

Independent evaluation of the 'Implementing Expanded Naloxone Availability in the ACT (I-ENAACT)' Program, 2011-2014

Final Report August 2015

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Executive summary

The Canberra Alliance for Harm Minimisation and Advocacy (CAHMA), ACT Health, the Alcohol Tobacco and Other Drug Association ACT (ATODA) and a multidisciplinary group of stakeholders initiated Australia's first take-home naloxone (THN) program in April 2012. The program involves comprehensive opioid overdose management training and the prescription and supply of THN to eligible participants who are not health professionals. Using a collaborative approach, the program is coordinated and delivered by CAHMA, with prescriptions provided by local physicians. The program was funded by ACT Health.

This independent, external evaluation of the program used a mixed methods strategy to assess the effectiveness and value of the program in the ACT context with a view to providing new evidence on the feasibility of THN in the Australian context, recommendations around the continuation of the ACT program and examination of potential expanded naloxone availability in other settings.

Based on our evaluation we find that naloxone can be safely distributed to, and successfully used by, people other than health professionals to reverse opioid overdose in the ACT community. Thus, we recommend continuation of the ACT program, and make suggestions about delivery format, scope, partnerships and funding that could improve the reach and sustainability of the program. More broadly, our evaluation also uncovered local and national systems issues and legislative barriers requiring attention in the consideration of expanding naloxone distribution in other jurisdictions and settings.

All suggestions present opportunities for the ACT to take a leading role in the development and practices of expanded naloxone availability and overdose prevention in the Territory and at a national level.

Key findings against the evaluation questions:

1. Can naloxone be used appropriately by people in a non-medical setting within the ACT context?

Yes.

- Over 200 participants were trained in overdose prevention and naloxone administration over the period April 2012 – December 2014, and the majority of these received a prescription for naloxone.
- 18 inmates at the Alexander Maconochie Centre (Canberra's prison, which holds both sentenced prisoners and those on remand) were trained in overdose prevention and naloxone administration and some of these received prescription naloxone after release.
- Participants' opioid overdose identification and response knowledge, particularly their knowledge about naloxone, was higher after the completion of training than before training. Learnt knowledge about signs of overdose was sustained over time. Although knowledge about

appropriate actions to take at an overdose declined in the months after training, this did not affect successful use of naloxone.

- Practitioners involved in delivering the program, other stakeholders who interacted with program participants, as well as the program participants themselves, were all supportive of the program and its continuation.

2. Did the program result in successful overdose reversals?

Yes.

- 57 overdose reversals using program-issued naloxone were documented during the evaluation period. All reversals were successful and no serious adverse events were reported.

3. Did the program have any unintended consequences, either positive or negative?

Yes.

- Program participants reported positive emotional impacts of being involved in a community-based opioid overdose reversal. Many also described educating their peers and family members about naloxone.
- The program-distributed naloxone not only gave participants the ability to save lives, but to take control in overdose situations.

4. Should the program continue and, if so, what changes in the program and its contexts are desirable?

Based on the success of the program during the evaluation period, we conclude that it is important that it continue. The evaluation identified a range of issues that need to be considered. These include suggestions to:

- Modify the workshop content and delivery, including shortening the length of the workshop, reinforcing the need to call an ambulance in overdose situations and offering refresher workshops to reinforce knowledge and practice.
- Modify the program, including offering the training workshop outside of the city centre, enhancing coordination with relevant services (especially the prison and alcohol and other drug services), streamlining prescription refills for participants, increased staffing to scale-up and continue the program, secure supply of naloxone in pharmacies across the territory and review of the territory emergency call centre script relating to overdose (to ensure that use of naloxone by a community member is encouraged where appropriate during a 000 phone call).
- Review relevant legislation to address the potential legal implications for program participants under the 'Good Samaritan' provisions of the *Civil Law (Wrongs) Act 2002* (ACT) (Civil Wrongs Act) (including the use of naloxone on people to whom it was not prescribed) as well as clarification of medico-legal implications for physicians who prescribe naloxone in the Territory.
- Monitor any changes in naloxone availability. At the time of writing, naloxone is listed as a schedule 4 drug available on the Pharmaceutical Benefits Scheme (PBS). Given the rapidly changing landscape of naloxone access in Australia, including possible rescheduling of the drug, different

international models for naloxone access need to be considered for application in the ACT.

- Continue current funding practices around THN naloxone but monitor changes in pricing structure to determine any program impacts.

5. Does the program have a sound program theory and program logic?

Yes, and these are documented in this evaluation report.

6. To what extent was the program implemented as intended?

The program was carefully designed from the outset and implemented as intended. Several changes were made to the program during its first two years, largely responding to changes in the external environment. The most significant change was that the packaging of naloxone changed from glass vials to Minijets®.

7. What were the costs of the program in terms of financial outlays and staff time?

Total expenditure over the first two years of the program was \$75,888. The largest components were staff time for developing the program (including the training workshops) and staff time for delivering the training workshops.

National implications

In 2014 the World Health Organization produced guidelines recommending that countries expand naloxone access to people likely to witness an overdose in their community in order to reduce the global burden of death from overdose. Our findings add to 15 years of international evidence showing that the provision of naloxone, with appropriate training, to people who inject drugs, family members and outreach workers can lead to safe and successful opioid overdose reversals.

Alongside international evidence on the effectiveness of various models of THN programs our findings demonstrate the feasibility of THN in Australia. These data can inform delivery models of THN in the community as well as associated policy and legislative responses. Since the initiation of the ACT program, THN programs have been developed in other jurisdictions including NSW, SA, WA, Qld and Vic, using a variety of delivery modes including peer-to-peer training (similar to the ACT), nurse or physician delivery and drug service delivery. Evaluations of these programs, coupled with findings from this report, provide a sound base from which to develop Australian policy and legislative action around naloxone availability at both the state and national levels.

In May 2015 an application was made to the Therapeutic Goods Administration (TGA) to reschedule naloxone from schedule 4 (prescription-only medication) to schedule 3 (pharmacist-only medication). Rescheduling would increase access to naloxone in the community. However, two issues emerged with the proposed change to schedule 3: (1) who bears the responsibility for training in overdose management and naloxone administration? and (2) who would bear the cost of

the medicine (ideally, at a minimum, naloxone needs to be subsidised for Health Care Card holders)?

Given the success of the ACT program and the broadening policy landscape of non-medical access to naloxone, internationally recognised delivery models should be considered for use in the Australian context:

- Delivery of training and naloxone provision across a *range of settings*:
 - peer-to-peer in drug user organisations
 - one-on-one in pharmacies
 - one-on-one in General Practice settings
 - one-on-one in opioid substitution therapy (OST) settings
 - workshops or one-on-one in specialist drug treatment and withdrawal services
 - workshops or one-on-one in prisons and other correctional services
 - workshops or one-on-one in Aboriginal Medical Services.
- Delivery of training and naloxone provision to a *range of people*, targeting those who use opioids as well as those in regular contact with people who use opioids:
 - those in drug user organisation networks
 - those on OST
 - those in specialist drug treatment services
 - friends and family of those who use opioids
 - at risk prisoners as well as those under community-based court order or parole
 - the alcohol and other drug workforce
 - needle and syringe program workers
 - Aboriginal Medical Service staff.
- A variety of *training delivery models*:
 - one-on-one
 - group workshops
 - brief training on naloxone administration
 - comprehensive training on overdose recognition and response.
 - a combination of the above
- Options for *accessing naloxone*:
 - prescription
 - over-the-counter.

Finally, there is considerable momentum around THN in Australia presenting possibilities for a national approach to naloxone training and provision. For example, in 2012 the Scottish Government invested in a National Take Home Naloxone program providing a national coordinator, support for development of local naloxone programs including naloxone kits for at-risk prisoners upon release from incarceration, financial support for distribution of naloxone kits, and a national monitoring and evaluation program. The most recent data from the Scottish National Naloxone program shows a fall in overdose death rates.

Furthermore, governments in many of the nations with naloxone programs have enacted laws (such as specific Good Samaritan legislation) to support access to naloxone outside the medical setting and protect members of the public who administer it in an overdose emergency.

There is clear national and international evidence for the wider distribution of naloxone to laypersons in order to reduce harm and death from overdose, and support for THN programs is growing in Australia. Our report indicates that THN programs are feasible and successful in the Australian context, providing the foundation for expanded approaches to naloxone provision across the nation.

Introduction

Program overview

Naloxone (often referred to as Narcan®) is an opioid antagonist used to reverse the effects of opioid overdose. It has no psychoactive effect, is not a drug of dependence and is available on prescription through the Pharmaceutical Benefits Scheme (PBS). Naloxone is a schedule 4 drug¹ in the ACT that is routinely used by health personnel to reverse opioid overdoses. Consistent with developments internationally, on the initiative of the Canberra Alliance for Harm Minimisation and Advocacy (CAHMA) and ACT Health, the alcohol and other drug sector in the ACT collaboratively designed a public health program to expand naloxone availability in the ACT, with the aim of reducing opioid overdose morbidity and mortality.

In December 2011, Ms Katy Gallagher, ACT Chief Minister and Minister for Health, launched the Implementing Expanded Naloxone Availability in the ACT (I-ENAACT) program at the ACT Legislative Assembly. The I-ENAACT Committee includes ACT and national stakeholders and experts, and provides expert guidance and support to the program. The initial program was run from April 2012 to December 2014 and was evaluated during this time.

The I-ENAACT program involves comprehensive overdose management training and the supply on prescription of take-home naloxone (THN) to eligible participants who are not health professionals. This is similar to models for community intervention in the case of anaphylactic shock where adrenaline is administered. Under the program it is intended that people prescribed THN will be administered it by a trained person (usually a friend or family member) in the event of an opioid (primarily heroin) overdose.

Key values and assumptions underpinning the program include that:

- the community values the lives of people who use drugs and is willing to act to do what it can to enhance their well-being
- people who use drugs care about their health and well-being and the health and well-being of their peers
- people who use drugs will take the necessary action to enhance their health and well-being, particularly if society provides resources and helps to create an enabling environment.

¹ Under the Poisons Standard 2012, schedule 4 drugs are 'Prescription Only Medicine,...– Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription'.

This report contains findings from an independent external evaluation of the program using a mixed methods strategy, assessing implementation fidelity and participants' experiences of the program—particularly the training and the administration of naloxone in community settings. The primary aim of the report is to assist in planning for the continuation of the program, providing a range of potential improvements and suggestions for action, as well as informing the development of similar programs in other Australian jurisdictions.

Key stakeholders

The key stakeholders with an interest in the outcome of the evaluation are:

- * people who use opioid drugs in the ACT, whether used illegally or obtained on prescription, or both, who are at risk of opioid overdose
- * the friends and families of people who use opioids who are concerned about their well-being
- * ACT Ambulance Service members who attend opioid overdose incidents (as the program has potential to revive overdose casualties before an ambulance arrives)
- * officers in ACT Health who need to make decisions about the future of the program, including the desirability or otherwise of continuing it, modifying it and/or expanding it
- * staff from organisations and facilities in which the training has been conducted (such as the ACT adult detention facility, the Alexander Maconochie Centre, and an Aboriginal community controlled health organisation)
- * people thinking about developing similar programs in other settings.

The underlying program theory

One component of this evaluation is to make explicit the program theory underlying the I-ENAACT intervention. Program theory has been defined as:

...an explicit theory or model of how an intervention, such as a project, a program, a strategy, an initiative, or a policy, contributes to a chain of intermediate results and finally to the intended or observed outcomes. A program theory ideally has two components: a theory of change and a theory of action. The theory of change is about the central processes or drivers by which change comes about... The theory of action explains how programs or other interventions are constructed to activate these theories of change.²

² Funnell, SC & Rogers, PJ 2011, *Purposeful program theory: effective use of theories of change and logic models*, Jossey-Bass, San Francisco, CA, p. xix.

The program theory used within this evaluation was developed to collect information about the implementation and impact of the intervention in order to make judgements about it, improve or further develop it, and to inform decisions about future interventions. Based on the understanding that the naloxone intervention can reduce overdose-related deaths (change) if implemented effectively (action), this evaluation was developed to explore program effectiveness without a randomised trial. Thus, the evaluation rests on several assumptions captured in the following statement of the program theory.

The theory of change

Opioid overdoses are significant public health problem in Australia, with 500 accidental deaths attributed to opioids in 2008, and over 700 expected in 2010 pending closure by state coroners.^{3,4} Non-fatal overdoses cause considerable morbidity and are frequently experienced by people who inject drugs (PWID), with 45% of a sample of PWID recruited from across Australia reporting ever having overdosed on heroin alone.⁵ When administered at an early enough stage in an overdose, naloxone reverses the opioid component of an overdose (even in polydrug overdoses). Naloxone has been demonstrated to be safe to use by trained but non-medically-qualified people and, in such circumstances, to be effective in reversing overdoses.

People who use opioid drugs, whether sourced illegally or on prescription, care about their health and that of other people who use opioids, and are willing to act to help people recover from an overdose. The incidence of overdose recoveries (and consequent reduction in opioid-related morbidity and mortality) can be increased markedly through training people who use opioids, and others associated with them, in overdose management including the use of naloxone. If training is implemented effectively, with the right participants and with a sufficient number of participants, and naloxone is available to the people who have been trained, the drug will be administered by overdose witnesses, with positive outcomes.

The theory of action

The I-ENAACT THN program comprises training in overdose management provided under the auspices of CAHMA to people who use opioids and others who are potential overdose witnesses. This is being supported by ACT Health through the provision of financial resources and creating an enabling policy

³ Roxburgh, A. and Burns, L. (2012). *Accidental drug-induced deaths due to opioids in Australia, 2008*. Sydney: National Drug and Alcohol Research Centre.

