given entry into the trial are heavy users of heroin. Dependence is not an absolute and the screening criteria have to be carefully developed.

The use of naloxone eye drops may also be an effective screening tool and should be investigated in Stage 2. [Naloxone reverses the effects of opioids and one effect of opioids is to constrict the pupils.]

A trial such as this would not be suitable for non-dependent users for a variety of reasons. It is difficult to adequately screen non-dependent users to ensure that provision of trial drugs does not increase use. In addition, for many non-dependent users of heroin the setting and context of the use is as important as the drug. A treatment setting is regarded as inappropriate (see Volume 2, Chapter 1: Illegal Drug Use in Canberra). An analogy with alcohol may be useful here. If trial conditions were applied to the consumption of alcohol, a convivial drink after work would be impossible; instead individuals would need to attend a clinic to obtain a glass of beer and would have to drink it under supervision.

Australia's international treaty obligations would also seem to prohibit inclusion of non-dependent users on a trial (see Volume 2, Chapter 5: Legal Issues).

A disadvantage of restricting a trial to dependent users is that non-dependent users are at risk of the same health problems as dependent users of illegal heroin. In addition, such restrictions may provide an incentive for non-dependent users to become dependent in order to qualify for participation on the trial. About one in six of the non-dependent users surveyed as part of this study indicated that they would increase their use a little or a lot to get on the trial (see Volume 2: Chapter 8: Attitudes to A Trial, Table 4.69) and police and service providers also thought that at least a few non-dependent users would do this (Table 4.15). Ethically it may ultimately be an open question as to whether the incentive effects are a problem if the trial generally has a good effect on participants. However the question of balancing undesirable incentive effects against the positive outcomes of a trial requires measurement of the extent of incentive effects and not simply whether they exist (see Volume 2, Chapter 7: Ethical Issues). This problem should receive further consideration in Stage 2. On the

other hand, as indicated above, if non-dependent users were included in a trial, ready access to high quality heroin might also be a stimulus for them to increase their use.

A number of authors (see Volume 2, Chapter 6: Options for A Trial - Literature Review) have also suggested that if non-dependent users are not included their demand for illegal drugs would keep the black market flourishing so that the cost of maintaining the criminal justice and customs systems would not be affected.

Recommendation 12. The following categories of people should be excluded from the trial: non-ACT residents, people dependent on prescribed opioids for pain relief, and dependent people with current or recent major psychiatric illness.

There is some concern that an ACT-based trial would attract users from interstate (see Volume 2, Chapter 8: Attitudes to a Trial; Table 4.56) and that this would increase crime and place a large burden both on the trial and on law enforcement and welfare services. This must be minimised by clear and rigidly enforced residency criteria. Careful consideration needs to be given to how those people who do not meet residency criteria should be dealt with. For example, consideration should be given to liaising with state-based (especially New South Wales and Victorian) treatment sevices so that non-ACT residents can be offered assured access to treatment in their home state.

People who are dependent on prescribed opioids for pain relief should be excluded from the trial. The aims of the trial are directed at users of illicit opioids. Despite a number of studies which have shown that heroin has no major analgesic benefits over other narcotics, there is still great interest in heroin being made available for pain relief. Consideration of this issue is outside the terms of this feasibility study.

Dependent users with current or recent major psychiatric illness should also be excluded from the trial. They are unlikely to be able to provide informed consent or participate in the negotiation process which underpins the trial (see Recommendations 9 & 10). In addition, severe psychiatric illness may significantly affect the outcomes being measured by the trial, so that changes produced by the trial drugs might not be clear-cut.

Recommendation 13. The trial should be designed with the ability to allow all dependent users who meet the selection criteria to participate. However in Stage 2 further detailed consideration should be given to whether or not the following groups should be eligible for the trial: pregnant women, people who are HIV positive, people under the age of 18 and people who would be referred to the trial from the courts. Applicants for the trial who do not meet the selection criteria should have a different (i.e. outside the randomised controlled trial) oral methadone program available to them.

