‘From little things big things grow’ - Policy and practice diffusion and development in wider availability of naloxone in Australia 1999-2023.

Simon Lenton[1], Paul Dietze[1,2], Suzanne Nielsen[3], Grace Oh[4], Paul Dessauer[5], Sione Crawford[6], Nick Lintzeris[7,8]

[1]National Drug Research Institute & enAble Institute, Curtin University, Perth, Australia.
[2]Behaviours and Health Risks Program, Burnet Institute, Melbourne, Australia.
[3]Monash Addiction Research Centre, Monash University, Melbourne, Australia.
[4]Australian Drug Education & Consultancy, Perth, Australia.
[5]Peer Based Harm Reduction WA, Perth, Australia.
[6]Harm Reduction Victoria, Melbourne, Australia.
[7]South East Sydney Local Health District, Sydney, Australia.
[8]Discipline of Addiction Medicine, The University of Sydney, Sydney, Australia

Presenter’s email: *s.lenton@curtin.edu.au*

Acknowledge Traditional owners

I would like to recognise The Ngunnawal people traditional owners of the Canberra Region

I would like also like to recognise all the traditional owners of Australia including the Whadjak People of the Noongah Nation on the land where I was born and work

Outline

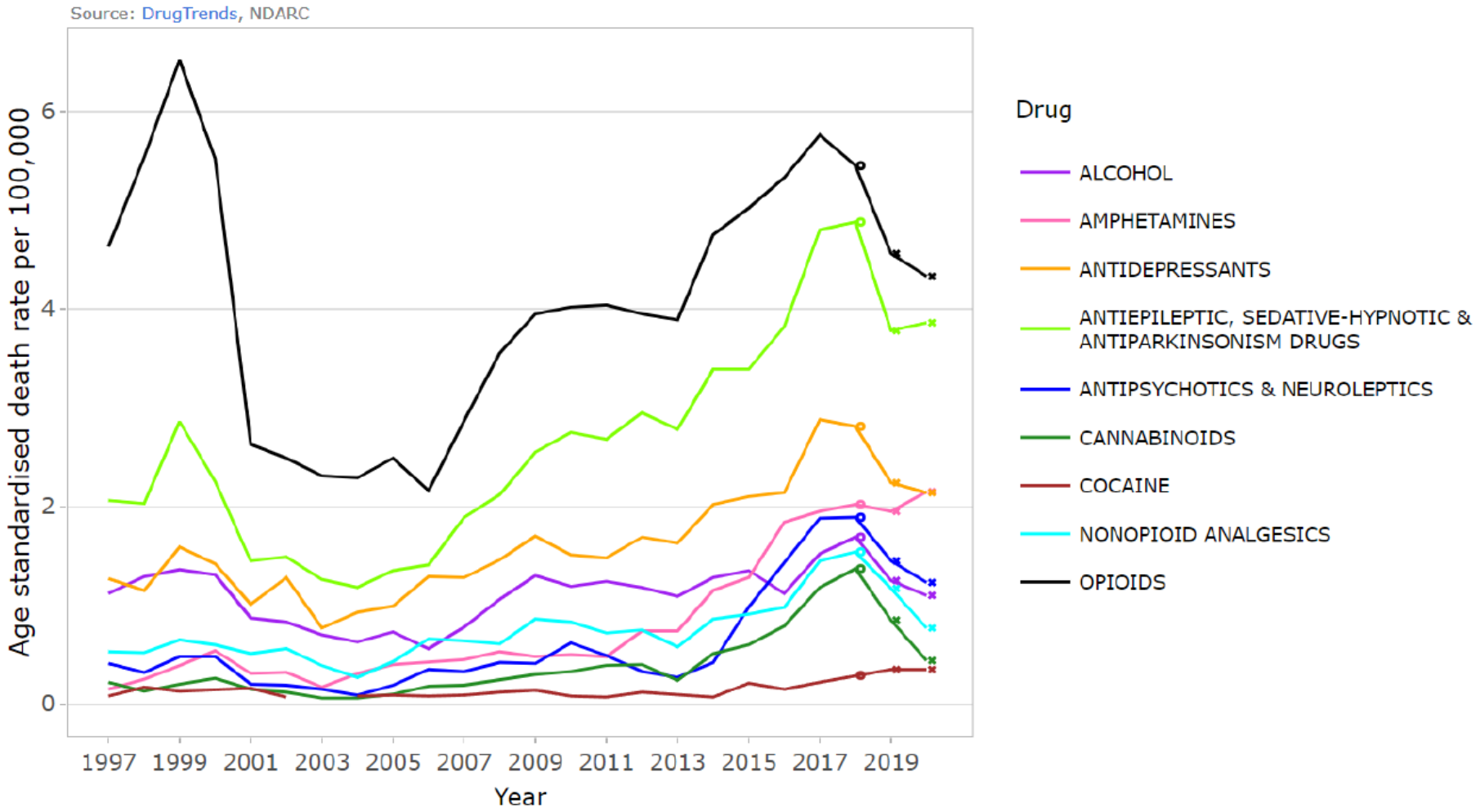
Aim:

- to track the development of THN in Australia from a small-scale program in one jurisdiction, through to THN availability across the country at no charge.

Why?

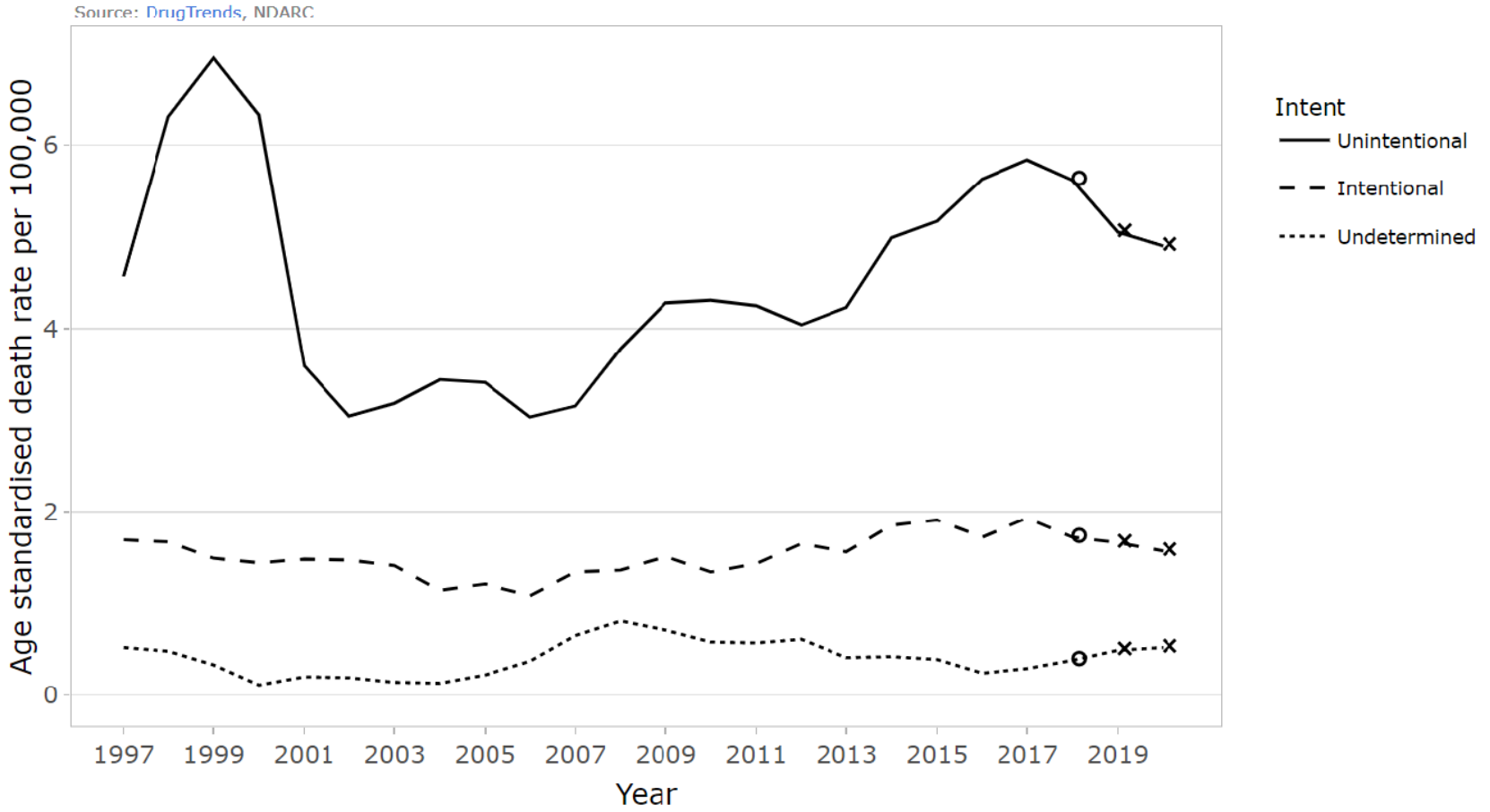
- Unlike in North America, an opioid overdose crisis has never been declared in Australia.
- Yet, it has been possible to advocate for the establishment of THN and develop an evidence base and advocacy coalition that has led to a nationwide free naloxone program and empowering those most at risk of opioid overdose related harms.
- Although there is more to be done.