⁴ Stafford, J. and Burns, L. (2011) Australian Drug Trends 2010. Findings from the Illicit Drug Reporting System (IDRS). Australian Drug Trend Series No. 55. Sydney, National Drug and Alcohol Research Centre, University of New South Wales

⁵ Stafford, J. and Burns, L. (2011) Australian Drug Trends 2010. Findings from the Illicit Drug Reporting System (IDRS). Australian Drug Trend Series No. 55. Sydney, National Drug and Alcohol Research Centre, University of New South Wales

environment. Potential trainees are recruited by CAHMA and undergo a training course presented by CAHMA personnel with the support of health professionals. This training is acknowledged by ambulance and medical professionals, and ACT Health, as being of a high standard. People who successfully complete the course are prescribed naloxone. In community settings when opioid overdose occurs, a witness who is trained in using naloxone and is able to respond will implement an overdose management plan which includes administering naloxone as well as clearing airways, calling 000, administering basic life support as appropriate, and monitoring the person post-naloxone administration. This will result in the reversal of overdoses and minimise the risk of overdose-related morbidity. Through these mechanisms the incidence of fatal overdose will be reduced, as will the incidence and prevalence of morbidity caused by non-fatal opioid overdoses. The necessary policy, legislative and financial resources are available in the ACT, and sufficient skilled trainers and trainees are available to implement the program on a large enough scale to have a positive impact.

Underpinning evidence

This statement of program theory is underpinned by two assumptions:

- (a) the need for action to reduce opioid overdose mortality and morbidity, and
- (b) the effectiveness of THN programs focusing on potential overdose witnesses.

The body of evidence that gave confidence to the developers of I-ENAACT to proceed included the following.

Accumulating international evidence since 2000 shows that the provision of naloxone, with appropriate training, to PWID peers, family members and outreach workers can lead to successful opioid overdose reversals and that it is a remarkably safe intervention with few, if any, adverse effects. THN programs operate in many countries and many governments have enacted laws to support access to naloxone outside the medical setting and protect members of the public who administer it in an overdose emergency.^{6,7} As of 2010 there had been over 53,000 kits containing naloxone distributed through 188 programs across 16 US states, with 10,171 overdose reversals incorporating naloxone administration having been reported.⁸

Importantly, none of the major concerns about THN,⁹ such as unsafe administration of naloxone and problems with re-intoxication where longer-

⁶ Kim D, Irwin KS, Khoshnood K. Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality. *Am J Public Health*. 2009; 99(3):402-7.

⁷ The Network for Public Health Law. Legal interventions to reduce overdose mortality: Naloxone access and overdose good samaritan laws. St Paul, MN: The Network for Public Health Law. (Accessed online at: http://www.networkforphl.org/_asset/qz5pvn/network-naloxone-10-4.pdf) Access Date 91.03.2013, 2012.

⁸ Wheeler E, Davidson PJ, Stephen Jones T, Irwin KS. Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010. *Morbidity and Mortality Weekly Report*. 2012; 61(6):101-5.

⁹ Lenton S, Hargreaves K. Should we trial the provision of naloxone to heroin users for peer administration to prevent fatal overdose? *Medical Journal of Australia*. 2000; 173(4):260-3.

acting opioids have been used, have been borne out within interventions to date.¹⁰ Furthermore, there has been no evidence of THN leading to more risky drug use. Indeed the opposite appears true, with those engaged in naloxone programs reporting having reduced their drug use.^{11,12,13} Additionally, re-intoxication once naloxone wears off appears to be a very rare phenomenon, occurring in fewer than 0.2% of cases,¹⁴ if at all.^{15,16}

Second, with regards to shelf-life, studies show naloxone to be a very robust medication, being temperature resistant over an enormous range (–20°C to +70°C)¹⁷ and, if stored under recommended conditions, remaining viable on average for 77 months (range 66–90).¹⁸

Recent evidence

Other evidence supporting THN has emerged in the period since the ACT project commenced. Two recent systematic reviews reached similar conclusions: based on the current evidence from non-randomised studies, bystanders (mostly opioid users) can and will use naloxone to reverse opioid overdoses when properly trained,^{19,20} and that training is effective in increasing the knowledge of, and positive attitudes towards, the correct use of naloxone and overdose management.²²

An audit of THN programs internationally, conducted as part of a systematic review, confirmed that naloxone training is provided in a range of settings and locations (street, treatment agency, training room, etc.) and durations (ranging from 5 minutes to well over an hour), with many protocols, materials and videos available online.²¹ Evidence suggests that even brief training is effective, with

¹⁰ See, for example, Enteen L, Bauer J, McLean R, Wheeler E, Huriaux E, Kral A, et al. Overdose Prevention and Naloxone Prescription for Opioid Users in San Francisco. *Journal of Urban Health*. 2010;1-11.

¹¹ Maxwell, S. Distributing Naloxone...because dead addicts NEVER recover. The Australian Drug Conference: Public Health and Harm Reduction. Melbourne Australia. 2010; 25-26 October.

¹² Maxwell S, Bigg D, Stanczykiewicz K & Carlberg-Racich S. Prescribing Naloxone to Actively Injecting Heroin Users: A Program to Reduce Heroin Overdose Deaths. *Journal of Addictive Diseases*. 2006; 25: 89-96.

¹³ Seal K, Thawley R, Gee L, Bamberger J, Kral A, Ciccarone D, Downing M & Edlin B. Naloxone distribution and cardiopulmonary resuscitation training for injection drug users to prevent heroin overdose death: A pilot intervention study. *Journal of Urban Health: Bulletin of the New York Academy of Medicine*. 2005; 82: 303-311.

¹⁴ Rudolph S, Jehu G, Nielsen S, Nielsen K, Siersma V & Rasmussen, L. Prehospital treatment of opioid overdose in Copenhagen--is it safe to discharge on-scene? *Resuscitation*. 2011; 82(11): 1414-8.

¹⁵ Vilke G, Sloane C, Smith A, Chan T. Assessment for Deaths in Out-of-hospital Heroin Overdose Patients Treated with Naloxone Who Refuse Transport. *Academic Emergency Medicine*. 2003; 10(8): 893-6.

¹⁶ Wampler DA, Molina DK, McManus J, Laws P, Manifold CA. No deaths associated with patient refusal of transport after naloxone-reversed opioid overdose. *Prehosp Emerg Care*. 2011; 15(3):320-4.

¹⁷ Küpper T, Bettina S, Burkhard R, Hemmerling AV, Volker S, Juergen S. Drugs and drug administration in extreme environments. *J Travel Med*. 2006; 13(1):35-47.

¹⁸ Lyon RC, Taylor JS, Porter DA, Prasanna HR, Hussain AS. Stability profiles of drug products extended beyond labeled expiration dates. *J Pharm Sci*. 2006; 95(7):1549-60.

¹⁹ Clark AK, Wilder CM, Winstanley EL. A systematic review of community opioid overdose prevention and naloxone distribution programs. *Journal of addiction medicine*. 2014; 8(3): 153-63.

²⁰ European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Preventing fatal overdoses: a systematic review of the effectiveness of take-home naloxone, EMCDDA Papers. 2015 Luxembourg: Publications Office of the European Union.

²¹ Clark AK, Wilder CM, Winstanley EL. A systematic review of community opioid overdose prevention and naloxone distribution programs. *Journal of addiction medicine*. 2014; 8(3):153-63.

one recent study showing that fewer than 10 minutes of training in intranasal naloxone administration is sufficient for successful reversals,²² and another finding no statistically significant differences in desirable responses such as help-seeking, rescue breathing, staying with the victim, or successful naloxone administration, between trained and untrained rescuers.²³ Still, overdose management training is related to increased knowledge about overdose. For example, in one study of family members and other carers of opioid users group based THN training was compared with an information-only control (covering basic information on overdose management). At three-month follow-up, those who had received the THN training reported greater overdose-related knowledge, greater knowledge of how to administer naloxone, and more positive opioid overdose-related attitudes than the information-only control group.²⁴

It has long been known that risk of opioid overdose is high in the first weeks after prison release due to tolerance to opioids reducing during incarceration.²⁵ The most recent data from the Scottish National Naloxone program shows a fall in overdose death rates during the first four weeks after prison release, from 9.8% at baseline to 4.7% in 2013, coinciding with introduction and provision of THN kits to at-risk prisoners upon release from incarceration.²⁶

Furthermore, in a program recognising that people on OST such as methadone are likely to witness overdoses amongst their opioid-using peers, 1553 methadone maintenance program participants in Massachusetts were trained in overdose management from 2008 to 2010. Ninety-two successful overdose reversals were reported by these participants.²⁷

There is growing evidence for the successful use of THN by other groups of non-medical bystanders. In many parts of the US, for example, police and fire officers are the first and sometimes only source of pre-hospital emergency care when emergency services are called to overdoses. As a result, some jurisdictions have expanded naloxone availability and training to non-paramedic first responders.

²² Behar E, Santos GM, Wheeler E, Rowe C & Coffin PO. 2015. Brief overdose education is sufficient for naloxone distribution to opioid users. *Drug and Alcohol Dependence*, 148, 209-212.

²³ Doe-Simkins M, Quinn E, Xuan Z, Sorensen-Alawad A, Hackman H, Ozonoff A & Walley A. 2014. Overdose rescues by trained and untrained participants and change in opioid use among substance-using participants in overdose education and naloxone distribution programs: A retrospective cohort study. *BMC Public Health*, 14(1):297.

²⁴ Williams AV, Marsden J & Strang J. 2014. Training family members to manage heroin overdose and administer naloxone: Randomized trial of effects on knowledge and attitudes. *Addiction*, 109, 250-259.

²⁵ Binswanger IA, Blatchford PJ, Mueller SR & Stern MF. 2013. Mortality after prison release: Opioid overdose and other causes of death, risk factors, and time trends from 1999 to 2009. *Annals of Internal Medicine*, 159, 592-600.

²⁶ National Health Services Scotland. 2014. National Naloxone Programme Scotland – naloxone kits issued in 2013/14 and trends in opioid-related deaths Publication date – 28 October 2014. Available at: Scottish Drugs Forum. <http://www.isdscotland.org/Health-Topics/Drugs-and-Alcohol-Misuse/Publications/2014-10-28/2014-10-28-Naloxone-Report.pdf>

²⁷ Walley AY, Doe-Simkins M, Quinn E, Pierce C, Xuan Z, Ozonoff A. 2013. Opioid overdose prevention with intranasal naloxone among people who take methadone. *Journal of Substance Abuse Treatment*, 44(2):241-247.

In two projects in Massachusetts, firefighters administered naloxone 114 times, and police 201 times, between 2010 and 2013.²⁸

A recent cost-effectiveness modelling analysis concluded that naloxone administration by trained lay persons is likely to reduce overdose deaths, and these findings remained robust even under very conservative assumptions.²⁹ These findings, coupled with recent ecological-level evidence of program effectiveness,³⁰ suggest that THN is an effective addition to overdose prevention strategies.

In light of these findings on the efficacy of THN programs and naloxone provision for the reversal of opioid overdose by non-medical bystanders, the World Health Organization's newly published *Guidelines for the community management of opioid overdose*³¹ calls for wider access to naloxone for people who are likely to witness an opioid overdose, including the following statement which goes to the overall efficacy of increased naloxone availability and the issue of training:

The GDG [Guideline Development Group] judged the risk-benefit profile to be strongly in favour of naloxone distribution, due to its clear potential for saving lives and apparent low risk of significant adverse effects. While training was considered an important and intrinsic component of increased naloxone availability, the GDG cautioned against making it compulsory or institutionalizing it as there were concerns that lack of certified training may be used as a barrier to provision of naloxone. The panel noted that while minor adverse events from naloxone administration (such as vomiting and opioid withdrawal) were not uncommon, serious adverse events were extremely rare. (p. 8)

Timely naloxone administration is crucial in preventing morbidity and mortality associated with opioid overdose. Evidence shows that the wider distribution of naloxone to laypersons who are likely to be potential overdose witnesses can reduce these harms.

Evidence relating to the need for an initiative addressing opioid overdose

The need for improved approaches to preventing opioid overdose incidence, morbidity and mortality is confirmed by epidemiological evidence suggesting that Australia is once again on an upward epidemic curve of opioid overdose

²⁸ Davis CS, Ruiz S, Glynn P, Picariello G, & Walley AY. 2014. Expanded access to naloxone among firefighters, police officers, and emergency medical technicians in Massachusetts. *American Journal of Public Health*, 104, e7-e9.

²⁹ Coffin PO, Sullivan SD. Cost-effectiveness of distributing naloxone to heroin users for lay overdose reversal in Russian cities. *Journal of Medical Economics*. 2013; 16(8):1051-60.

³⁰ Walley AY, Xuan Z, Hackman HH, Quinn E, Doe-Simkins M, Sorensen-Alawad A, et al. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. *BMJ* 2013; 346:f174

³¹ World Health Organization. 2014. *Community management of opioid overdose*. Geneva: WHO.

incidence.³² A large proportion of the burden of disease and injury associated with illicit drug use in Australia relates to mortality—57% in 2003, the latest year for which data are available.³³ For those who survive, non-fatal overdose has been linked to a range of morbid conditions including cardiac complications and cognitive impairment.^{34, 35}

The latest finalised national mortality data for people aged 15 to 54 years covers deaths registered in the 2010 calendar year.³⁶ Nationally, in that year, 613 accidental deaths were attributed to opioids, 33% of which were due to heroin. The number that occurred in the ACT is not published owing to privacy considerations. In 2007, the latest year for which these ABS data have been published, there were seven accidental opioid-caused deaths in the ACT.³⁷ These seven deaths were 2.3% of the total opioid overdose deaths for that year, whereas the ACT had just 1.6% of Australia's population.

The National Coronial Information System (NCIS) has reported on all opioid deaths (accidental and intentional) reported to an Australian coroner from 2007 to 2011.³⁸ In this five-year period, 4,102 opioid-related deaths were reported, 744 in 2007, 863 in 2008, 934 in 2009, 849 in 2010 and 712 in 2011, a 14% increase from 2007 to 2010.³⁹ Some 71% of those where intent had been determined were classified as unintentional, i.e. accidental deaths. Heroin was the opioid most frequently identified (27% of the deaths), followed by methadone (21%) and oxycodone (19%). It was more common for opioids to be involved as part of a multiple drug toxicity than as a single drug.

ACT Health has extracted data from the NCIS database pertaining to ACT deaths in which opioids were involved, covering the period 2003 to 2014. Table 1 shows a total of 151 deaths, an average of 13 each year. (These numbers are conservative as they do not include open investigations, and will increase as additional cases (especially for 2014) are finalised by the ACT Coroner.) Note that the data represent closed cases; for some death cases, non-opioid drugs were also present; and overdose deaths may have been intentional or unintentional.⁴⁰

³² National Coronial Information System (Australia) 2014, *Opioid deaths 2007-2011*, NCIS Fact Sheet August 2014, [Southbank, Vic.].