There are a number of in principle reasons for including all eligible people who wish to participate in the trial. One is that evaluation of trial outcomes will be facilitated by larger numbers. Another is that the more people who are able to participate, the smaller the likelihood of people being 'hassled' by those not on the trial. This may

impact significantly on the likelihood of trial drugs being diverted onto the black market and on episodes of violence between drug users. However, logistic factors may be a constraint. In particular, because people will have to administer drugs at the distribution sites, there will be a limit to how many can be accommodated comfortably. There is also legitimate concern regarding large numbers of people congregating in public places near the distribution points.

It is difficult to obtain an accurate picture of the number of heroin users in the ACT. There are various ways of making estimates and the range is from around 700 to around 8000 (see Volume 2, Chapter 1: Illegal Drug Use in Canberra). The best evidence available suggests that there are around 1000 dependent heroin users in Canberra. It may therefore be reasonable to use a figure of 600 participants in considerations of trial logistics. Stage 2 of the feasibility study should investigate more closely the likely numbers of participants and how many would be needed to allow proper evaluation of different outcomes.

There is some debate about whether or not four particular groups of users should be included in or excluded from the trial. The groups are: pregnant women, people who are HIV positive, people under the age of 18 and people for whom participation in the trial is an alternative to gaol. On one hand it can be argued that people in these groups have the greatest need for access to a range of treatment options (pregnant women, people who are HIV positive and people sent through the court system) or would be most likely to benefit from a trial (people under 18). On the other it can be argued that there are only relatively few such people and that there are particular problems with including them in a trial, which may make evaluation of outcomes difficult. These issues need further investigation in Stage 2.

If a decision is made not to include these people, they should be offered access to a methadone program or some other form of treatment.

Careful consideration also needs to be given to the options which should be offered to any people who become HIV positive or pregnant while on the trial.

Recommendation 14. All drugs should be administered at the distribution points. After participants have been on the trial for 3 months, consideration should be given to allowing those taking oral methadone (in either the 'opioids' or 'control' groups) to administer at home.

Drugs must be administered at the distribution site. The main consideration here is that allowing drugs to be taken away increases the possibility that they will become available to people not on the trial. It is thought likely by users, service providers and police that trial participants would be 'hassled' for their drugs by those not on the trial (see Volume 2, Chapter 8: Attitudes to A Trial, Table 4.40) and that this would be likely to lead to physical violence which could even be life threatening (Tables 4.47 & 4.48). There was strong support among all of the groups surveyed for drugs to be administered at the distribution site (Table 5.6).

This requirement has important logistic disadvantages. It means that the number of people who can be accommodated on the trial will be limited by space and staffing

considerations to a much greater extent than if trial drugs could be taken home. A take-home system would be also be more likely to be able to be geographically dispersed, for example through pharmacies. The need for frequent travel by trial participants also becomes an important consideration (see below: Rationale for Recommendation 15). It is also likely that distribution sites will be a point of congregation for users, and the fewer distribution sites there are, the greater the number of people likely to congregate.

Administering the drugs at the distribution site will impose constraints and structure on the daily lives of trial participants. To that extent, they lose the ability to structure their lives for themselves. This may be an advantage for people whose lifestyles are very 'chaotic', but will be an important difficulty for people who have other commitments (e.g. through employment or family responsibilities) and may inhibit the development of more autonomous forms of personal organisation.

The risks of diversion of oral methdone, especially if it is readily available to users through treatment services are likely to be much smaller than the risks for diversion of heroin. A number of the disadvantages listed above associated with drug administration at the distribution site could be overcome, for at least some trial participants, if 3 days' doses of oral methadone could be collected at any one time and taken home by trial participants after they had been on the trial for three months. It might also be necessary for them to meet other criteria (such as being in paid or voluntary employment). Such criteria must be carefully defined and should not be at staff discretion. The option of take-away methadone needs to be examined further in light of the trial design, to ensure that it does not make outcomes difficult to measure or interpret.

