



ATODA Submission to the ACT Budget Consultation 2011 – 2012 Excerpt

Attachment A: Increased Access to Naloxone Trial Proposal

A1. Proposal

To reduce the incidence of death, disability, and injury from opioid overdoses in the ACT by conducting an overdose prevention program targeted at people who may be present at an opioid overdose, which includes an evaluated trial of the implementation of naloxone distribution.

A2. Background and Rationale

Opioid overdose is a continued and substantial contributor to death, disability, and injury among individuals who misuse opioids in the ACT. Since 2000, reduced heroin availability has drastically reduced the number of fatal and non-fatal heroin overdoses in Australia.ⁱ However, this period has also seen a substantial increase in the number of prescriptions for pharmaceutical opiates, such as MS Contin and OxyContin. The diversion of these pharmaceutical opiates, and their use in conjunction with other depressant drugs, such as alcohol, benzodiazepines, and heroin are leading to an increase in the number of opiate-related overdoses in Australia.ⁱⁱ In the first six months of 2010, the ACT Ambulance Service responded to more than 40 suspected heroin overdoses. However an ambulance is only called to a minority of overdoses.ⁱⁱⁱ

If warnings of an influx of heroin into Australia over the coming years^{iv} prove to be correct, the incidence of fatal and non-fatal opioid overdoses is likely to increase. Consequently, it is in the interests of the ACT Government and community to implement strategies to reduce opioid overdoses now, so that preventive interventions can be evaluated and refined before the number of overdoses increases further.

A3. Increased availability of naloxone to reduce overdose deaths

Since the 1990s, there have been repeated calls from researchers, public health professionals, advocates, and user groups to initiate trials allowing heroin users, their peers, and family members with access to naloxone for use in instances of heroin overdose.

Naloxone (Narcan ©) is an opiate antagonist used specifically to reverse the effects of opioid overdose. It is widely used in Australia and internationally by paramedics and emergency room staff in cases of suspected opioid overdose. It is usually administered intramuscularly in pre-hospital settings. It has no psychoactive effect, is

not a drug of dependence, and therefore, is not a substance which is likely to be diverted or misused.

An Australian review of the literature on peer administered naloxone was undertaken by Lenton and Hargraves in 2000.^v They concluded that making naloxone available to peers of heroin users showed promise in reducing the number of fatal overdoses as part of a comprehensive overdose response.

The Australian National Council on Drugs, in a series of position papers addressing heroin-related overdose, supported these claims and nominated a number of options to increase the availability of naloxone.^{vi} One of these options was: “Distribute naloxone widely, for use by injecting drug users and their peers, families and friends.” However, due to the rapid decline in the number of heroin-related deaths since 2000, such attempts were not pursued. Anex, a national leader in public health, has recently released a position paper on naloxone distribution in Australia.^{vii}

The argument for the wider distribution of naloxone stems from findings that show that:^{viii}

- People who inject drugs commonly experience overdose;⁷⁻⁸
- Overdoses are often witnessed by people who can respond;⁹⁻¹⁰
- Peers, family members and others can successfully respond to assist in the management of overdoses among people who inject drugs;¹¹⁻¹² and,
- Peers and family members are keen to respond to overdoses if they occur.¹⁰
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A4. Aims and Strategies

The primary aim of the program is to reduce opioid overdose-related morbidity and mortality, through:

- Increased effectiveness of interventions in opioid overdose management;
- Provision of comprehensive overdose management training;
- Provision of take-home naloxone to identified program participants; and,
- Reduction in opioid overdose through overdose prevention education.

Additional expected benefits include a reduction in costs to the ACT health system through a reduction in ambulance call outs and a reduction in hospitalisation as a result of opioid overdose.

A5. Evidence of Effectiveness and Safety

Since 2000, international evidence has accumulated demonstrating that making naloxone available to appropriately trained injecting drug users, family members, and outreach workers can lead to successful overdose reversal with few, if any, adverse effects.^{ix,x,xi}

A 2010 survey identified 155 programs operating in 16 states in the USA with 53,339 naloxone kits having been dispensed and 10,194 overdose reversals reported.^{xii} Where evaluations of these programs exist, none of the major concerns raised by some commentators (e.g. unsafe administration of naloxone, problems with re-intoxication where longer acting opioids had been used, or more risky drug use if

heroin was to be seen as less dangerous) eventuated.^{xiii} This evidence has led to renewed calls in Australia and the ACT to support wider access to naloxone.^{xiv,xv}

Australian experts in this field^{xvi} have identified that ‘peer’ and other wider naloxone distribution programs established overseas have clear evidence that:

- Peers and non-medically trained professionals can be trained to administer naloxone for overdose reversal;^{12 14-18}
- People who come into contact with people experiencing opiate overdose can recognise the signs of overdose and administer naloxone appropriately;¹⁴
- Naloxone that has been administered in the context of these programs has successfully reversed the effects of overdose; and, ^{12 15-17 19 20}
- Having naloxone as part of overdose response training assists those present to respond to overdose¹⁹ and helps engage otherwise hard to reach populations of drug injectors to contact service agencies.¹⁵

A6. Priority groups

Individuals who die from heroin overdose tend to be single, unemployed men aged in their late twenties and thirties, with a long history of dependence. Individuals not in treatment, those combining opioids with alcohol or benzodiazepines, and those with a recently depleted tolerance to opioids are also at elevated risk.^{xvii} These risk factors help to identify priority populations for opioid overdose prevention strategies in the ACT. These populations include: people exiting prison, people exiting opioid detoxification, people exiting opioid maintenance therapy, and Aboriginal and Torres Strait Islander injecting drug users.

A6.1 People exiting prison

People with a history of heroin dependence are at an elevated risk of overdose in the four weeks immediately following release from prison.^{xviii} This is because of a reduced tolerance to opioids following periods of abstinence or opioid maintenance therapies. Consequently, recently released prisoners are priority groups for interventions which reduce the risk of fatal and non-fatal opioid overdose. Making naloxone available to injecting drug users is one manner in which the risks of overdose after release from prison can be addressed.

Incorporating a comprehensive overdose prevention strategy for at-risk prisoners in the period prior to release, combined with increased access to naloxone among non-incarcerated injecting drug users, is likely to have an impact on the number of fatal opioid overdoses in this population.^{xix} Any trial of increased availability of naloxone should consider targeting peers or family members of injecting drug users who are due for release from the Alexander Maconochie Centre and/or the prisoners themselves.

A6.2 Aboriginal and Torres Strait Islander Injecting Drug Users

The number of Aboriginal and Torres Strait Islanders who inject drugs is increasing as a proportion of the total injecting drug using population.^{xx} Additionally, this group is less likely to be in treatment and more likely to be incarcerated than other injecting drug users.^{xxi} Aboriginal and Torres Strait Islander people are often at an elevated risk of overdose compared with other populations. Given this, Aboriginal and Torres Strait Islander people should be considered a priority group for any opioid overdose

prevention program, including the provision of naloxone. Training individuals who have an understanding of Indigenous cultural practices and conventions and regular contact with Aboriginal and Torres Strait Islander injecting drug users may be able to help reduce overdose deaths, disability, and injury among this population.

A7. Policy Context

The program is:

- Consistent with the principles of continuity of care emphasised in the *ACT Adult Corrections Health Services Plan 2007 – 2010*;
- Consistent with initiatives being undertaken through the Alexander Maconochie Centre including the throughcare and evaluation of drug polices and services at the Alexander Maconochie Centre;
- Consistent with and progresses Actions 20, 36, 50, 59 from the *ACT Alcohol, Tobacco and Other Drug Strategy 2010 – 2014*;
- Consistent with and progresses Action 26 from the *A New Way: The ACT Aboriginal and Torres Strait Islander Health and Family Wellbeing Plan 2006 – 2011*;
- Strategically aligned with the development of the *National Pharmaceutical Misuse Strategy*, as agreed to by the Ministerial Council on Drugs; and,
- Consistent with the National Heroin Overdose Strategy that states “*It is important to engage drug users in the development of strategies as this may enhance uptake and effectiveness, and accordingly drug users, and drug user organisations have an important role to play in this Strategy*”.^{xxii}

A8. Issues for consideration

A8.1 Comprehensive program to address overdose

A naloxone trial will need to be part of a comprehensive overdose prevention program, which will increase its effectiveness and result in fewer adverse events than may otherwise be the case.^{xxiii,xxiv} Comprehensive training programs for people who are provided naloxone will need to be developed and evaluated. Training programs can be modelled on those used in the USA by services such as the Chicago Recovery Alliance. Such a program will need, at a minimum, to address the following:

- Risk factors and prevention techniques for opiate overdose;
- Signs and symptoms for the early recognition of opiate overdose;
- Prevention of choking and aspiration in the unconscious patient;
- Techniques for rescue breathing;
- Routes of administration and dosing guidelines for Naloxone;
- Blood-borne virus risks and universal precautions;
- Protocols for follow up care;
- Protocols for maintenance, safe storage, and replacement doses; and,
- Information and instructions on participating in an evaluation component of program.