³³ Begg, S, Vos, T, Barker, B, Stevenson, C, Stanley, L & Lopez, AD 2007, *The burden of disease and injury in Australia 2003*, AIHW cat. no. PHE 82, Australian Institute of Health and Welfare, Canberra, p. 88.

³⁴ Warner-Smith, M, Lynskey, M, Darke, S & Hall, W 2001, *Heroin overdose: prevalence, correlates, consequences and interventions*, ANCD research paper; no. 1, Australian National Council on Drug, Woden, ACT.

³⁵ Begg, S et al. 2007, p. 89.

³⁶ Roxburgh, A & Burns, L 2014, *Accidental drug-induced deaths due to opioids in Australia, 2010*, National Drug and Alcohol Research Centre, Sydney.

³⁷ Roxburgh, A & Burns, L 2011, *Drug-induced deaths in Australia, 2007 edition*, National Drug and Alcohol Research Centre, UNSW, Sydney. Note that the 2011 data from this source is probably an underestimate.

³⁸ National Coronial Information System (Australia) 2014, *Opioid deaths 2007-2011*, NCIS Fact Sheet August 2014, [Southbank, Vic.].

³⁹ The National Coronial Information System advises that the 2011 figures are probably an underestimate, and will be updated in due course.

⁴⁰ The NCIS dataset does not claim to be representative of all relevant cases within the time period specified. This may be due to cases still under coronial investigation, missing data, occasional processing and coding errors. The Department of Justice & Regulation Victoria, where the NCIS is located, accepts no

The increase in the incidence of deaths from five in 2012 to 18 in 2014 is notable.

Table 1: ACT opioid related deaths 2003 to 2014

<i>Year</i>	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
No.	15	9	15	8	11	10	18	16	12	5	14	18

Table 2 provides additional information about the drugs involved in the 2013 and 2014 opioid-related deaths. Heroin alone (i.e. not in combination with other drugs) was the opioid most frequently recorded, in around half of the deaths in both years. The number of ACT opioid-related deaths in those two years (32) was almost twice the number of people who died in motor vehicle crashes in the ACT over the same period (17—seven in 2013 and 10 in 2014).

Table 2: Opioids involved in ACT opioid-related deaths 2013 and 2014

<i>Opioid type</i>	<i>2013</i>	<i>2014</i>
Heroin alone	7	10
Other opioid types, alone or in combination*	7	8
<i>Total</i>	<i>14</i>	<i>18</i>

* Oxycodone alone, morphine alone, codeine/oxycodone, oxycodone/morphine, heroin/methadone, fentanyl/morphine, ‘opiates’

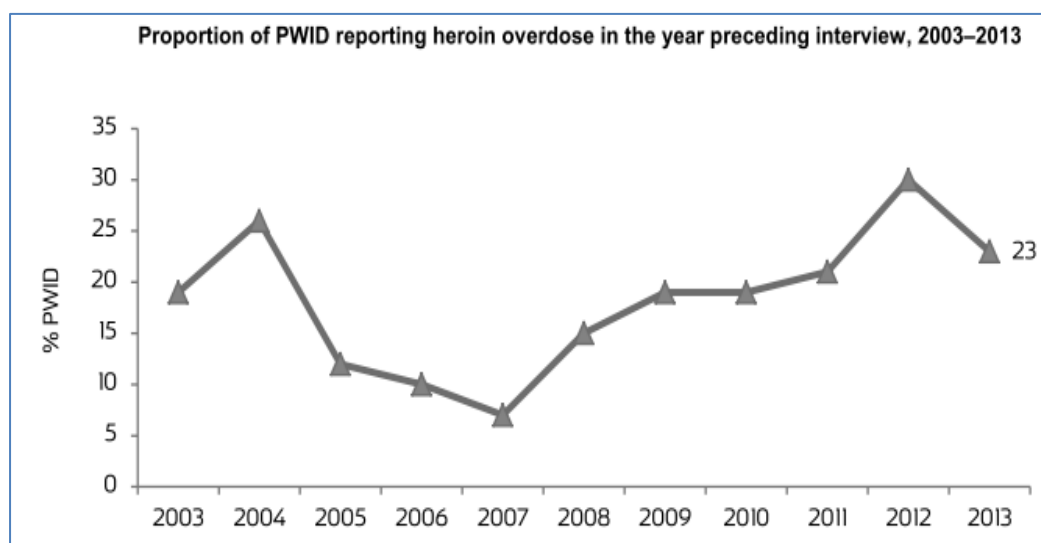
The Illicit Drug Reporting System (IDRS) provides annual self-report data on the overdose experiences of a non-representative sentinel sample of people in Canberra who inject illicit drugs,^{41, 42} as part of a national study conducted in each capital city in the country. In 2013 there were 100 Canberra participants, and 48% of them reported having overdosed on heroin at least once at some point in their lives, similar to the 51% in 2012. Of participants who reported ever having overdosed on heroin, the median number of times overdosed was one (range=1–200). As can be seen from Figure 1 (below), in 2012, 30% of participants reported having overdosed on heroin in the year prior to the interview, compared to 21% in 2011. One participant reported overdosing on heroin in the past month.

liability for any loss or damage that may arise from any use of or reliance on the data. Please note that, as with all statistical reports, there is the potential for minor revisions of the data in this report over its life.

⁴¹ Butler, K & Burns, L 2013, *ACT drug trends 2013: findings from the Illicit Drug Reporting System (IDRS)*, National Drug and Alcohol Research Centre, University of New South Wales, Sydney, NSW.

⁴² Stafford, J & Burns, L 2014, *Illicit Drug Reporting System (IDRS): National Report 2013*, National Drug and Alcohol Research Centre, University of New South Wales, Sydney, NSW.

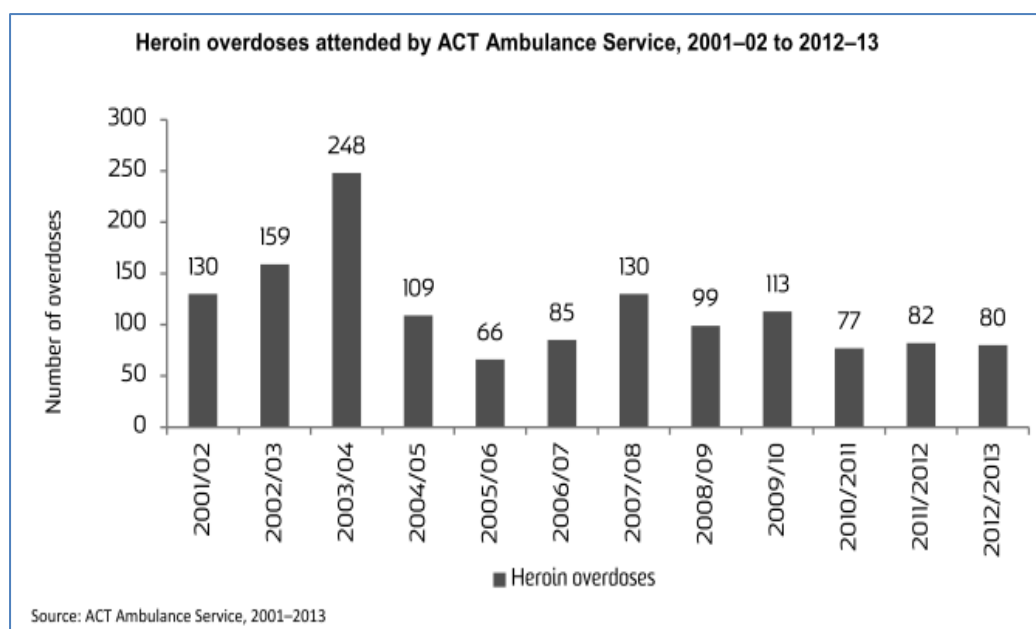
Figure 1: Percentage of participants who reported heroin overdose in the past year



Notes: These are data for the ACT. PWID means 'people who inject drugs'.

As shown in the figure below, the same source provides information on ACT Ambulance Service callouts. During the 2012-13 financial year there were 1,183 ACT callouts for overdoses (791 in the previous year), 80 (7%) of which were heroin overdoses, far fewer than recorded during the heroin glut period prior to 2001.⁴³

Figure 2: ACT Ambulance callouts for overdoses



Source: ACT Ambulance Service, 2001–2013

⁴³ Cassar, J, Stafford, J & Burns, L 2009, *ACT drug trends 2008: findings from the Illicit Drug Reporting System (IDRS)*, Australian Drug Trends Series no. 21, National Drug and Alcohol Research Centre, University of New South Wales, Sydney.

Training program description

The ACT THN program is peer led, run by CAHMA at locations across the city of Canberra. Prospective participants are recruited by word-of-mouth and poster advertising. Participants are asked to attend a pre-scheduled training session with up to 12 other program participants. During the evaluation period participants completed a contact details sheet and provided consent to be a part of the evaluation at the start of the session. A pre-training quiz is completed before participants are trained in relation to:

- understanding overdose causes and consequences
- recognising signs and symptoms of overdose
- responding to overdose, including principles of resuscitation techniques
- naloxone and naloxone administration
- infection control
- medical and other support (including the need for calling an ambulance).

The training runs for 1.5–2.5 hours. At the end of the training participants complete a written test. Participants are then introduced to a General Practitioner (GP) prescriber who assesses the overdose response knowledge (including naloxone) of each participant individually using both the post-training test and a short clinical assessment. If the GP is satisfied that the participant has sufficient knowledge to use naloxone appropriately, naloxone is supplied on prescription to the participant, together with a naloxone kit containing:

- five pre-loaded syringes (Minijets®) of 400 mcg naloxone hydrochloride solution (2 mg in total)
- five needle attachments for the syringes
- swabs, gloves and a disposable face mask
- information on how to perform resuscitation (including naloxone administration)
- helpline numbers.

NOTE: From April 2012 to April 2013 naloxone was supplied in glass vials with needles and syringes for administration.

There are three key requirements in relation to the training course as currently implemented. These are that:

- a registered nurse be present at the training workshops during the delivery of the CPR component of the workshop
- a registered nurse deliver the instruction to participants on administration of an intramuscular injection
- the CAHMA staff member delivering the training hold a current Senior First Aid Certificate and a Certificate IV in Workplace Training and Assessment.

The evaluation framework

Key evaluation questions

The evaluation deals with the worth and merit of the I-ENAACT program. It focuses on program implementation within the specific ACT context (the worth of the program), as the intrinsic efficacy of THN (the merit of the program) has already been established (to sufficient extent to justify implementing the program in the ACT) in studies conducted in other contexts.

Primary evaluation questions:

1. Can naloxone be used appropriately by people in a non-medical setting within the ACT context?
2. Does the program result in successful overdose reversals?
3. Does the program have any unintended consequences, either positive or negative?
4. Should the program continue and, if so, what changes in the program and its contents are desirable?

Secondary evaluation questions:

1. Does the program have a sound program theory and program logic?
2. To what extent was it implemented as intended? Did it change in response to identified needs and/or changing contexts?
3. What were the costs of the program in terms of financial outlays and staff time?

Although the underlying rationale of the I-ENAACT program is that THN is expected to reduce the incidence of opioid-related overdose deaths, this is not one of the specific evaluation targets. The reason for this is the relatively low number of overdose deaths in the ACT each year, as detailed above (in the 'Underpinning evidence' section), meaning that there is probably insufficient statistical power to detect statistically significant changes in mortality incidence as a result of the I-ENAACT program. Since THN programs are being scaled-up in other jurisdictions, in the future it would be feasible to track THN impacts on mortality incidence in Australia more widely.

Purpose of the evaluation

The purpose of the evaluation is to provide new information about THN in the ACT. The most significant new information will be about the feasibility of doing so, the effectiveness of the training of people who are likely to be bystanders to an opioid overdose, the practical aspects of obtaining and maintaining the supply of naloxone to program participants in a form suitable for use in non-medical/non-ambulance settings, and program participants' use of naloxone to reverse opioid overdoses.

A secondary purpose will be to provide information that will assist people in other parts of Australia who are considering introducing THN programs.

Evaluation team

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Evaluation model and methods

Model

The utilisation-focused evaluation model underlies the design and implementation of the evaluation. Utilisation-focused evaluation is defined as follows:

*Program evaluation is the systematic collection of information about the activities, characteristics, and results of programs to make judgements about the program, improve or further develop program effectiveness, inform decisions about future programming, and/or increase understanding. Utilization-focused program evaluation is evaluation done for and with specific intended primary users for specific, intended uses.*⁴⁴

Since most of the evaluation questions focus on obtaining new information about the feasibility of implementing THN within the specific ACT context, the evaluation is largely formative in nature rather than focused on outcomes. Nonetheless, the evaluation methodology includes specific provisions for identifying unintended consequences of the intervention, both positive and negative. This reflects the fact that, from the outset, there was a degree of uncertainty about what the outcomes might be.

Methods

We have evaluated I-ENAACT using a concurrent triangulation mixed methods strategy.⁴⁵ The qualitative and quantitative data collection occurred concurrently and the integration of the two types of data occurred at the interpretation stage.

The study was approved by the ACT Health Human Research Ethics Committee's Survey Resource and Approvals Sub-Committee (ETH.7.11.163).

⁴⁴ Patton, MQ 2008, *Utilization-focused evaluation*, 4th edn, Sage Publications, Thousand Oaks, p. 39.

⁴⁵ Creswell, JW 2003, *Research design: qualitative, quantitative, and mixed methods approaches*, 2nd edn, Sage Publications, Thousand Oaks, Calif.; Teddlie, C & Tashakkori, A 2009, *Foundations of mixed methods research: integrating quantitative and qualitative techniques in the social and behavioral sciences*, Sage, Thousand Oaks, CA.

The evaluation sample

Data were collected at three main points: (1 and 2) Questionnaires administered both before and after the THN training; and (3) at follow-up interviews primarily held between three and six months after the THN training or after the report of an overdose reversal.

Overall, pre- and post-workshop survey data were collected from 198 individuals and follow-up survey data were collected from 86 individuals, who composed 43% of those completing pre/post interviews. Although we attempted to contact all workshop participants three or more months after workshop attendance, this was not always possible. As such, the follow-up interviews with workshop attendees are limited to those who were contactable after the workshop and willing to participate.

Participants were also asked to contact the evaluation team or CAHMA after any use of program-issued naloxone. Thus, a small number of participants were interviewed sooner than three months post-workshop and a small number of participants have been interviewed more than once due to repeated use of program-issued naloxone. The 110 individuals who were followed-up participated in 131 interviews (11 individuals were interviewed more than once due to experiencing or witnessing overdoses during the evaluation period).