Figure 14. Age-standardised rate per 100,000 people of drug overdose deaths for the Australian population, by drug class, 1997-2020.



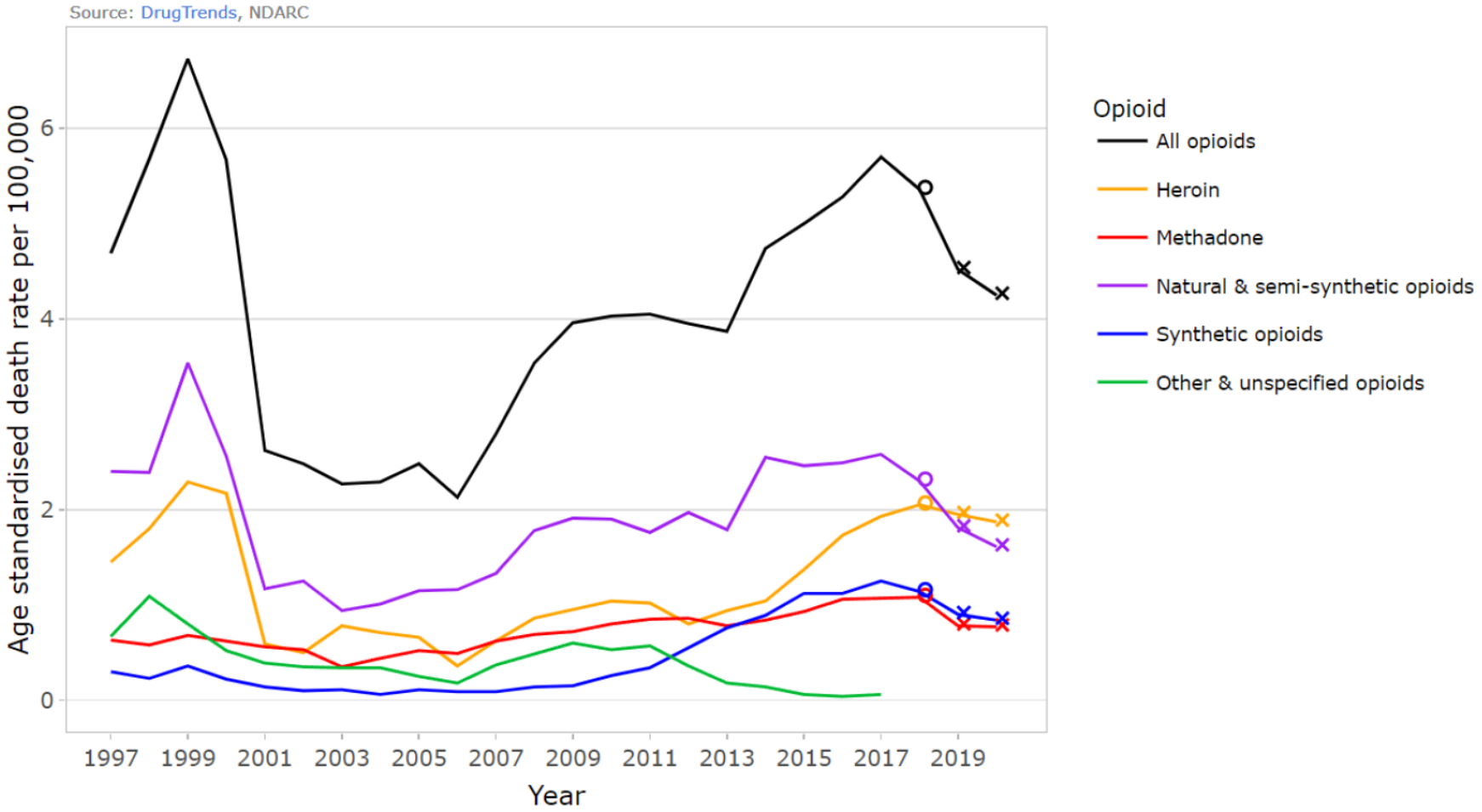
(Chrzanowska, Man, Sutherland, Degenhardt, & Peacock, 2022).