Recommendation 15. In Stage 2, consideration should be given to the number of distribution points and hours of opening which are feasible, particularly in terms of resources. Ideally, there should be three distribution points with extended hours of operation. While it should not be necessary for each point to be open for 24 hours per day, consideration should be given to at least one distribution site being open at any one time. There should be one principle site, where medical and social assessments are also conducted.

It is desirable for there to be a number of distribution sites (possibly three) in different locations so that travelling by participants is minimised. A number of considerations are relevant to this:

- Participants who need to visit the clinic three times per day will have difficulty doing so if the travelling time involved is long. Such inconvenience may lead either to people dropping out of the trial or to their waiting at or near the distribution site between administrations, which is likely to be publically unacceptable.
- It is not known to what extent opioids impair the ability to drive safely. While there is evidence that users currently drive under the influence of both legal and illegal opioids (driving under the influence of methadone is legal for those attending methadone clinics), it would be problematic to introduce a trial without detailed knowledge of the effects of opioids on driving. Depending on the results, this may lead to a limitation in the dose prescribed (which is likely to encourage top-ups), requirements for people to stay at the distribution site for a set length of time after

drug adminstration (which may cause space difficulties and inconvenience to participants) or the need to ensure that alternative forms of transport are used (provision of transport would probably be an expensive option).
- More than one distribution point would also make it possible for users to avoid other users if there were personal difficulties.

Extended hours are necessary for a number of reasons. One is to cater for people who are given three doses per day; the doses will have to be spread out across the day. Another is to cater for people in paid employment or who have other constraints on their time who will have to be able to come to the sites before and/or after work. Another is to cope with the volume of people.

While it should not be necessary for each point to be open for 24 hours per day, consideration should be given to at least one distribution site being open at any one time. At least some trial participants may not be able to schedule their visits to distribution points within restricted hours. A disadvantage is that the risks to staff (from, for example, armed robbery) may well be much greater between midnight and 5 am. Public transport is also not available at these hours (and is restricted at weekends).

Recommendation 16. Distribution points should be inconspicuous and should be located in busy public places, close to public transport and to medical facilities.

Distribution points should be inconspicuous and should be located in busy public places so that the people using them can also remain relatively inconspicuous. They should be close to public transport so that they are accessible to people who cannot or do not wish to drive. Because there is always a risk of overdose, the distribution points should be close to medical facilities.

Recommendation 17. The distribution sites and the procedures used will have to be adequately secure to prevent theft of drugs.

Attention will also need to be given to the design of the distribution points from a security angle. Heroin is a highly attractive commodity and there is a real risk of robberies being attempted. Security measures must also be taken to minimise the risk of theft by trial participants and staff.

Recommendation 18. Each distribution point should have a special 'fixing room' where injectable drugs are administered under supervision.

Other design aspects which need to be considered are the provision of 'fixing' rooms where people can inject drugs under supervision and the provision of adequate ventilation if drugs are smoked. There will also need to be suitable waiting rooms and rooms for people to relax after they have administered their drugs.

Recommendation 19. The distribution sites should be staffed by a mixture of medical and non-medical personnel.

It will be essential to have at least some medically trained staff so that the health of trial participants can be adequately assessed and to deal with unforseen emergencies. A mixture of medical and non-medical staff is likely to be most cost-effective and acceptable to the trial participants.

Recommendation 20. Recruitment should not be through widespread public advertisement, rather it should be through low-key methods like word of mouth.

Advertising for such a trial would be illegal under current laws (Volume 2, Chapter 5: Legal Issues), but should also be restricted to avoid attracting people other than dependent users. It is also important that the trial is kept low-key, so that participants can remain inconspicuous. Further, it is important to avoid 'glamorising' heroin use, especially to young people.

A disadvantage of using recruitment techniques such as word of mouth is that recruitment to the trial may be slow and that mis-information or only partial information about the trial may be passed from person to person. Posters at service agencies could partly overcome this problem.

Recommendation 21. No payment should be required for participation in the trial.