A8.2 Scheduling of Naloxone

Naloxone is a schedule 4 drug and therefore needs to be provided through prescription. Program participants could be provided with a prescription of naloxone that is to be administered to them by a third party. “Any schedule 4 drug can be

prescribed for use with the primary restriction being that the drug will be used on the patient for whom the drug is prescribed in accordance with the doctor's instructions.^{xxv}

If naloxone was re-scheduled in the future to schedule 3, this would remove the necessity for a prescription and allow over the counter availability. Re-scheduling naloxone from schedule 4 to schedule 3 could be achieved through ACT Health or a professional association making an application through the Therapeutic Goods Administration.^{xxvi}

A8.3 Duty of Care

Individuals who administer naloxone could place themselves at risk of criminal prosecution or civil liability.^{xxvii} Regardless of any need to legislate, clarification must be obtained as to any duty of care arising from administering naloxone in emergency situations and to define what standard of care is necessary, if any. Possible legislative options include the following:

- Amendment to the ACT Civil Law Act 2002 - Remove the specific mention of 'impairment by a recreational drug' to ensure bystanders who administer naloxone are protected from liability under this Act;
- New legislation that specifically addresses issues related to naloxone administration; and/or,
- Amend current legislation to protect third parties who act in good faith administering a life saving drug (Good Samaritan legislation). The United Kingdom has implemented such legislation.

A8.4 Community Acceptance

Making naloxone available to injecting drug users is consistent with an Australian culture of resuscitation. Increasing the availability of naloxone in the community is analogous to the introduction of public access defibrillators through Project HeartStart Australia^{xxviii} or supplying persons with an allergy an epi-pen for use in case of an allergic reaction. Individuals should be promoted to act in ways that save lives, even when such actions incur some risks. The risks, in the case of naloxone, are minimal.

This pilot program would be the first in Australia to distribute naloxone with the intention of making it a permanent part of our community's response to minimising the harms caused by opioids. Ensuring the support of the ACT community for the program is important. Several key stakeholders have expressed their support, including:

- Specific General Practitioners (GP) have expressed interest in participating in the trial;
- ACT Division of General Practice's GP adviser for alcohol and other drug issues has given support;
- Illicit drug users, user groups, peers and families;
- ACT Ambulance Service;
- Alcohol, tobacco and other drug treatment services; and,
- Researchers and technical experts.

The ACT Minister for Health has also stated:

“I am very keen to see a trial like this in the ACT. I think it makes an incredible amount of sense. And I think we are a community that would support a proposal like this.”^{xxix}

A Committee has been established to drive the development and design of the proposed trial.

A9. Program Design and Evaluation

The program will include:

- A governance model, including advisory structures;
- Training and education as part of a comprehensive response to overdose; and,
- An evaluation, which can be informed by protocols that have been used in other countries.

The evaluation would contribute to the evidence base both within the ACT, nationally and internationally.

A10. Funding Estimates

Preliminary estimates are that the initiative could be trialled for 24 months at a cost of \$100,000 annually. This estimate includes:

- \$50,000 for a service to implement the program; and,
- \$50,000 for external research consultancy and evaluation of the trial.

