



# ANCD POSITION STATEMENT

## Expanding Naloxone Availability

September 2012

- Opioid overdoses are estimated to cause approximately one death per day in Australia;
- Though there are no national data on non-fatal overdoses, which can cause injuries and brain damage, overdoses are commonly experienced by people who use drugs;
- Overdoses are often witnessed by other people and these witnesses are eager to respond when overdoses occur;
- The opioid antagonist naloxone can quickly reverse the effects of opioid overdose;
- A substantial body of evidence shows that expanding naloxone availability and training potential overdose witnesses to administer naloxone is a remarkably safe and effective intervention for preventing opioid overdose fatalities, with the potential to prevent opioid overdose related injury;
- There is no evidence that expanding naloxone availability encourages riskier drug use or has any other adverse consequences;
- There are no legal barriers to expanding the availability of naloxone to potential overdose victims, nor to training potential overdose witnesses in its administration;
- The training of potential overdose witnesses in the use of naloxone can effectively be integrated into comprehensive overdose prevention and response training programs;
- To date only the Australian Capital Territory (ACT) has introduced a program to train potential overdose witnesses in the use of naloxone as part of comprehensive overdose prevention and response training.

In September 2000 the Australian National Council on Drugs (ANCD) released a primary position paper on Heroin Related Overdoses. This was complemented in June 2001 by the release of a series of secondary position papers, which provided detail and implementation advice to governments on specific strategies highlighted in the original position paper to reduce heroin related overdoses. One of those strategies was to expand the availability of naloxone (Narcan).

Naloxone, an opioid antagonist, can quickly reverse the effects of opioid overdose. It is regularly used by paramedic or emergency department staff when attending overdose incidents, and is effective for overdose from heroin, prescription opioids (e.g. Oxycontin or MS Contin), and other opioids. However, the time between the identification and reporting of an overdose and naloxone administration by paramedic staff can significantly increase the risk of fatality or permanent injury to the victim. In addition, an ambulance may not be called in all overdose situations. The ANCD's 2001 naloxone availability position paper presented options that could be implemented to minimise delay in administration of naloxone to a victim of opioid overdose, together with a series of recommendations.

They were (1) That naloxone be made available in all ambulances and that all paramedics are trained in its use; (2) That a trial be conducted, making naloxone available for use by frontline workers such as needle and syringe program workers, outreach workers, drug and alcohol workers and possibly police, with appropriate training for all those to be involved; and (3) That further investigation to assess the efficacy, issues (legal, training etc) and consequences associated with making naloxone more available (e.g. to families of drug users in treatment and peers), be conducted.

Since these recommendations were made, a reduction in the supply of heroin in Australia and a shift in the patterns of drug use occurred; resulting in a reduction in heroin related overdoses and deaths. While not reducing the need to promote the availability of naloxone, the perception of urgency had been diminished. Since 2004 the year-on-year reduction in the number of accidental deaths due to opioids in Australia has ended, and concerns about the consequences of an increase in the prescription of pharmaceutical opioids are starting to be realised. Approximately one death per day occurs from opioid overdose in Australia, and there are indications that the number of non-fatal overdoses, which may lead to permanent injuries or other health problems, are increasing.

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This time has also seen an increase in the evidence supporting strategies to improve the availability of naloxone, and international examples of safe and successful programs to distribute naloxone for administration by peers. In 2012, the UN Commission on Narcotic Drugs' resolution on drug overdoses recognised the role of naloxone in reducing mortality and as part of a comprehensive approach to services for people who use drugs.

Until recently, there had been little movement by any Australian government towards expanding the availability of naloxone. Some emergency services staff have still not been authorised to administer naloxone, and no trials of expanding naloxone availability have been conducted in Australia. Legal and regulatory issues which may be barriers to expanding naloxone availability throughout Australia over the longer term still need to be addressed.

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EXPANDING THE AVAILABILITY OF NALOXONE TO POTENTIAL OVERDOSE WITNESSES, INCLUDING FRONTLINE WORKERS, EMERGENCY SERVICES STAFF, PEOPLE WHO USE DRUGS, THEIR FRIENDS AND FAMILIES, AND OTHER POTENTIAL OVERDOSE WITNESSES IS LIKELY TO HELP REDUCE THE IMPACT OF OPIOID RELATED OVERDOSES.