The results of the survey undertaken as part of this feasibility study showed that there is a high level of support for charging for trial drugs (see Volume 2, Chapter 8: Attitudes to A Trial, Table 5.5). There are also in principle reasons why participants should pay for the drugs.

However, enforcing payment for trial drugs may be difficult. While this could potentially be solved in a program, it causes a real problem for a limited-term trial. It is likely that issues surrounding payment for trial drugs may influence the outcomes being measured, particularly if there are sanctions for non-payment. This may then make interpretation of the results difficult. Two other factors mitigate against a charge. First, it is unusual for people to be asked to pay to participate in a trial and second, oral methadone is currently available free of charge, so it may be difficult to institute a requirement to pay for that drug.

Recommendation 22. Data collection is fundamental to a trial and the provision of information will be a requirement for trial participation. There are also three other fundamental principles which govern data collection: informed consent, confidentiality, and protection of privacy. Trial participants and researchers should be protected by the Epidemiological Studies (Confidentiality) Act 1981 and/or an ACT equivalent drafted especially for the trial.

As discussed under the rationale for Recommendations 1 and 3, it is essential that a trial asks real questions which can be adequately answered. Data collection is, of course, essential for this. Ethically, it is important that information is only collected from people with their knowledge and consent, and only for specific valid purposes. It is also important that the information is only used for the purposes that it was gathered for (see Volume 2, Chapter 7: Ethical Issues).

Recommendation 23. There should be a register and identification system for trial participants.

There obviously must be some record and identification system for people participating in a trial. The exact form for such a system needs further consideration in Stage 2.

Recommendation 24. There should be appropriate legal protections for trial participants.

This issue is dealt with in Volume 2 (Chapter 5: Legal Issues).

Recommendation 25. The legal protections which will need to be instituted for the use of trial drugs should not be extended to non-trial drugs. In other words use of 'street' drugs should continue to be a criminal offence.

This is not a trial of legalisation but of controlled availability and an important outcome measure is whether or not controlled availability reduces the amount of illegal drug use. The criminality associated with illegal drug use should therefore not be changed. It is intended that this also means that continued use of 'street' opioids is illegal and that trial participants who are arrested for using or selling illegal drugs would be dealt with in the usual way.

Recommendation 26. Use of illegal drugs should not bar people from receiving trial drugs, except when this might lead to a risk of overdose.

If use of illegal drugs was a bar to continuation on the controlled trial, an important outcome could not be measured and it would significantly skew the trial. It might also lead to a large reduction in the number of participants.

Consideration should be given to using information about ‘top-ups’ with illegal street opioids to review the drugs, doses and routes of adminsitration of trial drugs.

Consideration should be given to the possibility of ill-effects through drug interactions. This may occur if trial participants have used street opioids shortly before using trial drugs. It is more likely, however, that ill-effects will result from combining trial drugs

with alcohol or benzodiazepines. Mechanisms for preventing this need careful consideration in Stage 2.

Recommendation 27. At the distribution site, there should be certain behavioural standards which trial participants will be required to meet, including non-violence and courtesy.

This is self-evident.

Recommendation 28. Diversion (i.e. selling) of trial drugs should be strictly forbidden.

It would clearly be undesirable for trial drugs to become available to people not on the trial. Whether or not trial participants try to divert drugs should also be an important outcome measure.

Recommendation 29. There should be sanctions for not meeting behavioural standards and for diversion of trial drugs. Consideration of effective standards should be undertaken in Stage 2. In addition, if people are found to be selling rather than using trial drugs there should be a review of the drugs they are taking and of the doses and frequency of administration. The procedure for imposing sanctions should be clearly laid down and should not be at staff discretion.

Further consideration should be given in Stage 2 to effective sanctions which could be applied. This is likely to be a difficult issue and may need on-going work in Stages 3 and 4.

The Marks/Parry program has found withholding of (in their case, prescription) drugs for varying lengths of time (depending on the infraction) to be effective (see Volume 2: Chapter 6: Options for a Trial - the Marks/Parry Program). A disadvantage of such sanctions is that if people return to using street drugs during the time when trial drugs are withheld, their health is at risk and they commit criminal offenses. It is for this reason that sanctions should not include barring people from the trial.