Quantitative data

A range of quantitative data was collected during the course of the evaluation. These data include implementation measures, measures of the impact of program participation and associated outcomes.

Implementation was examined through the number of participants and naloxone prescriptions issued. These data were recorded by CAHMA program staff during the provision of training courses.

The *outcome* of program training on participants' reported knowledge of overdose management and response was measured through the pre- and post-workshop questionnaires and the subsequent follow-up surveys. These questionnaires were adapted from the Opioid Overdose Knowledge Scale (OOKS) developed by Williams et al.⁴⁶ This scale has four subscales designed to measure knowledge across the following domains: overdose risks, overdose signs, appropriate actions around overdose and naloxone. The OOKS has 45 items across these domains. For the purposes of I-ENAACT, 31 items were drawn from the four scales (overdose risks = 7 items, overdose signs = 7 items, appropriate actions = 9 items, how naloxone is used = 8 items). These items were scored according to the scoring criteria used by Williams et al., producing a maximum score of 31. Additional questions were included to canvass previous experience

⁴⁶ Williams, A. V., Strang, J., & Marsden, J. (2013). Development of Opioid Overdose Knowledge (OOKS) and Attitudes (OOAS) Scales for take-home naloxone training evaluation. *Drug Alcohol Depend*, 132(1-2), 383-386.

of naloxone, willingness to use naloxone, confidence about its use and willingness to train others in overdose management and naloxone administration.

The pre- and post-training questionnaires were largely identical. Questionnaires were distributed by CAHMA trainers before commencement of the overdose training and again at the end. Questionnaires were collected by trainers and passed on to the evaluation team for processing. Follow-up questionnaires contained similar items, but the response options for some of the OOKS items did not require the forced choice of the pre- and post-workshop questionnaire, meaning that comparisons between the three time points should be treated with caution. All questionnaires were entered onto an Access database (developed for the study) that allowed linkage between questionnaires. Data were extracted from the Access database and descriptive statistics generated. The modified repeated OOKS scales were compared pre- and post-workshop using paired-sample t-tests, with mean difference calculated with a 95% Confidence Interval for the difference (if the Confidence Interval does not cross zero, this indicates statistical significance at $p < 0.05$) and retention across all three time points was examined using Generalised Estimating Equations with exchangeable correlation structure using Stata SE 13.

Outcome measures collected include the number of reported overdose reversals, and the circumstances and contexts in which overdose occurred. Missing data for some variables means that we have presented denominators where appropriate to highlight the maximum possible number of cases that can be included in analysis.

Qualitative data

Qualitative data were collected from 110 training workshop attendees who attended their follow-up interview. Qualitative data collected from workshop participants included: (1) open-ended questions on workshop feedback, and (2) in-depth interview questions about naloxone use.

In-depth interviews were also conducted with key stakeholders. These stakeholders were purposively sampled. Individuals who had some engagement with staff and participants from the I-ENAACT program were approached by the evaluation team and asked to participate in an interview about their experiences of, and attitudes to, the naloxone program in the ACT. Eleven stakeholders were interviewed including medical practitioners (GPs, pharmacist and nurse), paramedics (field and office staff) and drug user advocates.

Between April 2012 and December 2014 the evaluation team were also involved in informal discussions with key stakeholders about the progress of the program, barriers to implementation and logistical issues. This information was used to inform the suggestions and conclusions made in this report.

Methods: Researchers administered follow-up questionnaires to training workshop participants. All participants were initially asked open-ended questions about their views and feedback on the workshop training. Program participants who had either administered or been revived by program-issued naloxone were further interviewed using a semi-structured interview schedule. Those who had administered naloxone were asked to describe what happened before the overdose; what drugs the victim had been using; possible reasons for the overdose; details of their actions during the overdose; and what happened after the person had been revived. Those who had experienced overdose and received program-issued naloxone were asked to describe: what happened immediately before the overdose, including the drugs they had been using; why they might have overdosed; details of others present, and any information about their actions during the overdose; experience of receiving naloxone; and what happened after they had been revived.

Interviews with stakeholders were conducted by a member of the evaluation team or a research assistant. Participants were asked open-ended questions about their experiences of the program, views and feedback on the program and suggestions for naloxone training and prescription in the future.

Analysis: All interviews were digitally recorded and professionally transcribed verbatim. Qualitative data were entered into Atlas.ti⁴⁷ for storage, organisation and analysis. Thematic analysis was used to identify and analyse themes within the data.⁴⁸ Transcripts were re-read and re-coded, systematically comparing interviews to establish themes. Analysis of interviews with workshop attendees was guided by topics from the research literature and interview questions related to appropriate use of naloxone and experiences of successful overdose reversals. Data were also analysed for views and experiences of overdose and naloxone. All identifying information, aside from sex and age, has been removed.

Similarly, analysis of interviews with stakeholders was guided by topics from the research literature and interview questions related to attitudes to the program. Data were analysed for views of overdose prevention and naloxone prescription in the future. All identifying information, aside from occupational identity, was removed.

⁴⁷ Muhr T, Fries S (2004) Users manual for ATLAS.ti 5.0. Berlin: Scientific Software Development.

⁴⁸ Braun, V & Clarke, V (2006) 'Using thematic analysis in psychology'. *Qualitative Research in Psychology*. 3(2): 77-101.

Evaluation findings

Participant details

Between April 2012 and December 2014 CAHMA ran 30 training workshops including 211 participants, of whom 64% were male, with a mean age of 38.8 years. Most participants were eligible for and were prescribed naloxone, but the total trained included a small number of friends/family of people who inject drugs or people who did not wish to be prescribed naloxone.

A total of 110 participants were followed-up after receiving their training, 60% of whom reported that they were single, and 39% reported that they were living alone. Fourteen per cent reported that they were of Aboriginal or Torres Strait Islander descent. One third reported that they were not in treatment, with 63% reporting that they were currently on OST.

Eleven stakeholders, including medical practitioners (three GPs, a pharmacist and a nurse), paramedics (three field and one office staff) and two drug user advocates also participated in an interview about their experiences of, and attitudes to, the naloxone program in the ACT.

Can naloxone be used appropriately by people in a non-medical setting within the ACT context?

This question was examined in four ways.

1. Changes in knowledge of overdose management and response among participants in the I-ENAACT overdose education and prevention program.
2. Knowledge retention among participants in the I-ENAACT overdose education and prevention program.
3. Participant experiences of: (a) administering naloxone, and (b) being revived using program issued naloxone.
4. Stakeholder experiences of and attitudes to the program.

1. Examining changes in overdose management and response knowledge among program participants

A total of 197 pre-training questionnaires were available for analysis. Some post-training questionnaires were unavailable as they were incomplete or lost. As a result, there were 188 complete cases for analysis.

Table 3 shows the pre-and post-training scores for the OOKS variant overall and subscale scores. Training led to significant improvements in knowledge of overdose management and response. This suggests that participants' capacity to recognise signs (e.g., deep snoring) and risks for overdose (e.g., mixing drugs), as well as knowledge on appropriate actions to take at an overdose (e.g., call an

ambulance) and appropriate use of naloxone, all increased. All these pre-post differences were statistically significant ($p<0.001$), with scores higher after the completion of training than before training. The largest change occurred in the actions subscale, which includes items about how to respond appropriately to overdoses. There were smaller changes on the other three subscales, with changes of one or no items noted for the risks, signs and naloxone subscales. (See reference 45 for further details on subscales.)

Table 3: Pre- and post-training scores on modified version of the OOKS, valid data only

Scale/question	Pre-training	Post-training	Mean difference (95% CI)	<i>t</i>
OOKS risks (7 items, n=184)	5.53	6.23	0.69 (0.34-1.05)	3.87
OOKS signs (7 items, n=187)	4.88	5.90	1.02 (.80-1.24)	9.21
OOKS actions (9 items, n=178)	6.16	8.34	2.18 (1.86-2.49)	13.55
OOKS naloxone (8 items, n=188)	6.13	7.44	1.31 (1.07-1.56)	10.59
OOKS overall (31 items, N=174)	22.72	27.97	5.25 (4.45-6.04)	13.02

Further changes in knowledge and behaviour were evident in the post-training survey responses. Unsurprisingly, almost all (97%—the remainder incomplete) participants reported having heard of naloxone after training, up from 92% prior to training. The percentage reporting that they would ever give naloxone in an overdose situation rose from 88% prior to training to 97% after receiving training. Similarly, the percentage of participants reporting being either confident or very confident at giving a naloxone injection increased from 71% before training to 99% after training. Finally, the percentage of participants reporting being willing to train others in overdose management and naloxone administration rose from 90% before training to 96% after training.

2. Knowledge retention

Participant knowledge retention was examined in the follow-up surveys (which generally occurred 3–6 months after the training) and in the interviews with people who had administered naloxone during the evaluation period. Contrast was made between some of the items listed in Table 3 on recognising the signs of overdose and the actions that should be taken at overdose situations. Table 4 shows the marginal means generated from the GEE analysis of the changes in the population average across the three measurement points.

Table 4: Marginal means showing knowledge scores from pre-post training surveys and at follow-up

Scale/question	Pre-training	Post-training	Follow-up interview
Signs (7 items)	4.83	5.90	5.68
Actions (7 items)	5.21	6.05	4.58

The changes in scores for recognising *signs of overdose* over time were statistically significant, with the mean increase in scores for reporting of signs of overdose from pre-training to post training of 1.07 (95% CI=0.85-1.29, $p<0.001$), and pre-training to follow up of 0.85 (95% CI=0.55-1.15, $p<0.001$). The decline between post-training and follow-up of 0.22 (95% CI=-0.09-0.53) was not statistically significant. This finding indicates that improvements in knowledge from pre-post training were retained at between three and six months follow-up.

The changes in scores for *actions to be taken at overdose* over time were statistically significant, with the mean increase in scores for reporting of signs of overdose from pre- to post-training of 0.85 (95% CI = 0.51-1.018, $p<0.001$), and pre-training to follow-up of -0.63 (95% CI =-1.09—0.17, $p=0.007$). The decline between post-training and follow-up of 1.47 (95% CI=-1.01-1.93, $p<0.001$) was also statistically significant.

As detailed above, the questionnaire wording and format changes between post-training and follow-up for these actions items could explain the unexpected decline between pre-workshop training and follow-up. Here, the initial questionnaires asked ‘Which of the following actions are important when faced with an opioid overdose?’ followed by a five-point scale ranging from strongly agree to strongly disagree. For the follow-up questionnaire, the question was changed to ‘What are the most important steps to take when someone has overdosed? (Please tick all that apply)?’ This change in wording could explain why the differences were observed, as the original questions forced participants to make a choice around an item, which was not the case at follow-up (participants were asked to tick all that applied).

Of the 110 participants who answered the question ‘What are the recommended intramuscular injecting sites on the body for naloxone?’, 64% were able to correctly identify the upper arm, thigh and buttocks (Table 5).

Table 5: Participant identification of recommended sites for naloxone injection at follow-up interview

Recall of recommended injection sites for naloxone	Number of participants
Correctly identified all three recommended injection sites for naloxone	70 (64%)
Correctly identified two of three recommended injection sites for naloxone	29 (26%)
Correctly identified one of three recommended injection sites for naloxone	10 (9%)
Did not correctly identify any recommended injection sites for naloxone	1 (1%)

Other sites for intramuscular injection of naloxone were identified by 18 participants (Table 6). These sites were not described in the workshop and are not recommended.

Table 6: Incorrect sites for injection of naloxone named by participants at follow-up interview

Incorrect site for intramuscular injection	Number of times incorrect site identified (n= 18 with one participant giving two incorrect sites)
Stomach	10
Back of thigh	3
Chest	2
Lower arm	1
Vein	1
Groin	1
Neck	1

In addition to the questionnaires, in-depth interviews with individuals who had used or received naloxone during the evaluation period captured misconceptions or incorrect beliefs about overdose and naloxone inconsistent with the program training. These included misunderstanding how naloxone works; misunderstanding/underestimating that heroin mixed with other depressants increases the risk of overdose; and forgetting key aspects of overdose response (such as the recovery position and not walking people around the room). Most concerning from the perspective of safety, but not efficacy, was a man who revived an individual by injecting naloxone into the chest muscle.

These instances of incorrect behaviours were rare and we are not aware of any instances of poor outcomes for the person administering the drug or the person who overdosed.

Experiences of training and expectancies reported at follow-up

Participants were asked about their experiences of training at the follow-up interview. Ninety-seven percent (107/110) reported attending the training (three people who did not attend the training were interviewed because they had been revived using program naloxone or were an overdose witness). Most (65%, 68/107) were interviewed more than three months prior to interview, 95% (101/106) reporting getting their naloxone at the training mostly (67%, 48/72) as ampoules (the remainder in the Minijet® form). Importantly, 33% (35/106) reported training someone else since being trained. Participants reported high levels of confidence in their capacity to recognise and manage overdoses, as outlined in in Table 7 (n = 106).

Table 7: Percentage of participants reporting confidence in being able to engage in elements of overdose response

Response	% sample
Could recognise an overdose	93
Could manage an overdose	94
Would call an ambulance	84
Could check a person's airway	99
Would check a person's airway*	96
Could give expired air resuscitation	98
Would give expired air resuscitation	93
Could place person in recovery position	95
Would place person in recovery position	96
Would be able to give naloxone	97
Would give naloxone	97

*other respondents said 'maybe'

Sharing their new overdose response knowledge and skills, several participants also described training other opioid users in overdose response and the effects of naloxone.

... he wasn't a very educated user. He thought that if this guy dropped calling the ambulance meant police were going to turn up, and so I had to explain all of that, that no they won't turn up, that they'll [ambulance staff] just turn up for five minutes, give him some narkan, naloxone, and they'll be on their way and that's it. But I did have to explain to him that it [naloxone] doesn't strip the drug out of his system, it just kickstarts you again, and that he will

be still stoned, so you will still have to keep an eye on him. There is still a possibility that he might go under once the naloxone starts to wear off kind of thing. (Woman, 33 years old, witnessed overdose)

3. Participant experiences of administering naloxone and being revived using program issued naloxone

Fifty-seven instances of program-administered naloxone were reported between April 2012 and December 2014.* In addition, the evaluation captured 10 cases where training from the workshop was applied to an overdose situation and an ambulance was called, but no program-administered naloxone was used. All reported instances of overdose and use of program administered naloxone resulted in successful reversals.