Figure 8. Age-standardised rate per 100,000 people of drug overdose deaths for the Australian population, by intent, 1997-2020.



(Chrzanowska, Man, Sutherland, Degenhardt, & Peacock, 2022).

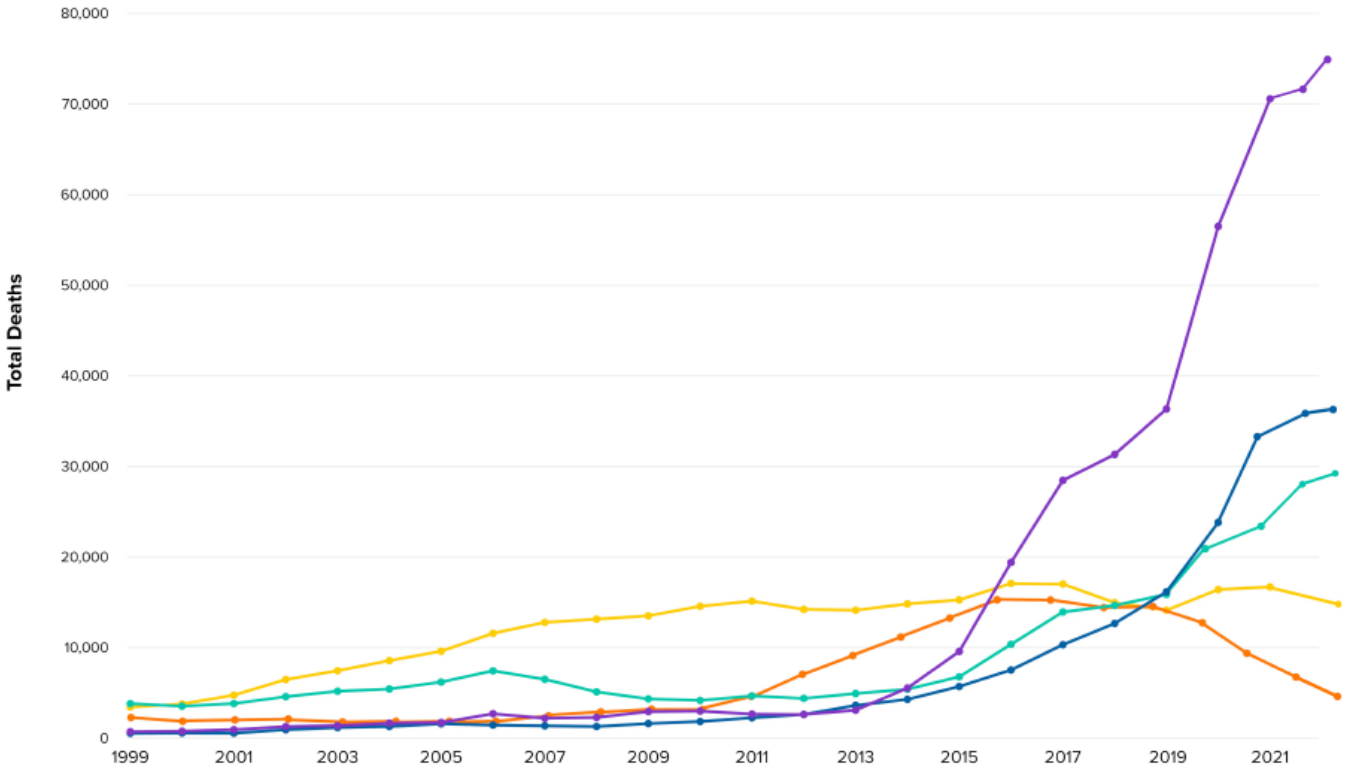
Figure 20. Age-standardised rate per 100,000 people of opioid-induced deaths for the Australian population, by opioid type, 1997-2020.