- ⁱ Degenhardt L, Day C, Gilmour, S, Hall, W. (2006) The 'lessons' of the Australian 'heroin shortage'. *Substance Abuse Treatment and Prevention*; 1: p. 11.
- ⁱⁱ Degenhardt, L, Rozbourgh, A. (2007) *Accidental drug-induced deaths due to opioids in Australia, 2005*. Sydney: National Drug and Alcohol Research Centre.
- ⁱⁱⁱ Powis B, Strang J, Griffiths P, Taylor C, Williamson S, Fountain J, Gossop M (1999) Self-reported overdose among injecting drug users in London: Extent and nature of the problem. *Addiction*. 1999 November, 94(11): pp1745-6.
- ^{iv} Ass. Prof. Ali R (March 2009) Australia at Risk of Increased Quantities of Heroin Coming In, Australian National Council on Drugs, Media Release. Available online at: <http://www.ncnd.org.au/media-releases/australia-at-risk-of-increased-quantities-of-heroin-coming-inmarch-2009.html>
- ^v Lenton S, Hargraves K. (2000) Should we trial the provision of naloxone to heroin users for peer administration to prevent fatal overdose. *Medical Journal of Australia*; 173: pp. 260-3.
- ^{vi} Australian National Council on Drugs (2001) *Naloxone availability: A Secondary Position Paper on Heroin Related Overdoses*. ANCD Position Paper. Canberra. Available online at: http://www.ncnd.org.au/images/PDF/Positionpapers/pp_heroin_overdoses3.pdf.
- ^{vii} Anex (2010) *Lifesavers: A position paper on access to Naloxone Hydrochloride for potential opioid overdose witnesses*. Anex, Melbourne, Australia. Available online at: <http://www.anex.org.au/downloads/AnexPositionPaperNaloxoneOctober2010.pdf>
- ^{viii} Excerpt from: Dietze P, Lenton S. (2010) *The case for the wider distribution of naloxone in Australia*. (unpublished)
- ^{ix} Green T.C, Heimer R, Grau L.E. (2008) Distinguishing signs of opioid overdose and indication for naloxone: an evaluation of six overdose training and naloxone distributions in the United States. *Addictions*; 103: pp. 979-89.
- ^x Piper T, Rudenstein S, Stancliff S, et al. (2007) Overdose prevention for injection drug users: lessons learned from naloxone training and distribution programs in New York City. *Harm Reduction Journal*; 4: p. 3.
- ^{xi} Kim D, Irwin K.S, Khoshnood K. (2009) Expanded access to naloxone: options for critical response to the epidemic of opioid overdose mortality. *American Journal of Public Health*; 49: pp. 172-7.
- ^{xii} National Conference of the Australasian Professional Society on Alcohol and Other Drugs (1 December 2010) Building Capacity in Overdose Prevention. *Symposium: Increasing community access to naloxone to prevent opioid overdose deaths: lessons for Australia*. Canberra: APSAD.
- ^{xiii} Green T.C, Heimer, R, Grau L.E. (2008) Distinguishing signs of opioid overdose and indication for naloxone: an evaluation of six overdose training and naloxone distributions in the United States. *Addictions*; 103: pp. 979-89.
- ^{xiv} Lenton C, Dietze P.M, Degenhardt L, Darke S, Butler T.G. (2009) Editorial: Now is the time to take steps to allow peer access to naloxone for heroin related overdose in Australia. *Drug and Alcohol Review*; 28: pp. 583-85.
- ^{xv} Lenton C, Dietze P.M, Degenhardt L, Darke, S, Butler T.G. (2009) Naloxone for administration by peers in cases of heroin overdose. *Medical Journal of Australia*; 198: p. 469.
- ^{xvi} Excerpt from: Dietze P, Lenton S. (2010) *The case for the wider distribution of naloxone in Australia*. (unpublished)
- ^{xvii} Australian National Council on Drugs (2001) *Naloxone availability: A Secondary Position Paper on Heroin Related Overdoses*. ANCD Position Paper. Canberra. Available online at: http://www.ncnd.org.au/images/PDF/Positionpapers/pp_heroin_overdoses3.pdf.
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- ^{xx} Return on Investment 2: DoHA (2009) available online at p163 or 168: [http://www.nchecr.unsw.edu.au/NCHECRweb.nsf/resources/Reports/\\$file/RO-2ReportLQ.pdf](http://www.nchecr.unsw.edu.au/NCHECRweb.nsf/resources/Reports/$file/RO-2ReportLQ.pdf)
- ^{xxi} National Indigenous Drug and Alcohol Committee (2009) *Bridges and Barriers*. ANCD, Canberra. Available online at: http://www.nidac.org.au/images/PDFs/nidac_bridges_and_barriers.pdf
- ^{xxii} Commonwealth Department of Health and Aged Care (2001) *National Heroin Overdose Strategy*, Australian Government, Canberra
- ^{xxiii} Piper T, Rudenstein S, Stancliff S. et al. (2007) Overdose prevention for injection drug users: lessons learned from naloxone training and distribution programs in New York City. *Harm Reduction Journal*; 4: p. 3.
- ^{xxiv} Sherman S, Gann D, Scott G, Carlberg S, Bigg D, Heimer R. (2008). A qualitative study of overdose-responses among Chicago IDUs. *Harm Reduction Journal*; 5: p. 2.

^{xxv} Best D, et al (2001) *Overdosing on opiates*. Part 11- Prevention. Drug and Alcohol Findings. Issue 5: pp. 4-18

^{xxvi} New scheduling arrangements will come into force on 1 July 2010 and the NDPSC will be replaced by the Secretary of the Department of Health and Ageing (DoHA) - or her delegate - as the decision maker for the scheduling of medicines and chemicals. Two new expert advisory committees, the Advisory Committee on Medicines Scheduling and the Advisory Committee on Chemicals Scheduling, will be established to provide advice and make recommendations to the Secretary (or delegate) on medicines and chemicals scheduling decisions. The finer details of the revised scheduling process are currently being developed but are expected to be made available shortly. More information on these new scheduling arrangements can be found on www.tga.gov.au/ndpsc.

^{xxvii} Williams, P, Urbas, G. (2001) Heroin Overdose and Duty of Care. Australian Institute of Criminology *Trend and Issues in Crime and Criminal Justice* No. 188. AIC: Canberra.

^{xxviii} St John Ambulance Australia website for Project HeartStart Australia:

http://www.stjohn.org.au/index.php?option=com_content&view=article&id=37&Itemid=51

^{xxix} Radio interview on the ABC with ACT Health Minister, Katy Gallagher (1 December 2010) Available online at:

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