If trial participants are found to be selling their trial drugs on the street, it is possible that they are receiving higher or more frequent doses of drug than they really need or that they are not receiving their preferred drug (hence selling the drugs they are receiving in order to buy other drugs). It is for these reasons that there should be a review of the drugs they are taking and the doses and frequency of administration. It is unlikely to be problematic to cut down dose or frequency of administration. It will be more difficult to deal with people (in either the opioids or control group) for whom the trial drug is not the drug of choice. This must be given further consideration in Stage 2.

Recommendation 30. There should be no other requirements for behavioural standards.

There should be no other behavioural standards for two reasons. The first is that behavioural change in people on the trial is an outcome measure and should not be artifically manipulated. The second is that it is likely to be difficult to impose sanctions against behaviours committed away from the premises. This can be illustrated with an example. If it was decided that sanctions should be imposed if criminal offences were committed, this could not be done until the person had been found guilty of committing the offenses through the due processes of the law. There is generally a long delay between charging and the court process, by which time the drug trial is likely to be over.

Recommendation 31. There should be no compulsion on trial participants to undertake counselling or other treatment, although these should be freely available and trial participants should be encouraged to use them.

While trial participants should be encouraged to use counselling and other treatment services and these should be freely available, there should be no compulsion on them to do so. It is unreasonable to attach unrelated 'strings' to a trial, as this can be seen to constitute unethical manipulation of people. Compulsion is also unlikely to lead to successful counselling or treatment.

Recommendation 32. Trial participants in both the 'opioids' and control groups should be regularly assessed with regard to their social functioning and referred to appropriate services (legal aid, housing assistance etc) as necessary.

The social functioning of trial participants should be regularly assessed, both as an outcome measure and as a way of helping them improve their lives. This assessment should be the same for both opioids and control groups.

Rather than set up parallel services, referrals should be made to existing services.

Recommendation 33. There should be no compulsion on medical or non-medical staff to work on the trial.

It is clearly unethical to compel staff to work on the trial.

Recommendation 34. Stage 2 of the feasibility study should explore ways to facilitate rotation of trial staff to positions away from the trial, if and when staff request a transfer.

It is possible that working on the trial will be highly stressful. As well as considerations for the well-being of staff, stressed staff also become ineffective; thus, if it is at all possible, it should be easy for staff to transfer away from working on the trial.

Recommendation 35. There should be appropriate legal and safety protections for trial staff.

These legal protections are dealt with in Volume 2 (Chapter 5: Legal Issues). Occupational health and safety considerations are clearly also important.

Recommendation 36. At the conclusion of the trial all participants should have oral methadone available to them. At the commencement of the trial, participants need to understand that there is no guarantee that provision of heroin (or methadone through other than oral routes of administration) will continue after the trial has concluded.

If a trial is successful according to pre-determined criteria established by both opponents and proponents of a trial, there should be some political commitment to instituting a program based on it, so that participants should continue to receive trial drugs. If the trial is unsuccessful, there are likely to be a number of problems associated with continuing trial participants on heroin and routes of administration other than oral. Trial participants should however be guaranteed access to methadone which is the standard treatment.

While this stance can be defended ethically, the issues are not clear-cut. One approach is to argue that, provided that informed consent was given, the participants received the benefits of the trial for its duration, so that there is minimal obligation to them. There is however some argument about whether consent is meaningful when it is given by people for whom a short-term inducement far outweighs possible long-term ill-effects. Another approach is to argue that it is highly likely that the trial will be successful for at least some participants, particularly in allowing them to stabilise their lives in terms of family relationships and employment. Ethically, it would be desirable to continue to provide assistance as long as it was needed in such cases (see Volume 2: Chapter 7: Ethical Issues).

Stage 2 must consider what would happen to trial participants in the time between the evaluation of the trial and the establishment of a long-term treatment program if the trial is successful.