(Chrzanowska, Man, Sutherland, Degenhardt, & Peacock, 2022).

Trends in U.S. Drug Overdose Deaths (December 1999–June 2023), by Drug Type*

The overdose crisis has evolved over time and is now largely characterized by deaths involving illicitly manufactured synthetic opioids, including fentanyl and, increasingly, stimulants.



Synthetic opioids excluding methadone overdose deaths increased **103-fold**

Psychostimulants with abuse potential (primarily methamphetamine) overdose deaths increased **64-fold**

Cocaine overdose deaths increased **7.6-fold**

Rx opioid overdose deaths increased **4.1-fold**

Heroin overdose deaths increased **2.5-fold**

U.S. Department of Health & Human Services

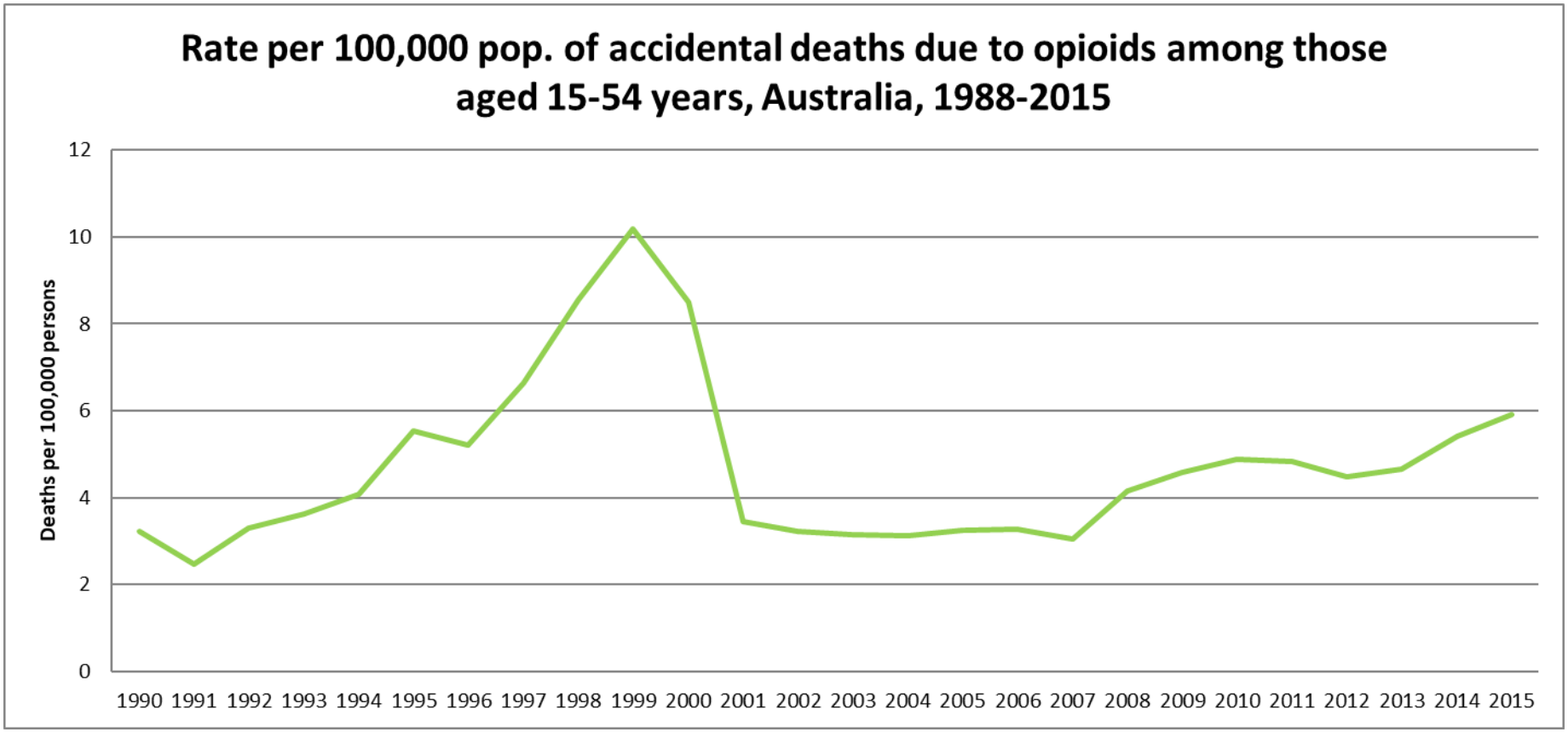
Overdose Prevention Strategy

Naloxone for peer Administration

(Lenton & Hargreaves, 2000)

- Safety? Few complications in managing Heroin OD
- Just one part of emergency response to OD
- Poly drug use? Removing opioid usually prevents death
- Using alone? In 60% of fatalities person not alone
- Intoxicated Admin? Simpler than many other interventions
- Lead to more hazardous H use? Unlikely to be widespread
- Lead to more H users? Unlikely as H OD not main barrier
- Delay calling ambos? Some international evidence
- Increased mortality & morbidity? Possible but unlikely
- Shelf life? 18 – 24 months (+)
- Use as Rapid detox? Unlikely

Opioid related deaths in Australia



(From Roxburgh & Burns, 2017; Roxburgh, Dobbins, Degenhardt & Peacock, 2018)

MJA • Volume 191 Number 8 • 19 October 2009 LETTERS

Naloxone for administration by peers in cases of heroin overdose

Simon R Lenton, Paul M Dietze, Louisa Degenhardt, Shane Darke and Tony G Butler

To the Editor: We wish to call for the removal of scheduling and legislative barriers in Australia that prevent easy access to naloxone for administration by peers to people suffering from a heroin overdose.

Use of illicit opioids, typically heroin, remains the major cause of illicit drug-related mortality in this country, with at least one accidental opioid overdose currently occurring each day.[1] Although population levels have not reached those seen during the peak in the late 1990s, geographically localised and transient increases in overdoses are evident.[2]

Death from heroin overdose typically occurs some time after use. In many cases, other people are present, and there is considerable scope for intervention to prevent death.[3] Yet, in more than 70% of cases of fatal overdose, there is no intervention, and, where action is taken, calling an ambulance is seldom the first strategy, resulting in even greater risk of death.[3]