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As naloxone is currently a Schedule 4 (prescription only) medication licensed for the treatment of opioid overdose, there are no direct legal barriers to providing naloxone on prescription to persons at risk of overdose. In December 2011, a program to train potential overdose witnesses in overdose management and provide naloxone on prescription to people at risk of opioid overdose, was launched in the ACT. The Implementing Expanded Naloxone Availability in the ACT (I-ENAACT) program aims to train 200 participants over two years. Take-home doses of naloxone will be prescribed to eligible participants by a General Practitioner on completion of the training.

The training program has been developed from international models, and includes information on recognising an opioid overdose, risk factors for overdose, appropriate responses to overdose including naloxone administration, and how to store and manage a supply of naloxone.

The ANCD supports the I-ENAACT program. In light of these events the ANCD has reconsidered the issue and a number of options which could be used to further increase the timely administration of an opioid antagonist to a victim of an opioid overdose. The issues and evidence discussed and the results of these deliberations are presented below.

## Overdose in Australia

In Australia fatal overdoses involving opioids such as heroin have reduced since their peak in 2000. Unfortunately, at the time of writing there is no current data available on opioid overdose deaths. The most recent figures available, which may be an underestimate, are for 2009, when 433 accidental deaths due to opioids were reported. A 2005 change in the counting procedures adopted by the Australian Bureau of Statistics (ABS) also makes it problematic to compare overdose death rates before and after this date. The lack of current data on fatal overdoses impacts on policy and planning and is itself an issue of concern. Anecdotal reports indicate that overdose incidence is increasing. In addition, evidence in some jurisdictions indicates increases in the number of ambulance callouts to non-fatal opioid overdoses and to pharmaceutical opioid-related incidents over the past five years. Non-fatal overdoses can lead to brain damage or injury. Possible increased availability of heroin in Australia over the coming years and the continued growth in the misuse of pharmaceutical opioids suggest that deaths and injuries due to overdose are likely to increase rather than decrease in the future.

Stable or decreased rates of deaths and injuries from overdose would not diminish the need for intervention. However this situation does highlight the importance of implementing strategies to reduce fatal and non-fatal opioid overdoses, and expand access to these strategies, in the current environment, rather than waiting to react when fatalities and injuries are likely to be further increasing.

Expanding the availability of naloxone to potential overdose witnesses, including frontline workers, emergency services staff, people who use drugs, their friends and families, and other potential overdose witnesses is likely to help reduce the impact of opioid related overdoses. Death associated with opioid overdose typically occurs within 1-3 hours of taking the drug. Depressed breathing during this time is also known to place individuals at risk of brain damage due to hypoxia. Other injuries can occur as a result of overdose. Consequently, administering naloxone as soon as possible is of the utmost importance if deaths and injuries due to overdose are to be prevented.

## Rationale for expanding naloxone administration programs

A number of studies have estimated that no medical help is called in up to half of all overdoses (although recent research in this area suggests that the rate of ambulance calls to overdoses has improved in Australia over the last two decades). However, another person is present in approximately 60 percent of overdose situations. Because peers, family members, and other lay people are often the first to find an individual who has overdosed, they may be able to administer naloxone quickly. With an increase in the prescription of pharmaceutical opioids, a growing number of family members may be placed in situations where the need and opportunity to administer naloxone arises.

Peer administration of naloxone could also contribute to the development of a culture of community resuscitation and rescue, extending on other public health interventions such as Public Access Defibrillators for sudden cardiac arrest or the use of epipens for anaphylaxis. The I-ENAACT program, and similar programs which could be instituted throughout Australia, will enable family members and peers to administer naloxone prescribed to people at risk in the event of an overdose, after taking part in training.

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NALOXONE DISTRIBUTION PROGRAMS IN THE USA HAVE ACCOUNTED FOR OVER 10,000 DOCUMENTED OVERDOSE REVERSALS OVER THE LAST 15 YEARS.

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### Evidence

Peers and family members of people who use drugs, and other potential overdose witnesses, have been shown to successfully administer naloxone to reverse opioid overdose with few, if any, adverse effects. The evidence indicates that making naloxone available to potential overdose witnesses is effective and safe. Much of this evidence comes from the United States of America (USA) where more than 150 programs distributing naloxone for administration by peers have operated over the last 15 years, the first programs commencing in 1996. These programs have accounted for more than 10,000 documented overdose reversals. Several studies have also shown that naloxone programs are associated with local reductions in overdose fatality rates. A recent study providing support for a causal link between naloxone availability and reductions in overdose fatalities examined 18 cities in Massachusetts, some of which had naloxone training and supply programs locally. The study showed that training of more than 150 persons per 100,000 of the population reduced fatal overdoses by approximately 25 percent (using a comparison between areas which did and did not have naloxone administration training and supply programs).