Careful consideration of all these issues may mean that the trial needs to run for more than two years.

On a rather different tack, it is possible that a trial may have unintended negative consequences. It is crucial to have a list of reasons for halting a trial or for modifying it, even before detrimental effects can be shown to be statistically significant (see Volume 2: Chapter 7: Ethical Issues).

Recommendation 37. If in practical terms the methadone program instituted for the control group runs successfully, it should be continued after the trial is terminated.

A secondary evaluation should be made of the control methadone program. If it is found to be more successful than traditional methadone programs, it should be continued. This may best be done by incorporating it into the ACT drug treatment service program.

STAGE 2

Stage 2 requires examination of a number of logistic issues which would affect the structure of a trial. Some of the most important issues which will require careful consideration are outlined below. Stage 2 will only proceed if there is political commitment by the ACT Legislative Assembly. It is also possible that these logistic considerations will determine that Stage 3 should not proceed or that the proposed structure of the trial should be radically altered.

It is important that the issues to be addressed in Stage 2 are considered, where appropriate, in an extensive and continiung process of consultation with community groups, police, relevant service providers and illegal drug users.

Research Issues

There should be further research with community groups, police, relevant service providers and illegal drug users on the above recommendations to determine whether or not a trial so structured should proceed.

Careful consideration must be given to the measurement of outcomes. A process should be instituted whereby both proponents and opponents of the trial can nominate which outcomes should be measured. There needs to be a careful review of reliable and valid ways of measuring these outcomes. It may be necessary to develop new instruments and techniques and to conduct reliability and validation studies of new and existing methodologies.

Evaluation techniques should be developed for determining if illicit opioid users who have not sought treatment before are attracted to the trial and if the trial has measurable benefits to society at large, in terms of reducing the level of drug-related problems and the social and economic costs of drug use.

Evaluation techniques should be developed for determining if the trial improves relationships and lifestyles from the point of view of family members and others close to trial participants. They also need to be developed for mesuring the effects of the trial on existing drug treatment services and on law enforcement.

Evaluation techniques should also be developed for measuring unintended negative and positive effects of a trial.

Because a trial may have unintended negative effects, it is crucial to develop a list of reasons for halting a trial or modifying it, even before detrimental effects can be shown to be statistically significant.

Research also needs to be conducted into possible ways of measuring 'incentive effects' for non-dependent users (i.e. the number becoming dependent in order to qualify for a place on the trial).

Detailed methodology should be developed for measuring the cost-effectiveness of such a trial.

Criteria to judge whether the trial methadone 'program' has been successful need to be established.

Further research needs to be undertaken into estimating the number of heroin users in Canberra and the number likely to seek and be eligible for participation in a trial.

Careful consideration needs to be given to the number of trial participants needed in order to be able reliably to detect differences in various outcome measures between the opioids and control groups.

Further information should be collected on injecting behaviour (especially frequency) among heroin users, to determine the effects of restricting the number of administrations per day.

Research needs to be conducted into the development of tolerance to opioids among dependent users and the implications this may have to setting upper limits for the trial drug doses.

There should be careful review of cannabis and other illegal drug use in the likely trial population and of the potential of continued cannabis and other illegal drug use to influence the success of the trial.

Research should be conducted into the reliability and cost of using analysis of hair to monitor trial opioid and illegal drug use.

Research needs to be undertaken on the effects of heroin on the ability to drive safely.

Current information on the health effects of both active and passive smoking of herbal cigarettes needs to be assessed.

Research needs to be conducted into how well heroin is absorbed by the body when smoked.

The value of naloxone eye drops as a screening tool for people who apply to be part of the trial needs to be assessed.

Current information on the comparative effects of heroin and methadone on maternal and fetal health during and after pregnancy needs to be assessed.

Current information on the comparative effects of methadone and heroin, and of injecting itself, on the progression of HIV needs to be assessed.

Consideration needs to be given to the effects on the ability to evaluate the trial if it includes people who are HIV positive or have hepatitis B or C, people under the age of 18 and people referred to the trial from the court system. This needs to be balanced against other considerations for these groups.