Opioid substitution treatment (with methadone or buprenorphine) is the mainstay of overdose prevention in Australia. Other interventions implemented here include outreach services and education for injecting drug users about the risks of overdose and how to respond to it.[3]

In 2000, Lenton and Hargreaves summarised the evidence for distributing the opioid antagonist naloxone for administration by peers to prevent deaths from heroin overdose. They concluded that an Australian research trial was needed.[4] However, in 2001, the Australian heroin market was disrupted, her-

In our view, the international evidence clearly indicates that increased naloxone availability will prevent many cases of fatal overdose, that conducting a trial in Australia is now unnecessary, and that naloxone should be made available without delay to be administered by peers in cases of opioid overdose. Careful monitoring and evaluation should be a part of this process.

We call on all Australian states and territories to immediately enact Good Samaritan legislation to legally protect laypeople using naloxone in emergency situations. Naloxone should be reclassified from a Schedule 4 (S4) drug (available only on prescription) to S3 or S2 to make it available over the counter. As naloxone is no longer under patent,[5] there may be little financial incentive for a drug company to pursue rescheduling. However, it could be rescheduled in Australia under provisions that allow state health authorities, professional associations or the National Drugs and Poisons Schedule Committee to initiate the process.

Heroin overdose deaths are preventable. We need to take action now to enable peer-led intervention to reduce this serious outcome.

Competing interests: Louisa Degenhardt has received an untied educational grant from Reckitt Benckiser to investigate the diversion and injection of buprenorphine. No funder had any input to this letter.

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Paul M Dietze, Principal Research Fellow and Associate Professor[2]
Louisa Degenhardt, Professor and Assistant Director[3]
Shane Darke, Professor[3]
Tony G Butler, Associate Professor[1]

1 National Drug Research Institute, Curtin University of Technology, Perth, WA.
2 Burnet Institute, Monash Institute of Health Services Research, Monash University,

Drug and Alcohol Review (November 2009), 28, 583–585
DOI: 10.1111/j.1465-3362.2009.00125.x

EDITORIAL

Now is the time to take steps to allow peer access to naloxone for heroin overdose in Australia

Heroin overdose deaths are preventable. Overdose prevention in Australia has largely rested on opioid substitution treatment supplemented with outreach services and education for injecting drug users (IDUs) about overdose risks and responses. We believe now is the time to make naloxone hydrochloride (Narcan ®) available to Australian IDUs to help prevent overdose deaths.

At the end of 2000 heroin availability and harm in Australia rapidly declined [1].

Despite this, overdoses involving heroin or diverted pharmaceutical opioids continue to account for most illicit drug-related deaths in this country. In 2005, the last year reliable data were available [2], at least one citizen died from accidental opioid overdose each day, most related to the injection of heroin [3]. Heroin is still the drug of choice among the majority of Australian IDUs [2]. To date, there is no evidence that levels of heroin overdoses have increased to levels seen in the 1990s. However, transient geographical clusters of overdoses are evident in ambulance transport data (e.g. [4]). This pattern is consistent with the high number of low weight 'scatter importations' of heroin (through mail and air passenger traffic) that increasingly characterise heroin importations detected at the Australian border since 2004 [5].

Since the mid 1990s there have been calls to make naloxone available to heroin users, their peers and family members to prevent overdose deaths [6,7]. Lenton and Hargreaves reviewed the literature in 2000 and concluded that peer naloxone had real promise as part of a comprehensive overdose–response, but that an Australian trial was needed before naloxone was made more widely available in this country [8,9]. The dramatic decline in heroin overdose that accompanied the heroin 'shortage' [1,10] meant that the proposed trial did not proceed.