(*Note: There is likely to be some double counting in cases where more than one individual was involved in a reversal and where both the administrator and other witness provided interviews.)

Witnessed overdoses

Interviewees were able to describe and explain opioid overdose identification and response, reflecting both prior knowledge of overdose response and newly acquired knowledge from the training.

His lips started going blue. I laid him on the ground, listened for air. There was no air. I started breathing for him, and he couldn't breathe himself, so that's when I put the naloxone [intra] muscular. Tried breathing again, still no breath, so I gave him another two ... and that's when his breath came back. But he had a pulse through the whole time. (Man, 39 years old, witnessed overdose)

Overall, fifty-four people (48%, 54/113) reported having witnessed an overdose since receiving naloxone, while 119/131 (91%) had ever witnessed an overdose. Those who reported witnessing an overdose since receiving naloxone were asked to identify the signs of overdose (Table 8).

Table 8: Signs noted at witnessed overdoses

Shallow breathing	Blue lips	Pinned pupils	Unresponsive to pain	Unconscious	Fitting
50	70	19	46	74	6

Participants were also asked about what they believed caused the overdoses that they witnessed, as detailed in Table 9 (percentages out of 54 cases). The

'other' perceptions were mostly 'don't know' or reasons related to tolerance (n=5).

Table 9: Perceptions of overdose cause

Tolerance	Changed purity	Mixing drugs	Other
32%	20%	46%	41%

Participants were asked about the actions they took at the witnessed overdose, as shown in Table 10 (all percentages out of 54 cases).

Table 10: Actions taken during a witnessed overdose

Response	% sample
Stayed with person	89
Gave naloxone	89
Checked breathing	78
Placed person in recovery position	65
Called ambulance	59
Stayed until ambos arrived	56
Checked pulse	52
Checked airways	43
Performed mouth to mouth	39
Slapped or shook	22
Walked around room	19
Taken to hospital?	19
Shocked with cold water	4
Gave stimulants	4
Injected saline	0

Reported outcomes

There were no reported deaths during an event in which program issues naloxone was administered. Participants perceived that naloxone saved the person's life in 92% (48/52) of cases. Most reversals happened quickly, with 32/56 (57%) estimated to have regained consciousness in five minutes or less. Importantly, paramedics were notified that naloxone was given in 97% (27/28 in events at which the ambulance was called – the other response was a 'don't know'). Police were present at only one case (of 54).

However there were also some instances of reported overdose where the person was not unconscious and might have only been heavily intoxicated ('on the nod'). A couple of respondents recognised that the individual might not have

been at risk of overdose-related death but decided to use the naloxone anyway, thereby avoiding the risk of death.

... I could just see him as he was sitting on the edge of the concrete just start to, you know, fall forward ... And so we caught him before he fell headfirst into the concrete, lay him down ... Anyway, he was arguing and arguing that everything was fine when, you know, whilst going on the nod and trying to smoke a cigarette and being unsuccessful at it. So I went and grabbed the naloxone ... I was able to hit him in the arm with it, the top of his arm. And the other person knew what I was doing, so they kept talking to him ... And he came back around, you know what I mean? The colour came back into his face, picked back up his cigarette and he was able to sit upright without swaying down ... Yeah, it was really good, because my next step was to call the ambulance, you know? I knew that he was going down. (Woman, 33 years old, witnessed overdose)

He was breathing fairly slowly, but he was still breathing. So I asked if it was all right if I pulled out my naloxone kit, and she [the partner] was saying 'no, he'll be right, he'll be right' ... And I said 'well listen, you know, it's better to be safe than sorry. It's not going to harm anything.' ... I tried to explain it as—because she didn't quite understand what I was talking about. (Woman, 36 years old, witnessed overdose)

Complications were noted in 15% of cases of naloxone administration, mostly some aggression or annoyance, with the qualitative interviews suggesting that these complications were regarded as minor (see quote immediately below).

Well she was angry cos we straightened her up ... so we kind of stayed clear for a while. (Man, 38 years old, witnessed overdose)

Because I'm on methadone ... it sucks the opiates out of you straight away, so ... instant withdrawals temporarily. You get pissed off because your shot's been wasted and you're angry at the person that done it. It's a bit ridiculous. (Man, 32 years old, personal overdose)

Naloxone (roughly 50:50 ampoules and Minijets®) was used in 96% (53/55) of cases. The naloxone belonged to the person answering (i.e. the interviewee) in 71% (38/53) of cases. The interviewee administered naloxone in (45/56) 80% of

cases (in six cases paramedics did as well), through one 30/55 (55%) or two 18/55 (31%) injections, but up to four.

Several respondents (both those who administered and those who received the naloxone), reported that the recipient was sometimes unaware that they had been injected with naloxone. These recipients remained intoxicated but had regained consciousness and were able to respond to questions and breathe normally.

I think we had to tell him what had happened, really. I think he just figured he'd sort of nodded off, passed out and woken up again. Didn't even realise he was in a different room. (Man, 47 years old, witnessed overdose)

...he had no idea he'd even been out. He was going 'What? What? What? What happened?' ... He wasn't even aware of it ... Because they don't get enough to put them into withdrawal, which I don't think we'd been given that much, or you don't have the second one, they just think they've been on the nod. (Woman, 55 years old, witnessed overdose)

Ease of naloxone use

During the evaluation period there was a change to the naloxone forms available in Australia, and this was accommodated by the program. From April 2012 to April 2013 the naloxone available in Australia was largely in 0.4 mg vials. In April 2013, after a change in manufacture and distribution, the Minijet® (pre-loaded syringe) became the only form of naloxone available for purchase through the PBS. This new form of the drug has several advantages over the glass vials, as described below.

A few participants reported dropping and smashing the glass vials, or cutting their fingers when removing the top casing. Some also commented on the process of preparing the naloxone injection. Drawing up the naloxone from the small vial was difficult in the stressful context of an overdose, and a few people commented on the need to find intramuscular injecting equipment (a larger bore detachable needle, as opposed to single unit 1 mL needles and syringes manufactured for intravenous injection).

The last couple of times I went to go through the kit I had lost a few syringes and stuff like that. I lost little stuff along the way ... (Man, 32 years old, witnessed overdose)

All participants bar one reported that naloxone was easy or very easy to use at follow-up, and 89% reported that they were confident about their capacity to give the naloxone. Participants reported that the Minijet® naloxone preparation

was easy to use. There was only one potentially problematic situation reported, in which the participant could not find the needles (tips) for her Minijets®. In this case the participant squirted the liquid drug into a spoon and drew up into new syringe. This raises the potential for Minijet® syringes to get separated from the program-provided needles (Minijets® are not currently supplied with needles). In this particular case, there is also a sterility concern with respect to the spoon used. Few participants reported that their naloxone supply was replaced following administration (15%, 7/46), however this may not be an issue as most had used only one or two vials/Minijets® from their kit of five.

Appropriate use of the drug

In terms of appropriate administration of naloxone, all participants were aware that the program taught intramuscular injection. While almost all participants who administered naloxone reported using the intramuscular route, there were five reports of intravenous injection of naloxone by program participants. In all of these cases the participants knew the victim. In the case below the individual was using injecting equipment that was not supplied by the program and was not confident that the needle available to him would be appropriate for intramuscular injection. With the introduction of Minijets® this is not likely to be a common problem. Nevertheless, injecting naloxone intravenously is likely to bring on a more rapid withdrawal reaction than the recommended intramuscular injection, and should be avoided where possible. This issue needs further emphasis in program training.

... I injected it intravenously because I was starting to doubt whether the 1 mL [needle] ... I didn't know whether that would do the job ... that's the way I've seen it done every time by ambos, so I wasn't breaking new ground. I just didn't have the confidence that a 1 mL would be long enough ... I didn't know what I was dealing with. Veins, I do know, so I went with what I knew. (Man, 46 years old, witnessed overdose)

There was also one case in which a program participant injected naloxone to an overdose victim in smaller quantities than prescribed (i.e. administering the contents of a vial over several injections). There were no reported adverse outcomes from this event.

Despite concerns about misuse of the drug, no major problems were reported. However, some participants gave some of their prescribed naloxone to another person. Further, the naloxone was used on the person to whom it was prescribed only four times (in 7% of cases); that is, the majority of program-supplied naloxone was not used on the person to whom it was prescribed.

I went into the laundry ... yeah, in my flats ... and there was a guy and a girl in there ... She said that, you know,

her boyfriend had OD'ed [overdosed] ... So I went down, had a quick look at him ... and called the ambulance and told her ... to start breathing for him ... it actually took me a little while to bloody find the thing [naloxone kit]. And once I went back down, I was, I only had, two left ... cause I'd, actually given a couple away. (Man, 35 years old, witnessed overdose).

Given the nature of opioid overdose (a person is unable to administer naloxone to him/herself in an overdose situation) and the evidence that program participants commonly use their prescribed naloxone on others, the operation of 'Good Samaritan' provisions of the *Civil Law (Wrongs) Act 2002* (ACT) (Civil Wrongs Act) needs to be explored in this context. The Civil Wrongs Act means that people who assist others in good faith are protected from civil liability if they inadvertently cause injury to another person as a result of their action. However, section 5(2)(b) explicitly excludes a 'Good Samaritan' from the protection offered by the Good Samaritan provisions if the person's capacity to exercise appropriate care and skill was 'significantly impaired by a recreational drug.' A 'recreational drug' is defined as 'a drug consumed voluntarily for non-medicinal purposes, and includes alcohol.' This means that, in the unlikely event that a person suffered injury as a result of receiving emergency medical assistance, including the provision of naloxone, from a layperson whose capacity to exercise appropriate care and skill was 'significantly impaired by a recreational drug', the person could sue the layperson who administered naloxone.

There was only one report of prescribed naloxone being misused to the detriment of the recipient. One participant described unknowingly being given naloxone by her partner, which resulted in withdrawal and feeling unwell. In the vast majority of cases, naloxone will save lives and prevent injuries that can result from overdose. However, the mere risk of exposure to civil liability could significantly diminish the incentive for an intoxicated layperson to administer naloxone to someone who had suffered an overdose, out of fear that they might then be sued. These legal issues should be considered by the ACT government, in particular consideration of amendment to the Civil Wrongs Act.

Appropriate overdose response

The program encourages participants to call an ambulance, even when naloxone has already been used, but an ambulance was called in only just over half of the reported reversal events. Of the 57 reversal events using program naloxone, the ambulance attended 58% of overdoses. Reasons given for not calling an ambulance included the responder was uncertain whether the ambulance had been called; the ambulance was called and cancelled upon request from the victim/victim's friend; friends/partners of the victim asked them not to call an ambulance; concern about drawing attention to their drug use or involvement in an overdose situation, particularly if the overdose had happened at their house and children were present; and belief that an ambulance was not required

because naloxone had been administered and the victim had regained consciousness.

I think it was more her partner that was adamant about no ambulance, because he always associates if ambulance turn up and there's something, something fishy going on, then they call the cops straight away, you know what I mean? Which a lot of people do think. (Woman, 36 years old, witnessed overdose)

... you know, having a child there is just that view that, you know, if an ambulance comes and the child's in, you know, the child's in the house sort of asleep and what not, and that that then brings attention on us ... child services ... (Man, 31 years old, personal overdose)

And I didn't call the ambulance, because he was coming around ... I didn't really think that there was any need to drag them away from something else that could've been—yeah. (Man, 39 years old, witnessed overdose)

These responses suggest a need to further address attitudes, knowledge and beliefs regarding police attendance at overdoses and the importance of medical follow-up in an overdose situation. Those overdose responders who did call an ambulance were generally positive about interactions with emergency services operators and ambulance paramedics.

He wasn't coming to, so she got on the phone to the ambulance ... they were really good, they sort of said 'Oh your part of the community access program'... the ambo's were really, really good ... I personally was a bit worried, we had equipment sort of everywhere, they [paramedics] didn't, didn't seem to care ... (Male, 31 years old, witnessed overdose)

It will be important to relay these positive experiences with ambulance services to future workshop participants, encouraging them to call the ambulance even when program naloxone has already been used.

Personal overdose

Only 18% (10/56) of participants reported having an overdose since receiving naloxone (question asked only of those who reported ever having had an overdose). Naloxone was used on all of these occasions (although one entry was missing), mostly their own (60%) or their partner's (20%). In 88% of cases the naloxone was prescribed to the person giving it, the remaining response was 'don't know' for an administration involving a stranger.

Consistent with the witnessed overdoses reported above, complications were reported rarely (by only two participants), and these were simply coded as withdrawal symptoms. Seventy percent attributed the overdose to change in purity of the drug and/or mixing drugs, although 50% believed reduced tolerance was the cause.

In terms of the response undertaken at the overdose, 40% reported being placed in the recovery position and 60% reported that an ambulance was called. No police attendance was recorded for these overdoses, but 20% reported being admitted to hospital (presumably an emergency department). Importantly, 80% believed that the naloxone prevented them from dying.

4. Key stakeholder experiences of and attitudes to the program

Stakeholders were overwhelmingly positive about the program and how it has been carried out to date.

Appropriate overdose response

Two paramedics had attended an overdose after a community member administered program-supplied naloxone to an overdose victim. Importantly, neither reported prior knowledge of the program but were positive about the outcomes for the victim.

Yes, so I had not heard about it [the naloxone program] at all ... she told me that they had both been shooting up, that they had heroin and she had given him, she said, 'I'd given him the needle'. I didn't know anything about it so I questioned her and she then talked me through what the community program was and she said that she had used it [naloxone] before as well. Her and her partner made a pact that if they were using together that one would only have a little bit of heroin just to keep an eye on the other ... By the time we got there he was sitting up, he was breathing on his own ... (ACT Ambulance staff 3)

... his girlfriend had administered the naloxone and he regained consciousness by the time we got there. And so there was really nothing for us to do except take a set of obs [observations] ... She'd done the right thing by calling us as well ... It's a nice easy job for us, we probably spent as much time doing the paperwork as we did seeing the patient. The dose seemed—he had woken up, you know, without being overly agitated which sometimes we see when they're a large dose of naloxone ... she was quite worried that she'd done the right thing and we reassured

her that she had and it was all a good result ... clearly the training process had seemed to have been adequate for her because it was used appropriately and effectively. (ACT Ambulance staff 2)

Stakeholder information and training

Because key stakeholders in the ACT, such as paramedics, might be unaware of the THN program, one stakeholder identified the need for education for paramedics and call centre staff. While not a problem to date, ensuring that paramedics and call centre staff are aware of the program would reduce any confusion. This includes reviewing the call centre script relating to overdose to ensure that use of naloxone by a community member is encouraged where appropriate during a 000 phone call.