Naloxone is also available to potential overdose witnesses in Canada, Germany, Russia, Spain, Norway, China, Vietnam, Afghanistan, and other countries; and has been available over-the-counter in Italy since 1995. Essentially, the evidence arising from trials and programs shows that naloxone administration by trained peers is a remarkably safe intervention. Medical complications from naloxone administration are rare and in general limited to symptoms of opioid withdrawal. Peer administration of naloxone carries lower risks than peer administration of adrenaline for anaphylaxis, or glucagon for diabetic insulin reaction.

The concerns raised about expanding naloxone availability have proved unfounded. For instance, one concern was that re-intoxication followed by re-occurrence of overdose may follow naloxone administration due to the shorter half-life of naloxone than of most opioids, and this could lead to more fatalities or injuries if naloxone were administered in place of calling medical help. Although re-intoxication can occur, there have been no reports of fatalities following this occurrence in any peer-administration naloxone program, and published epidemiological follow-up studies of people revived using naloxone have found the same result. Thus, the evidence shows that fatalities associated with re-intoxication following naloxone administration are extremely rare.

Other concerns included that naloxone availability could encourage riskier drug use, or contribute to the spread of blood borne viruses. There is no evidence that these consequences have eventuated in any of the above locations. Similarly concerns that naloxone supplies may be stored incorrectly, decreasing their efficacy, are unlikely to be realised. Although it is preferable that naloxone be stored in accordance with the manufacturers' recommendations, one manufacturer reports that it has been stored at 40°C for six months and frozen for up to one month without compromising its chemical stability, and studies show it remains viable if stored under recommended conditions for more than 5 years. Further, naloxone programs in progress indicate that people who use drugs can manage their own personal supply of naloxone when trained appropriately. Recent findings around the use of intranasal naloxone sprays could also provide a simpler means of administration in future – indeed some programs already distribute naloxone for intranasal use.

Another concern is that persons administering naloxone would be less likely to call for medical help. Several studies indicate that medical help is called after naloxone administration at least as often as in overdose situations where naloxone is not available for administration, but in neither case is the rate of medical help being called very high. In this regard it is important to emphasise that I-ENAACT is a comprehensive overdose management program, and training in the use of naloxone is only one component of the training offered. The importance of obtaining medical help for anyone suffering an overdose is also part of the I-ENAACT training program and other programs developed in Australia should similarly make sure to emphasise this important step in any overdose response. Having well executed and effective protocols between ambulance services, police and drug consumer organisations which reinforce calling an ambulance and provide assurance that police do not routinely attend at overdoses, unless ambulance staff feel threatened, is also likely to be important in this regard.

No rigorous cost-effectiveness analyses of naloxone supply and training programs are available at the time of writing. However, naloxone is inexpensive, training programs can often be integrated into pre-existing overdose education and management programs or other outreach programs, and the potential gains of the intervention are significant in terms of lives saved while potential social or economic costs are low. Thus it is likely that training and supply programs will be very cost-effective.

There have also been several unexpected benefits of peer administration of naloxone revealed in the international research (although it should be noted that studies have not always systematically investigated these effects). Naloxone administration training programs are a useful outreach tool and can help promote awareness of overdose management and response more generally. There is some evidence that peer-to-peer education on overdose management and response can occur after training of potential overdose witnesses. There are also indications that people undertaking naloxone administration training programs may, as a result, be more likely to reduce drug use, enter treatment, and be tested for blood-borne viruses. Program participants (both those who use drugs and their peers and family members) have also reported that being able to administer naloxone is empowering, and that training programs promote positive messages of care for a marginalised social group.

Given the substantial body of international evidence regarding efficacy and safety, the ANCD believes that there is no longer a need to conduct trials in Australia. It is however important to evaluate the I-ENAACT program, and any similar programs introduced, in order to contribute to the evidence base and in particular to gain information on how naloxone administration programs can best be implemented. I-ENAACT will be independently evaluated by researchers at the National Drug Research Institute, the Burnet Institute, and the University of New South Wales.

While the ANCD does not believe it is necessary to await the results of the monitoring and evaluation before commencing similar programs elsewhere in Australia, the results should be used to inform development and expansion of such programs in Australia to population levels optimal for reducing opioid-related fatalities and injuries.

### **Expanding availability**

Currently there are no legal or regulatory barriers to instituting programs to train potential overdose witnesses in the use of naloxone and provide naloxone to potential overdose victims under medical prescription. The evidence shows that implementing such programs is likely to save lives. There are, however, several issues to consider in promoting the availability of naloxone beyond prescription and training programs over the longer term which need to be addressed, including availability to emergency services and frontline staff, legal liability, rescheduling, and training programs. These are discussed in the sections below.