Current information about drug interactions needs to be assessed and further research may need to be conducted.

Issues Relevant to the Day to Day Running of the Trial

A number of practical issues must be resolved through consultations with police, relevant service providers and illegal drug users. They include:

- the likely impact of restricting the number of administrations to three per day.
- the maximum dose of heroin and methadone to be prescribed.
- the structure of the initial interviews with people seeking trial participation to ensure that they would not be willing to undertake some other form of treatment and that they are not primarily attracted by the possibility of obtaining methadone under a more liberal regime.
- screening criteria for trial participants.
- how residency criteria could be enforced.
- the review process to ensure that trial participants are given adequate opportunity (without coercion) to reduce the harm associated with their drug using behaviour and that the review is comparable for the 'opioids' and control groups.
- options which should be made available for people who become HIV positive and to women who become pregnant while on the trial.
- criteria for reviewing the social functioning of trial participants.
- the process which will be gone through each time the trial participant is administered the drug. Problems may result from interactions between opioids and tranquillisers, and opioids and alcohol and there needs to be some way of checking that trial participants have not been using other drugs which may put them in danger. Similar considerations also apply if trial participants continue to use illegal opioids.
- the hours distribution sites should be open.
- ways of dealing with users if they congregate at or near distribution points.

- ways in which trial participants can safely access distribution points, particularly if it is found that heroin significantly impairs the ability to drive safely.
- under what conditions trial participants should be given take-home methadone.
- how trial participants can best be recruited.
- sanctions for diversion of trial drugs.
- the likelihood of violence and ways of dealing with it, including sanctions.
- criteria for administering sanctions.
- ways to minimise the stressful and unpleasant aspects of the work of trial staff.

In addition, detailed consideration must be given to whether or not people resident in Queanbeyan should be able to participate in the trial. Legal and policing issues are particularly important if Queanbeyan residents can participate and likely effects on housing and welfare services in the ACT as well as 'hassling' of trial particpants are important if they cannot participate.

Administrative Issues

A source for the heroin to be used in the trial needs to be determined.

Initial drafting for changes to ACT legislation should be undertaken.

Changes which need to be made to New South Wales and Victorian laws need to be determined.

Possible locations for distribution sites need to be determined.

Expert consultants should be hired to advise on the range of security issues relevant to the trial.

Expert consultants should be hired to advise on the best design for waiting rooms and entrances and exits to minimise the contact trial participants have with each other. Expert advice is also needed on ventilation.

Further consideration should be given to the desirability of allowing reliable trial participants to take methadone home.

There needs to be liaison with welfare, housing and other services to facilitate a smooth referral process for trial participants facing social difficulties.

Consideration must be given to a number of health and safety issues for trial staff, including ways of minimising the possibility of needle-stick injuries and avoiding the passive ingestion of drugs (if, for example, they are smoked by trial participants).

Careful consideration must be given to the possible circumstances, if any, under which the identity of trial participants might be revealed, so that this can be included in the process of seeking informed consent.

Consideration must be given to an effective way of obtaining informed consent to the conditions of trial termination.

Consideration must be given to the exact way in which the recommendations for trial termination would be implemented to minimise risks to trial participants. The wind-down of the trial needs to be carefully planned and budgeted for.

CONCLUSIONS

A trial such as the one proposed is not without problems. An attempt has been made to deal even-handedly with both the advantages and disadvantages of the strategy outlined, so that informed decisions can be made about the desirability of proceeding further. We believe there is a case for proceeding to the next stage.

The consequences of a decision not to proceed need to be considered carefully. The reasons which led to the enquiry remain and we have identified considerable community support for new approaches to the problems. Our study has unquestionably raised expectations in some quarters that change is a serious option.

Stage 1 has established a precedent for consultation with the community, police, relevant service providers and illegal drug users. For an issue as contentious as this, continuing consultation with all of these groups should be a central pillar for decision making.

TABLE OF CONTENTS

VOLUME 2: BACKGROUND PAPERS