... from memory, there was no information provided in the 000 call but that may have well been because of the way these calls are handled. When a 000 comes in, if the patient's unconscious or not breathing normally then next step is to start CPR ... potentially where something is identified as a heroin overdose, if there was some sort of process where we asked the question ... 'Do you have access to naloxone?' so that then we could actually prompt them to use it if they haven't thought to use it themselves. And if that's done in a formalised way it can become part of our process and our prompts for those sorts of cases. So that we can perhaps potentially fill a gap. (ACT Ambulance staff 2)

Despite the lack of formalised process for dealing with overdose emergencies involving THN, ACT Ambulance staff members felt that the program was effective. In particular, they felt that the program helped to make their jobs easier and that prompt administration of naloxone can be lifesaving.

... if for some reason we have a long response time to where ever the patient is, I guess in an extreme it is potentially lifesaving ... we as an emergency resource then become available more quickly because the treatment has been commenced prior to our arrival. (ACT Ambulance staff 1)

... certainly for that patient it probably was lifesaving ... depending on where the next available car was coming from perhaps it would've been a response time of five or ten minutes, I don't know. So his outcome could've been very different ... (ACT Ambulance 3)

ACT Ambulance staff members also made the point that despite the stigma associated with opioid overdose and people who inject drugs, opioid overdoses were less frequent and less problematic than alcohol related call-outs.

I've been a paramedic in this system for seventeen years ... I remember in my early days as a student, you would go to a heroin overdose every other day. So I've seen lots of them and yeah, you know, reasonably comfortable in the fact that we go in, give them the naloxone normally, get a thank you and are on our way. So the comment I often get from people I encounter is 'you must hate the drug addicts.' And my response to that is always 'I'll take a heroin overdose over a drunk any day of the week.' (ACT Ambulance staff 2)

Stakeholders also noted the rise in prescription opioid overdoses, which is currently relatively infrequent in Australia, but may change over time. One stakeholder raised the possibility of expanding THN to prescribed opioid users. Given the range of drug and overdose issues that paramedics and call centre staff deal with, it is likely that any future THN training and information directed at this stakeholder group will generally be well-received.

Appropriateness of THN

While a couple of stakeholders raised the theoretical possibility for the program to 'give these people a false sense of security' or allow people to 'be a bit more carefree about the amount of drugs they use', there was no evidence that this was actually happening in practice, and all agreed that naloxone was safe for use by community members to reverse opioid overdose.

People talk about, 'oh they can string out a hit' and that sort of thing, but I can't really see that myself. I can't imagine that people could be bothered to do that. So, yeah. For me I thought the biggest issue was that it would just go out of date. (ACT Ambulance staff 4)

... I mean naloxone is a relatively safe drug. It works appropriately for opiate overdose but it's probably not going to do any harm if it's administered inappropriately for an overdose that's not an opiate. And certainly, for some reason we're, we have a long response time to where ever the patient is, I guess in an extreme it is potentially lifesaving. (ACT Ambulance staff 1)

The fact that THN was likely to be used on individuals for whom it was not prescribed was also raised in interviews with stakeholders. This issue had most

relevance for GPs who can prescribe naloxone to patients. Prescribing a drug that is likely to be used on others could have medico-legal implications.

The main interesting thing around prescribing in the trial is if we're prescribing a prescription for Joe Bloggs, we're actually prescribing it for their use personally ... It's more than likely it's going to be used on one of their friends or relatives ... So if you were trying to then roll this out over time ... so that lots of GPs would be happy to be naloxone prescribers, that's [the medico-legal issue] one of the things that's going to be in the back of their minds because one of the things that really screws up your career is some sort of disciplinary thing. (Medical practitioner 1)

Does the program result in successful overdose reversals?

As reported above, all 57 reported instances of program administered naloxone resulted in successful reversals. Of those who reported administering the naloxone, 46 knew the person they revived. Five did not know the person and had either been asked to assist in an overdose situation or had found an individual who had overdosed. Eight individuals who were revived using program issued naloxone were also interviewed.

Does the program have any unintended consequences, either positive or negative?

Beyond the evidence for increased knowledge and successful reversals, interviews with participants revealed the positive emotional impact of being involved in a community-based reversal. Some participants commented on the value of peer delivery of the program. Many also described educating their peers and family members about naloxone or recruiting peers into the workshops.

I told people that were appropriate, that needed to know. A lot of people know that I've got it and a lot of people know that I use. I don't walk around with it saying, 'Naloxone here'. But it's a great program. It's great. A good friend of mine would be dead if it wasn't for it ... (Man, 47 years old, witnessed overdose)

Individuals who responded to an overdose situation tended to empathise with the overdose victim and were thankful to receive acknowledgement for their actions.

He just shook my hand and said 'thank you very much for doing what you done'. Yeah, that was about it really. He was very embarrassed about what had happened. I said 'don't worry about it, like these things happen to all of us, you know? It's not like you chose for that to happen, you know? It was a mistake'. Yeah, it wasn't—it was out of his control. (Man, 39 years old, witnessed overdose)

I felt good, but I felt a little bit—a little bit upset, just, just cause I know what it's like ... I'd like to think that I, I did the best thing that I could ... the best that I could ... (Man, 35 years old, witnessed overdose)

Those who had been revived in the community were generally positive about the program and praised the people who responded to their overdose.

The program is good, you know. Like, it's already saved one person ... because we don't want to die, you know? And the program works. It does ... When my daughter and my sons look at me, it's because of the program. (Man, 46 years old, personal overdose)

Most participants discussed their familiarity with opioid overdose and overdose-related death and the stress and grief associated with knowing people who had died. The emotional impact of overdose was also acknowledged by interviewed stakeholders.

I mean, a few of the people ... they've been really quite happy to be in the program because it gives them a sense that they have some control if something goes wrong—that will help them to avoid grief. So that's sort of from their point of view. I mean, I guess from a societal point of view we're going to have less people dying from overdoses and all the grief and strife that happens with that. (Medical practitioner 1)

The program-issued naloxone not only gave participants the ability to save lives, but to take control in overdose situations. These experiences were reported as novel and empowering.

It was actually ... It was the first time that you haven't had to be afraid when somebody drops, you know? And you can't explain how exhilarating that is, do you know what I mean? Because every other time it's a fucking panic, you know? It's just a panic. So it was really good, yeah. (Woman, 55 years old, witnessed overdose)

I've had to do it [revive someone] before ... And so it was good knowing that I had, at least had something that I could do myself ... in the interim. You know I wasn't just sitting there trying to do the bloody pumps on his chest and breathing for him and stuff ... Once he was awake I knew that okay—he's awake. (Man, 35 years old, witnessed overdose)

The fact that the program was driven by CAHMA, Canberra's peer drug user group, was considered positive, empowering and integral to reaching the affected community.

... well apart from saving lives it builds a bit of self-esteem, and a sense of a community that's worth looking after. And just a bit of respect for people and valuing their experiences and objectives, because there is a lot of discussion in those sessions and people are, you know ... that their lives really mean something in the world. (Medical practitioner 4)

Even the people that came for the money ended up not wanting to leave it just meant so much to them having the skills to back them up in case of an overdose, and overdose has affected so many in the community. (Community worker 1)

The positive outcomes described by participants and stakeholders also extended to CAHMA staff. Perceived as an organisation and group of individuals working to improve the lives of their peers, several respondents reported that the program has reflected positively on the organisation.

I think one of the big positives is that the initial driving force of the program was actually the community itself ... So for me one of the really positive things was that the community wanted this, the community pushed to have it happen and it's probably been very validating for them to then have everybody participate and assist them to achieve their goals, so I think that's probably the biggest positive thing about it. (Medical practitioner 3)

So it's certainly raised CAHMA's profile outside of Canberra and I think it's probably also indicates that a well-run drug user organisation can be trusted with an important pilot project like this. (Community worker 2)

Finally, some of the stakeholders noted the fact that there had been no reported negative events or 'bad press'. The lack of adverse reports reflects well on the program and has unintended positive consequences for the community.

... drug dependency is a polarising issue for the public, there's still I think quite a lot of prejudice against drug dependency, so I think, although there hasn't been a huge amount of publicity about this program, the publicity that there has been ... has been really quite positive because it's being able to focus on things like, okay, this is a program to save lives, this is a program about people getting educated as to how they could use a drug that could help to save lives. So it gives a positive spin to the public about how people with drug dependency can be responsible people and can be responsible for their own health and safety. So I think that is a very different image, I think the image that drug dependency often gets in the media. (Medical practitioner 3)

Should the program continue and, if so, what changes in the program and its contexts are desirable?

Participants

Participant feedback was overwhelmingly positive. Participants found the workshop training valuable, with 35/36 suggesting that they found the program useful. Particular aspects of the program described as useful included the practical elements of learning about naloxone and administration as well as life-saving techniques such as CPR. They also valued learning how to save lives, learning about the signs of overdose and myths associated with overdose and overdose reversal.

Parts of the CPR have changed since I last did it. Gaining the confidence to do what needs to be done. Know that I don't need to panic, I'm in control. (Man, 46 years old)

Getting the naloxone. The fact that walking away with it in my hand. I know that I can go to any doctor and get naloxone. (Woman, 46 years old)

Yeah, [the trainer]. She was great. She ... showed everybody how to work the resuscitation but I learnt a lot that night. It was a two-and-a-half-hour session and, my goodness, if I hadn't of learnt the things she taught me that night I think I would have lost four people. (Woman, 32 years old)

... the whole exercise you guys gave us along with the naloxone was really helpful. It made me feel confident, like I knew what I was doing already, you know? ... the CPR was really helpful. Resuscitating stuff and, yeah, administering ... like, how to break the thing and stick the needle in, draw it out, give them one full vial, wait ten minutes and then if he needs another administer another.
(Man, 32 years old)

Participants reported that they were happy with the training program and only a few had suggestions for program change. However, 36% (13/36) of participants noted the need for ongoing training. Suggestions for program change included:

- an instruction sheet to accompany the naloxone kit
- a refresher course
- increasing advertising to attract other participants to the training (especially posters and flyers/cards)
- more in-depth or longer training
- more interactive (participatory) training.

Stakeholders

Stakeholder feedback was overwhelmingly positive. Stakeholders described the program as positive, empowering, life-saving and effective.

To educate people into how to save lives empowers them, but situations where people actually go and use their skill it's incredible, people are transformed by that sort of thing. (Community worker 2)

I think it's a good idea, a fantastic idea ... it's obviously a harm minimisation. It's like we provide clean needles to patients and then, why should you not provide them with also the ability to use naloxone to stop someone from overdosing as well? It just makes sense to me. (Medical practitioner 5)

In particular, stakeholders approved of the peer-led model of development and delivery.

I think what CAHMA provides is that they probably provide an opportunity for people to interact further in CAHMA and see that they are a professional well-run organisation, that sort of thing and, therefore, may have more

confidence in using CAHMA for other purposes. (Medical practitioner 3)

A few stakeholders expressed theoretical concerns about the safety of the program including potentially creating a 'false sense of security' by providing easy access to naloxone.

... I suppose that some people might say 'but it might encourage more irresponsible use of drugs because people will say "oh, well, doesn't matter if I get an overdose somebody will give me naloxone"' ... No, never heard of anything like that, but theoretically you could say that something like could happen. (Medical practitioner 3)

The potential concerns about safety were outweighed by perceived benefits of THN. Stakeholders were supportive of expanding the program and reaching target groups in the outer suburbs of Canberra.

... overdose has affected so many in the community ... It [the program] needs to travel around Canberra. Canberra's so spread out and just holding it in Civic and expecting people to come here ... So I think it needs to be a bit more flexible, it needs to be able to go to different sides of town. (Community worker 1)

Several stakeholders suggested that the program could be broadened and normalised for people who use opioids, such as regular prescription by GPs. One stakeholder even suggested the possibility of ambulances re-stocking people with naloxone after attending an overdose.

... one could make an argument that everybody who goes on the methadone/buprenorphine program should perhaps get that sort of training because after all they're getting on the methadone/buprenorphine program because they are using opiates and I'd be very naïve to expect that they're going to stop using opiates as soon as they get on the program. So they would be part of the group that would be at risk of overdose ... you're talking about more than eight hundred people in Canberra. (Medical practitioner 3)

People that are using drugs should be, in my opinion, should be able to go to their GP ... they can discuss it with their doctor. Their doctor should be able to say 'here's a script for naloxone as well, you can get this at any pharmacy' ... I mean, it's the same like with diabetes, people that use insulin also have glucagon in case they

have too much insulin, etcetera ... It just makes sense.
(Medical practitioner 5)

Several stakeholders mentioned the possibility of extending the THN program to family members, friends and household members. They believed that there is a need to train other service providers in overdose prevention, such as corrections officers, drug and alcohol workers, needle and syringe program staff and pharmacists.

... it would be beneficial for pharmacists that are involved to have some level of training as well and it actually, that would be really easy ... because pharmacists in ACT, particularly that are involved in opiate substitution, have to do a training course, and you've got to update it regularly as well. (Medical practitioner 5)

... and I think there needs to be another component of it where drug and alcohol staff or friends and family of drug users are able to learn how to administer naloxone, learn about overdose, just without being prescribed it. I think there is a massive cry out for us to do that. We haven't really been able to do that because of the time it takes ...
(Community worker 1)

Enhanced integration of alcohol and other drug services into the program was considered potentially productive for improved referral pathways and sectoral collaboration. The Alexander Maconochie Centre was the only service with continued involvement in the program; four workshops were held at the prison. Several participants from the Alexander Maconochie Centre were trained in the prison and collected naloxone prescriptions at the CAHMA office post-release, but not all could be followed-up for collection of naloxone.

The time and staffing required to run the current program was noted, and is a major concern for continuing feasibility.