### Emergency services and frontline staff

Another way to expand availability of naloxone is to ensure that naloxone is available to all emergency services staff, and other frontline staff such as needle and syringe program workers, outreach workers, and drug and alcohol workers. While naloxone is currently used by paramedics (predominately higher level ambulance staff) and emergency room staff, not all emergency services staff (such as transport officers, including fire officers in some jurisdictions) are authorised to administer naloxone.

Since situations arise when these people are those best placed to quickly respond to opioid overdoses, authorising the use of naloxone by more emergency services staff and frontline workers, and providing naloxone to these groups, is another step which could be taken to prevent opioid overdose fatalities and injuries. Legislation enabling prescription or supply to potential overdose witnesses as well as victims is one option, and models for such a development can be found, for example in some areas of the USA. The rescheduling of naloxone to allow for over-the-counter dispensing is another alternative which could enable these groups to access and administer naloxone.

### Criminal and civil liability

An issue for expanding the availability of naloxone throughout Australia is the possibility of legal consequences for third-parties administering naloxone, in the event of injury or death caused by that administration; or for third-parties who fail to administer naloxone when appropriate. The administration of prescription medication by third party lay-people is standard with some other prescription medications, including adrenaline for anaphylaxis and glucagon for diabetic insulin reactions, and raises no legal issue in itself. However, while the law clearly identifies a duty of care for medically trained personnel, the law has not adequately defined any duty or standard of care for lay-people trained in the use of naloxone. In general, members of the community have no obligation to act to rescue others in emergency situations in Australia, but an obligation to do so may be created by a 'special relationship'.

Frontline workers who may administer naloxone in their capacity as employees or volunteers, or those who have received training in naloxone administration, could thus be held to a higher duty of care than lay people. A duty of care can also be created when a lay member of the community voluntarily embarks upon a rescue. Thus errors in naloxone administration, or failing to call an ambulance after administration, could potentially give rise to claims of criminal or civil negligence even for lay-persons, although it may be unlikely that a prosecutor would bring such a charge when the person was undertaking actions in good faith to try to save someone's life.

Most Australian states and territories do have ‘Good Samaritan’ laws which protect lay-people from liability when acting in an emergency. However, in some states such as the ACT and NSW these laws would exclude administration by anyone affected by drugs, and not all areas of Australia have such legislation. Legislation would be required at both the State/Territory and Commonwealth levels to protect members of the general population who administer naloxone in emergency situations from criminal prosecution or civil liability, and to clarify the duty of care required in such situations. Examples of Good Samaritan legislation to protect lay people administering naloxone from civil liability claims have been implemented in the United Kingdom and some states in the USA. Existing state and territory Good Samaritan legislation and legislation governing needle and exchange programs in Australia may also provide some guidance.

There are also potential legal ramifications for persons administering naloxone to someone other than the person named on the prescription, which could legally be considered misuse of a medication. While naloxone has no adverse effects on people who are not suffering overdose, and legal action being taken against a person acting in this way in an emergency is unlikely, considering rescheduling naloxone in the future is one measure that would resolve this issue.

### Rescheduling

Naloxone is currently included in Schedule 4 (S4; prescription only medicine). Rescheduling of naloxone to Schedule 3 (S3; pharmacist only medicine) or Schedule 2 (S2; pharmacy medicine) would facilitate expanded availability. This would enable all ambulance workers, frontline staff, and the general population to obtain and administer naloxone. In some areas including New York, California, New Mexico, and Connecticut in the USA, naloxone can be prescribed to third party lay-people; and in Italy, naloxone can be obtained as an over-the-counter medication. No adverse consequences from providing access to naloxone through these arrangements have been reported in the literature.

Naloxone is no longer under patent, and it is unlikely that a pharmaceutical company will seek to have it rescheduled. Consequently, it may be necessary for another individual or organisation to commence this process. This may be initiated by state health authorities, professional associations, or the National Drugs and Poisons Schedule Committee itself. As an alternative, individual states and territories are able to exempt certain drugs from Commonwealth scheduling (although this may best be done as an interim measure only).

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THERE ARE NO LEGAL OR REGULATORY BARRIERS TO INSTITUTING PROGRAMS TO TRAIN POTENTIAL OVERDOSE WITNESSES IN THE USE OF NALOXONE AND PROVIDE NALOXONE TO POTENTIAL OVERDOSE VICTIMS UNDER MEDICAL PRESCRIPTION.