... the naloxone program is just such a huge task ... it really needs its own worker ... we've had drug and alcohol workers call saying that they've witnessed four overdoses in two weeks and would love to do the program and other services have said the same thing. (Community worker 1)

Barriers noted around continuing and expanding the THN program included staffing, provision of scripts, patient record-keeping, program-supported script refills, and so on. The lack of continued funding was considered a barrier, including the potential removal of the participant workshop payment.

It needs to travel around Canberra. Canberra's so spread out and just holding it in Civic and expecting people to come here, yeah, there's a payment of \$25 but often they need the \$25 to get here and it is three hours out of people's time ... So the talk in the future ... they'd [the participants] have to use that \$25 to pay for their Naloxone script. And so these are things that I just don't think are going to work. (Community worker 1)

Stakeholders reported that they were supportive of the training program and its continuation but raised issues concerning feasibility and program change. These included suggestions to:

- consider shortening the length of the training workshop
- expand the program to other regions of Canberra beyond Civic (noting the decline in the number of training workshop participants over time)
- enhance integration of the Alexander Maconochie Centre into the program
- extend THN to other members of the community (noting that training should be provided separately to current workshops in order to assist confidentiality and openness among PWID)
- ensure specific long-term funding, including continuing participant payment
- address logistical issues such as the difficulty of obtaining prescription refills (as the prescribing doctor is off-site) and expanding naloxone supply across ACT pharmacies
- consider the medico-legal implications of THN for GPs and other prescribers so that concerns can be addressed
- consider the appropriateness and acceptability of ACT Health contributing to payment of participant scripts within the PBS system.

Does the program have a sound program theory and program logic?

The program theory underpinning the ACT's THN initiative is documented in the Introduction section; there the theory of change and the theory of action are differentiated. Here we answer the evaluation question 'Does the ACT's naloxone initiative have a sound program theory and program logic?'

The overall assessment of the evaluation is that the rationale underpinning the design and implementation of the program (the program theory) is sound. This conclusion is based on four criteria:

- the validity of key underpinning assumptions
- the fidelity of program implementation
- the extent of implementation
- the availability of resources.

Each of these criteria is discussed briefly below.

Assumptions

The evaluation literature identifies four categories of assumptions relevant to assessing the soundness of a program theory, namely diagnostic assumptions, prescriptive assumptions, transformational assumptions and external assumptions.⁴⁹

Diagnostic assumptions are ‘...stakeholders’ expectations or beliefs of the major and minor causes of core problems’. Through the I-ENAACT process the key stakeholders developed a set of shared understandings about the nature of the problem (opioid overdoses) and its causes. This was based on evidence about the extent and nature of opioid overdose in Canberra and other jurisdictions, and the many factors that impact upon its incidence and severity.

The diagnostic assumptions are sound.

Prescriptive assumptions ‘...relate to the intervention or strategy devised for the problem to reach a stated objective, which represents stakeholders’ beliefs of what could be the best way to address the problem or need’. Again, through the I-ENAACT process, the key stakeholders informed themselves about the strengths and weaknesses of the various strategies for reducing the incidence of opioid overdoses and the severity of their outcomes. The discussions were informed by the scientific literature on THN programs, particularly those focusing on overdose witnesses, including the peers of people at risk. This led to the design of the intervention.

The prescriptive assumptions are sound.

Transformational assumptions ‘...relate to how the immediate results of a strategy, program or intervention (outputs) are expected to lead to long-term desired changes’. Challenges always exist when people design interventions that are relatively small but that address large, multi-causal problems that are particularly serious—and this is a fair characterisation of opioid overdose-related morbidity and mortality. That said, the program developers were confident that the ACT THN program would create a cohort of potential overdose witnesses who had access to naloxone, had the skills to administer it properly, and felt confident enough to do so. On this basis, they were cautiously confident—and this is one of the key evaluation questions that we are answering—that overdose witnesses would actually use the naloxone and reverse overdoses, thus

⁴⁹ The source of the quotations in this section is American Evaluation Association 2013, ‘Working with assumptions in program evaluation’, AEA365: A Tip-a-Day by and for Evaluators, <http://aea365.org/blog/apollo-m-nkwake-on-working-with-assumptions-in-program-evaluation>. Further details are available in Nkwake, AM 2013, *Working with assumptions in international development program evaluation*, Springer, New York.

achieving the overarching goal of minimising the individual and public health impacts of opioid overdoses in Canberra. Furthermore, there was an assumption that the initial period would lead to the scaling-up of the program, and placing it onto an ongoing, sustainable footing.

The first set of transformational assumptions have been found, through this evaluation, to be sound. The soundness of the second set of assumptions, regarding the scaling-up of the program and its sustainability, cannot be determined within the timeframe of this evaluation.

Finally, the *external assumptions* are concerned with the ‘...preconditions for program success that are beyond the control of the program stakeholders’. The preconditions include evidence that the key ACT Government agencies would maintain their support of the program; the training would result in potential overdose witnesses developing attitudes favourable towards using naloxone to reverse overdoses; participants would actually use the naloxone to reverse overdoses; funds would be available from external sources to meet the costs of the first two years of the program; and there would be no significant community or political opposition to the program.

These external assumptions have been found to be sound.

The fidelity of program implementation

The second broad criterion for determining the soundness of the program theory is fidelity of program implementation, i.e. the degree to which the program was actually implemented as intended. This topic was addressed directly by this evaluation. A high degree of program fidelity has been observed, covering domains as diverse as CAHMA personnel effectively recruiting trainees and implementing the training program as intended, maintaining the professional inputs from nursing and medical staff, maintaining the availability of naloxone to provide to potential overdose witnesses on completion of training, etc.

The evaluation concludes that a high degree of fidelity of program implementation has occurred, providing further evidence of the soundness of the underpinning rationale for the intervention.

The extent of program implementation

The extent of program implementation has also been as intended. At the design phase, decisions were made about the number of potential overdose witnesses who would be recruited into the training program, and the proportion who would be prescribed naloxone having successfully completed the training. Those estimates turned out to be appropriate, meaning that the scope of the program—the extent of implementation—was as intended.

The availability of resources

The final criterion for assessing the soundness of the underpinning program theory is the availability of resources to conduct the program. This is a central part of the program theory: were resources insufficient, or not available for a sufficiently long period of time, the validity of the theory of action, in particular, would be in question. In fact, sufficient funds continued to be available throughout the first two years of the program under review, further evidence for the soundness of the program theory.

Conclusions regarding the soundness of the program theory

The evaluation assessed the soundness of the program theory (which encompasses the theory of change and a theory of action) on four criteria: the validity of key underpinning assumptions; the fidelity of program implementation; the extent of implementation; and the availability of resources. On all four criteria the program theory was found to be sound, providing a firm underpinning for, and justification of, the program over the two years under review. Some aspects of the program theory, however, might become invalid in time. For this reason, some of the findings of the evaluation, documented below, focus on what is needed to maintain the strengths of the program and to ensure that the environment within which it operates is facilitative in nature.

To what extent was the program implemented as intended? Did it change in response to identified needs and/or changing contexts?

The program was implemented as intended in that it involved a comprehensive overdose education, resuscitation and naloxone administration workshop available for people who use opioids in the Canberra region.

The ACT program changed in response to identified needs and changing contexts including:

1. Change in packaging (vial to Minijet®) addressed in the workshop delivery and contents of the naloxone kits supplied
2. Change in PBS listing allowed for reduced and low-cost prescriptions for Concession Card holders. Full PBS price was paid for the duration of the evaluation
3. Staff turnover at CAHMA was prepared for and managed
4. Fewer partner organisations than anticipated presented fewer opportunities for widespread recruitment. However, the anticipated 200 participants were recruited in the expected timeframe
5. Negotiation and cooperation with the Alexander Maconochie Centre allowed for the first naloxone training program in Australian prisons
6. CAHMA initiated a refresher course at the request of participants.

What were the costs of the program in terms of financial outlays and staff time?

The estimates in Table 11 are based on the agreed budget prepared by ACT Health and CAHMA April 2012 and December 2014.

Table 11: I-ENAACT program budget

Item	Rationale	Budget
Purchasing training materials and participant recruitment	Resuscitation dummy, education and promotion materials, participant recruitment	\$6,000
Staff training development	Development of training packages, review best practice models, time to prepare and revise drafts	\$25,000
Staff training delivery	Delivery of the training program by CAHMA staff	\$25,000
Participant reimbursement	Reimbursements for participants (training program) @ \$25 per person x 200	\$5,000
Syringes and needles	Supply of syringes and needles in naloxone kits	\$350
Naloxone kit packaging	Purchasing and preparing of naloxone kits	\$1,030
Pharmacy bills	Purchasing of naloxone for participants, including refills	\$13,508
TOTAL		\$75,888

NOTES:

- The prescribing doctor's fees were bulk-billed for all participants, administered through the prescribing doctor's surgery.
- Evaluation and project coordination and governance costs were dealt with separately.

Table 12 contains a summary of estimated costs per (average) training session involving seven participants.

Table 12: Estimated cost per training session

Item	Cost
Participants payments	\$175
Naloxone	\$736
Staff time	\$410
Room hire	\$200
Catering	\$70
Naloxone kit packaging	\$70
TOTAL	\$1661 (\$237 per attendee)

Considerations for future budgetary planning

Two considerations emerged in relation to the budgetary implications of the program.

- Preparing materials, recruiting participants, coordinating attendees, coordinating the prescribing doctor, pre-ordering and collecting the naloxone, venue booking and hire, catering, travelling to and from and running the workshop takes a significant amount of staff time. Continued financial compensation for CAHMA staff is required.
- The addition of naloxone to the PBS in April 2013 allowed for ease of prescription. However, as a PBS-listed medicine, naloxone is now heavily subsidised by the federal government for concession holders. The cost of a 5-pack Minijet® is \$6.10 for a Health Care Card (concession) holder and \$36.10 for a person without a Health Care Card. Continued resourcing of these purchases needs to be explored, including clarification around the role of ACT Health paying for medicines within the PBS system.

Considerations for future program development

In addition to the findings of this evaluation, the evaluation team consulted with stakeholders regarding strategies to safeguard the success and ongoing sustainability of the program. While the program has been successful, several possibilities exist for future development of the workshop and improved sustainability of overdose prevention in the ACT.

The training workshop

The workshop was considered appropriate and successful by participants and stakeholders. In particular, stakeholders reported valuing the ‘hands on’ aspects of the workshop such as working on the CPR dummies. Nevertheless, the current workshop is 2–3 hours in length, which is expensive (in terms of staff time) and a barrier to some participants who do not have the time or do not wish to spend that quantity of time in a workshop. Models of naloxone training vary dramatically around the globe, including short 5–10 minute instruction, and there is no available evidence of differential effectiveness of these different training modes. Given the positive participant feedback received on the workshops, along with expert stakeholders’ suggestions to reduce the length of the training, revision of the workshop content should be considered. Revisions might include shortening the workshop or division of the training into two workshops, one focused on naloxone administration and the other focused on overdose prevention and first aid.

As with any training program, knowledge retention in the months after training declined. However this decline does not appear to have affected successful community use of naloxone, and may have partly been an artefact of the way questions were asked in the follow-up questionnaire. Nevertheless, retention of program information needs to be considered. This could be addressed by providing training and education in the form of ‘booster’ or ‘refresher’ training sessions, online modules and videos, or new written materials targeted at individuals who have been through the training. Stakeholders suggested that the provision of any ongoing community facilitation and training by CAHMA should be recognised and valued in future budgetary decisions.

The evaluation data show a relatively low rate of calls to the ACT Ambulance Service. Although there were no reported impacts of this on successful overdose reversals in the community, it remains an issue for further consideration. In 2014 CAHMA initiated refresher workshops on the request of previous workshop participants. Ongoing training and peer-led discussion about overdose could help maintain knowledge retention post-training and provide opportunities to reinforce the importance of appropriate actions such as calling an ambulance.

Legislative issues

Naloxone is a schedule 4 drug in the ACT routinely used by health personnel to reverse opioid overdoses, and is now available on prescription to the wider community. In the context of opioid overdose a person will generally be unable to administer naloxone to him/herself. Indeed, in our evaluation the majority of program-issued naloxone was used on individuals to whom it was not prescribed. While not surprising, this finding does raise medico-legal implications for GPs and other prescribers that should be investigated and addressed. Legal clarification should be sought on whether or how prescribers may be legally affected and strategies should be developed to educate prescribers on how to best protect their patients and practises.

Furthermore, layperson (or peer) administration of naloxone under the operation of the 'Good Samaritan' provisions of the *Civil Law (Wrongs) Act 2002* (ACT) (Civil Wrongs Act) has legal implications for program participants that should be addressed. Both ACT Health and ATODA have begun investigating the Civil Wrongs Act and a possible amendment to ensure that a person who administers naloxone to another person in good faith is protected from liability, even if the administering person's capacity to exercise appropriate care and skill was, at the relevant time, significantly impaired by a recreational drug. Support for this amendment by the ACT Government would assist in protecting program participants from potential civil liability.

Finally, several stakeholders suggested expanding the ACT THN program to include community members other than people who use opioids. International evidence suggests that training friends and family, as well as non-medical personnel such as police officers, is effective. Further legislative work is needed to facilitate these opportunities, perhaps in the form of naloxone-specific legislation that has been enacted overseas.

Logistical issues

The evaluation raised logistical issues related to access to naloxone in the ACT. During the evaluation period one primary GP attended the training workshops to provide prescriptions, and CAHMA collected the naloxone from the pharmacy for participants. In order to receive a prescription refill under the I-ENAACT program, participants needed to approach CAHMA, which in turn contacted the GP. Only with approval from the GP could CAHMA then collect the prescription refill from the pharmacy on behalf of the participant. As the GP was located off-site and only available part-time at the participating medical clinic, coordination of prescription refill approvals was cumbersome and could take up to a week. This issue might be linked to the low number of participants reporting obtaining prescription refills after witnessing overdoses.

Furthermore, only one pharmacy participated in the supply of naloxone for program participants. There were occasions when this supply was delayed by the

manufacturer. The project team are unaware of whether other ACT pharmacies stock naloxone, or intend to do so following naloxone becoming available under the PBS. There are different models for naloxone access, and the possible implications of these should be examined for the ACT. For example:

- Delivery of training and naloxone provision across a *range of settings* including:
 - one-on-one in pharmacies
 - one-on-one in General Practice settings
 - one-on-one in OST settings
 - workshops or one-on-one in specialist drug treatment services
 - workshops or one-on-one in prisons and other correctional services
 - workshops or one-on-one in Aboriginal Medical Services.

The reduction in number of workshop participants over time was attributed in part to the geographical location of the majority of workshops, which were held in Civic. Feedback from stakeholders and participants suggested that the program needed to be broadened through wider advertising as well as expansion to other parts of the ACT. Barriers to continuing and expanding the program include staffing, provision of prescriptions, patient record-keeping, program supported prescription refills, and so on. These barriers need to be considered in any continuation and/or expansion of the program.

Several stakeholders also suggested the need for investigation of whether naloxone should be made available to people who are prescribed opioids—not only OST but also opioids prescribed for non-cancer pain. Importantly, the follow-up data suggested that those who accessed the ACT THN program included a substantial percentage of people on OST. Further work is needed to access the broader prescription-opioid-using population in the ACT, including an exploration of the number of people on opioid prescriptions in the ACT, the number of non-heroin opioid overdoses in the ACT and the potential modes of training and prescription for this group.

The only service provider with continued involvement in the program was the Alexander Maconochie Centre. Other alcohol and other drug use services could be better integrated in to the program, including training staff in overdose response and enhancing referrals to the programs. The commitment of the Alexander Maconochie Centre and CAHMA to the program should be recognised and opportunities for expansion can be considered. Four small training workshops were run in the prison but not all participants received their naloxone on release, as they were required to pick up their supply from Civic. Successful post-release naloxone distribution in Scotland involves provision of naloxone kits at the point of release.⁵⁰ Such a procedure could provide an opportunity to build

⁵⁰ National Health Services Scotland. 2014. National Naloxone Programme Scotland – naloxone kits issued in 2013/14 and trends in opioid-related deaths Publication date – 28 October 2014.

on the established partnership, recognising that post-release prisoners are at high risk of fatal overdose.

Stakeholders expressed a desire to expand THN to alcohol and other drug workers, family and friends of people who inject opioids, needle and syringe program workers, and other professional groups. Any resultant training initiatives for additional community members should be provided separately from training workshops for people with a history of injecting drug use in the interest of confidentiality and openness.

Stakeholders also noted that the ACT ambulance service had only been partially integrated into the THN program; some staff were aware of the program, but not all. While this did not appear to impact on the success of the program, communication and response needs improvement. This includes informing all ACT Ambulance staff (including paramedics and call-takers) of the program during their training, and reviewing the call centre script relating to overdose to ensure that use of naloxone by a community member is encouraged where appropriate during a 000 phone call.⁵¹ Currently there is a lack of formalised process for dealing with overdose emergencies involving THN.

Financial sustainability

The addition of naloxone to the PBS in April 2013 allowed for ease of prescription of naloxone. However, as a PBS-listed medicine naloxone is now heavily subsidised by the federal government for concession holders. The cost of a 5-pack Minijet® is \$6.10 for a Health Care Card (concession) holder or \$36.10 for a person without a health care card. The model used in this program of THN, where naloxone is provided free of charge, was established prior to the listing of naloxone on the PBS. This means that any continuation of the program should consider how purchases are funded. It is important that costs to program participants should be minimised given the relatively impoverished circumstances of many PWID.

Issues and implications beyond the ACT ENNACT program

The findings of this study and the accumulating international evidence base have implications for expanding the availability of naloxone nationally.

An important recent development is that an application has been made to the TGA to amend the Poisons Standard to change the scheduling of naloxone to include single-use pre-filled syringe preparations for injection containing 400 mcg/mL of naloxone or less in Schedule 3.⁵² Such rescheduling would change this

⁵¹ Kirwan, A., Curtis, M., Cantwell, K., van Beek, I., & Dietze, P. (in preparation). Community naloxone education programs and calls to emergency services.

⁵² TGA (2015) Consultation: Invitation for public comment - ACMS meeting, July 2015, Public consultation on the proposed amendments to the Poisons Standard (Medicines) 2 April 2015. Available at:

naloxone preparation from a 'prescription only' medicine (Schedule 4) to an 'over-the-counter' medicine (Schedule 3). The closing date for submissions pursuant to this application was 7 May 2015, and it is scheduled for consideration at the July 2015 meeting of the TGA, although it is unclear when any decision would be made. We are aware of supportive submissions from individuals and organisations in Australia involved in advocacy and demonstration projects in this country (including some of the agencies represented by the authors of this report).

Should the re-scheduling application be approved it will likely resolve or simplify many of the organisational and legislative barriers to further expansion of naloxone in Australia, but it will also throw up some new logistical challenges which will need to be addressed. The experiences of the ACT I-ENAACT program reflected in this evaluation, along with similar small-scale programs in other Australian jurisdictions, means that there is now a substantial body of local knowledge that can be drawn upon to address these challenges. Our discussion of implications beyond the ACT trial will first consider the possibility that naloxone will be rescheduled, and then discuss a range of issues including scale-up, training, and other matters of relevance to naloxone provision in Australia.

Rescheduling

The proposed rescheduling application has the capacity to greatly improve access to naloxone in the community. We would therefore expect such a change to have an impact on population-level rates of opioid overdose mortality and morbidity much greater than that of the small demonstration programs currently in place in Australia.

Rescheduling would provide opportunities for:

- *Access for workers likely to witness an overdose.* Rescheduling could facilitate access to naloxone among those who are likely to witness overdoses as part of their employment (e.g., peer outreach workers, needle and syringe program staff, drug treatment workers, staff at shelters and other emergency accommodation services, and police and other emergency services workers who attend overdose scenes). These workers cannot be provided naloxone under the current prescription model, although they clearly identify a desire to have access to naloxone as evidenced by them requesting and attending naloxone training through the existing THN programs in Australia (including the ACT program).

- *Simplifying Good Samaritan protection.* Australian THN programs currently provide naloxone under prescription with the intention that it will be administered to the person whose name is on the prescription. Should the medication be administered to a third person in an emergency situation, any liability appears to be covered under Good Samaritan laws that exist across Australian jurisdictions, although coverage is not perfect. For example, in both ACT and NSW (Australian Capital Territory Parliamentary Counsel, 2013; Parliament of New South Wales, 2013) such laws exclude from protection persons intoxicated by a recreational drug. Although legal advice has been received that it would be extremely unlikely that legal action would be pursued against someone trying to save a life with naloxone, another potential benefit of the rescheduling of naloxone to S3 is that it would simplify, if not remove, this potential legal barrier for anyone who administers naloxone to a third party.

However, rescheduled naloxone brings up additional issues around:

- *Price and access.* If the naloxone Miniject® is re-scheduled to S3, it would be important to ensure that the PBS listing is not adversely affected. It is our understanding that those on a Health Care Card would continue to pay \$6.10 for up to five Minijects® should they access the drug across the counter, but the costs for those not on a Health Care Card could rise. As indicated above, cost is likely to be central factor in the uptake of naloxone, particularly for members of disadvantaged communities, and not all of the target group are Health Care Card holders.
- *Training and instructions.* Rescheduling to S3 would allow a range of new and innovative ways of providing training to maximise the benefits of wider naloxone availability on preventing morbidity and mortality. Current practice recognises that the administration of naloxone is but one component of a comprehensive response to prevention and management of opioid overdose. The current Australian and international training packages used by THN programs cover a range of important issues, including airway management, resuscitation, naloxone administration, post-naloxone care, and the need for replacement of naloxone deemed expired as it is beyond its use-by date. The most essential elements of these training packages will still need to be delivered to those who access naloxone over-the-counter through pharmacies. A combination of appropriately designed information materials within the naloxone package, combined with other brief materials (e.g., pointers to on-line training videos) and some brief advice or instruction by pharmacy staff, may serve this purpose. Internationally there is at least one call for pharmacists to take on this role,⁵³ and similar models have been applied in other settings (e.g. drug treatment⁵⁴). Given the benefits of

⁵³ Thomas SA. 2015. Opioid overdose rescue kits. U.S. Pharmacist, 40, HS2-HS6.

⁵⁴ Walley AY, Doe-Simkins M, Quinn E, Pierce C, Xuan Z, Ozonoff A. 2013. Opioid overdose prevention with intranasal naloxone among people who take methadone. Journal of Substance Abuse Treatment, 241-247.

overdose response training, in addition to training on naloxone administration, partnerships between pharmacies and training services could provide clients ready access to overdose management training outside of the pharmacy. Whilst ideally it would be best for the naloxone and the instruction to be provided concurrently, the general point is that this issue will need to be addressed and there is a range of possible solutions across different settings. The existing materials and training protocols that have been developed in Australia since 2012, and are based on international best practice, provide a useful starting point for such deliberations.

- *Packaging and presentation of the naloxone.* Currently naloxone is available in Australia in a 400 mcg pre-filled syringe (Minijet®) produced by UCB Pharma UK and distributed in Australia by CSL Biotherapies. While a single dose of this size is appropriate for reversing most opioid overdoses that have been dealt with in Australian THN programs, most programs offer more than one Minijet® (between two and five Minijets®) to enable sufficient doses in an overdose emergency if the initial dose is inadequate or if the person falls into overdose again once the initial dose has worn off. Having more than one Minijet® is also helpful where the rescuer has to manage situations where more than one person has overdosed simultaneously. The Minijet® is ideal for lay administration as it is easier to operate than using other formulations such as ampoules and a syringe. However, current Minijet® packaging is oriented to medical settings and does not come with the required needle or appropriate instructions for layperson use. Most existing Australian THN programs have been providing the naloxone as part of kits that typically include a 23-gauge needle per Minijet® suitable for intramuscular injection, along with brief instructional materials designed for lay administration, alcohol wipes, face shields (for EAR), disposable gloves and a sharps disposal container. Whilst it may not be feasible to include all such materials in over-the-counter naloxone sales, intramuscular needles and appropriately designed brief instruction materials will be essential. We argue that any materials should be designed through engagement with Australian drug user groups involved in current THN naloxone programs. However, the suitability of these materials for wider groups of people who use opioids will need examination.
- *Intranasal naloxone.* Intranasal naloxone has advantages over intramuscular injection, especially for people not familiar with injection practices, thereby potentially making naloxone training simpler, while at the same time eliminating the risk of blood-borne virus transfer.^{55, 56, 57} In the US naloxone is available in a higher concentration (2 mg/2 mL) for intranasal

⁵⁵ Doe-Simkins M, Walley AY, Epstein A, Moyer P. Saved by the Nose: Bystander-Administered Intranasal Naloxone Hydrochloride for Opioid Overdose. *American Journal of Public Health*. 2009;99:778-91.

⁵⁶ Kerr D, Kelly A-M, Dietze P, Jolley D, Barger B. Randomized controlled trial comparing the effectiveness and safety of intranasal and intramuscular naloxone for the treatment of suspected heroin overdose. *Addiction*. 2009;104:2067-74.

⁵⁷ Beletsky L, Rich JD, Walley AY. Prevention of fatal opioid overdose. *JAMA: The Journal of the American Medical Association*. 2012;308:1863-4.

administration with the application of a mucosal atomiser device unit on the end of the Minijet®, although this form is currently off-label for intranasal use in the U.S., pending FDA approval. A currently approved naloxone auto-injector device by EVIZIO has not had pricing determined,⁵⁸ but is likely to be many times more expensive than the available forms.⁵⁹ Naloxone is currently not approved for intranasal administration by the Australian TGA. It is anticipated that a cost-effective intranasal preparation of naloxone ideally suited to layperson use will be put before the TGA for approval in the next 12 months. However, this should not be a barrier to the TGA approval of the current application as for S3 scheduling of the Minijet® formulation for intramuscular administration.

Other matters

- *Prison.* As described in the introduction, international research shows that people who use opioids are at greatly increased risk of overdose during the first few weeks after prison release. There is now good and growing evidence that providing overdose education and naloxone distribution to prisoners before their release can drastically reduce the overdose rate for this high-risk group. Consistent with this, the ACT I-ENAACT program accessed prisoners within the Alexander Maconochie Centre who were trained in the prison and collected naloxone prescriptions post-release. At least one other THN program in an Australian jurisdiction is currently expanding THN into a prison setting. Opportunities for engagement with prison authorities are enhanced by their recognition of duty of care for prisoners beyond release especially because at least in one jurisdiction, counts of deaths in custody often extend to mortality in the post-release period (Grace Oh, Personal communication, 9/7/15). While it is likely that careful negotiation will be required with the various stakeholders, the existing THN programs show that it is possible to work through the relevant issues. Ideally THN should be provided to prisoners along with their other medications at prison discharge. This is important as overdose can occur very soon after release—before the released prisoner makes contact with other agencies or services, if they do this at all.
- *Different formats for different settings.* In Australia, as elsewhere, drug user groups have been central to the advocacy for and development of THN programs. Although the I-ENAACT program, and most of the other THN programs in Australia have been peer-led, there is a recognition that, consistent with international evidence, this need not be the only format or setting for providing overdose education and naloxone training and distribution. Indeed the OPEN program running in NSW is a health service based service (see⁶⁰). Different contexts are likely to provide different opportunities for overdose training incorporating naloxone to be provided in

⁵⁸ Thomas, S. A. 2015. Opioid overdose rescue kits. U.S. Pharmacist, 40, HS2-HS6.

⁵⁹ Kroll, D. 2014. FDA Rapidly approves naloxone auto-injector for heroin and prescription opioid overdose. Forbes Magazine (published 03/04/2014).

⁶⁰ Chronister KJ, Lintzeris N, Jackson A, Ivan M, Dietze P, Lenton S, Kearley J, van Beek I. (accepted). Findings and lessons learnt from implementing Australia's first health service based take-home naloxone program.

different ways. For example, in clinical settings, where clinic staff have an ongoing relationship and regular contact with their clients, part of the training could be provided by different clinic staff, e.g. practice nurses, with prescription happening later.

Conclusions

In summary, our evaluation shows that the ACT THN program has achieved its objectives in relation to recruitment and training of participants in overdose response, and participants can be trained to administer THN in appropriate circumstances. Furthermore, we documented 57 separate episodes of program-issued naloxone being used without adverse events.

A positive unintended consequence of the program was participants reporting a sense of empowerment, and positive emotional impacts associated with program participation. Both program participants and key stakeholders support the continuation of the program.

The I-ENAACT program represents one delivery model of THN programs. Alongside international evidence on the effectiveness of various models of THN programs, the findings of this report are evidence of the feasibility of naloxone programs in Australia and could be used in the consideration of a variety of THN delivery models in the community.