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Whether naloxone is rescheduled to S3 or S2 has implications for the type of advice provided at time of distribution and the capacity to promote its uptake in the community. Both classifications would ensure access to naloxone is accompanied by advice, either from a pharmacist (S3) or through an employee of a pharmacy (S2). Rescheduling would thus involve the need to consider how training delivery could be integrated into the supply of naloxone. There are already programs in operation providing potential overdose witnesses with comprehensive training in overdose response, so one option would be to include naloxone administration within these broader programs. With the progress of the I-ENAACT program more information on how training and supply could best be implemented can be developed.

Another consideration in rescheduling naloxone would be the potential contributions of costs between Governments and individual purchasers. Possible regulatory frameworks could range from an exclusively Government funded scheme to an exclusively user-pays scheme. Naloxone is relatively inexpensive, at \$12-\$25 for two doses, but it is important to ensure that the financial cost to potential purchasers will remain at a level not prohibitively expensive. The possibility of distribution at a reduced cost or without cost from needle and syringe programs warrants specific consideration. Legislation at the State/Territory level would be required to allow this to take place.

### Training

Much of the credit for the effectiveness and safety of the expanded availability of naloxone has been attributed to comprehensive overdose prevention programs. Consequently, it is important that potential overdose witnesses receive appropriate information and training in the identification of suspected opioid overdose, administration of naloxone, other correct resuscitation techniques, the issues affecting the effective administration of naloxone, storage and handling, the importance of calling for medical help, and post administration care and responses. These features are included in the training within the I-ENAACT program.

Needle and syringe programs, alcohol and other drug treatment services, and family support services are logical choices to provide a wider provision of such training. However, it should be noted that compulsory training is likely to act as a barrier to access and there are models elsewhere of written and pictorial instruction materials which are included in naloxone kits to good effect.

### Other issues for consideration

In Australia there is currently a rising rate of opioid prescription and misuse of pharmaceutical opioids. Many of the people misusing pharmaceutical opioids constitute a new population of at-risk opioid users with no prior history of substance use disorder, or connection with the drug using subculture or helping organisations. This may have long-term implications for how naloxone availability is best managed. Ongoing surveillance is needed to establish the extent to which overdose is an issue for this group and how overdose harm countermeasures can best be implemented. It should be noted that in the USA where most peer-naloxone programs have been rolled out, prescription opioids are involved in a high proportion of opioid overdoses.

As specific populations are at an increased risk of overdose, programs targeting these populations may have a higher level of effectiveness for reducing overdose deaths. I-ENAACT will aim to target at-risk populations, including Indigenous injecting drug users and people recently released from prison. Information on the best ways of implementing these programs should be forthcoming from trial evaluations.

Promoting awareness of the availability of naloxone will be necessary to maximise the effectiveness of any expansion of availability. Consequently, there will be a need to comply with regulations surrounding the advertising of medications.

## Recommendations

After considering the available options, evidence, and issues, the ANCD supports the I-ENAACT program and believes that a gradual rollout of similar programs in other jurisdictions to further expand the availability of naloxone to the general population is warranted. The ANCD therefore recommends:

1. That programs to expand the availability of naloxone as a prescription medication for potential overdose victims be instituted in all Australian states and territories;
2. That in the longer term, naloxone be rescheduled to be made available as a pharmacist only medicine (S3) or as a pharmacy medicine (S2);
3. That expanding the availability of naloxone be accompanied by appropriate programs which train potential overdose witnesses in comprehensive overdose prevention and management strategies including naloxone administration;
4. That expanding the availability of naloxone be subject to ongoing evaluation and monitoring, and that this evaluation be utilised to further develop the training programs and material provided;
5. That procedures are investigated to allow all emergency services workers, alcohol and other drug workers, and needle and exchange workers to be authorised to administer naloxone;
6. That all states and territories pass legislation that will protect all people from legal liability arising from the administration of naloxone in emergency situations;
7. That options are investigated for obtaining current, quality data on overdose deaths occurring in Australia.

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Alcohol Tobacco & Other Drug Association ACT

Canberra Alliance for Harm Minimisation and Advocacy

Prof Simon Lenton, National Drug Research Institute, Curtin University

Prof Paul Dietze, Centre for Population Health, Burnet Institute



For further information contact:

ANCD Secretariat

PO Box 205

Civic Square ACT 2608

Tel: 02 6166 9600

Fax: 02 6162 2611

Email: [ancd@ancd.org.au](mailto:ancd@ancd.org.au)

Website: [www.ancd.org.au](http://www.ancd.org.au)