However, accumulating international evidence since 2000 shows that the provision of naloxone, with appropriate training, to IDU peers, family members and outreach workers can lead to successful heroin overdose reversals with few, if any, adverse effects (e.g. [11–13]). Indeed, many thousands of doses of naloxone have been distributed for this purpose. In the US alone, over a thousand cases of overdose reversal by peers using naloxone have been documented [11]. By December 2008 there were 52 peer–naloxone distribution programs operating across 17 US States [13]. None of the major concerns about the intervention (such as unsafe administration of naloxone, problems with re-intoxication where longer acting opioids have been used, or more risky drug use if heroin were to be seen as less dangerous) have eventuated and naloxone has been shown to be a remarkably safe intervention when administered by trained IDU peers [11,13–15]. The effectiveness of the intervention probably reflects the fact that training heroin users and their peers in naloxone administration has only been implemented as part of a comprehensive approach to overdose management (e.g. [12,16–18]).

A major concern relating to peer naloxone has been the legal ramifications of administering drugs to a third party [8,19]. In response to this concern, specific 'Good Samaritan' legislation has been enacted in some jurisdictions (e.g. the UK and some states of the USA) in order to indemnify against prosecution those third parties who in good faith administer a life-saving drug. Prescription and scheduling issues also present as possible systemic barriers to implementing these programs. In California, New York, New Mexico and Connecticut naloxone can be legally prescribed to third-party lay people [13]. In other jurisdictions (e.g. Italy) naloxone is available over-the-counter, thereby eliminating the necessity of a prescription, and there have been no adverse consequences reported [13]. Another concern has been raised around the potential for blood-borne virus transmission as naloxone has traditionally been administered by injection [20]. However, intranasal administration of the drug has been successfully trialled with paramedics, thereby decreasing any risk of blood-borne virus transmission through needle stick injury [21]. Intranasal naloxone kits are distributed by health authorities in New Mexico and Massachusetts [13] and there are now case reports of 74 successful overdose reversals by peers using intranasal naloxone in Boston [16]. These developments show that the barriers to wider naloxone distribution are certainly surmountable [19]. An

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Ideas into ACTION: Nicole Wiggins CAHMA Carrie Fowlie ATODA

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In 2000, Lenton and Hargreaves summarised the evidence for distributing the opioid antagonist naloxone for administration by peers to prevent deaths from heroin overdose. They concluded that an Australian research trial was needed.[4] However, in 2001, the Australian heroin market was disrupted, heroin use and overdoses declined, and the trial did not proceed.

Since then, emerging international evidence has demonstrated that injecting drug-using peers, family members and outreach workers can successfully administer naloxone to reverse heroin overdose — with few, if any, adverse effects.[5] By December 2008 in the United States, 52 programs distributing naloxone for administration by peers were operating in 17 states, with over 1000 documented overdose reversals resulting from these programs.[5] Most concerns about the intervention — such as the possibility of unsafe naloxone administration, reintoxication or more risky drug use — appear to have been unfounded, and naloxone administration by trained peers has been shown to be a remarkably safe intervention.[5]

In our view, the international evidence clearly indicates that increased naloxone availability will prevent many cases of fatal overdose, that conducting a trial in Australia is now unnecessary, and that naloxone should be made available without delay to be administered by peers in cases of opioid overdose. Careful monitoring and evaluation should be a part of this process.

We call on all Australian states and territories to immediately enact Good Samaritan legislation to legally protect laypeople using naloxone in emergency situations. Naloxone should be reclassified from a Schedule 4 (S4) drug (available only on prescription) to S3 or S2 to make it available over the counter. As naloxone is no longer under patent,[5] there may be little financial incentive for a drug company to pursue rescheduling. However, it could be rescheduled in Australia under provisions that allow state health authorities, professional associations or the National Drugs and Poisons Schedule Committee to initiate the process.

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Tony G Butler, Associate Professor[1]
1 National Drug Research Institute, Curtin University of Technology, Perth, WA.
2 Burnet Institute, Monash Institute of Health Services Research, Monash University, Melbourne, VIC.
3 National Drug and Alcohol Research Centre, University of New South Wales, Sydney, NSW.
s.lenton@curtin.edu.au

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Canberra Times October 2010 News

Push for heroin overdose drug

By LOUIS ANDREWS

A HEROIN overdose medicine could be given directly to drug users and their families in a bid to intervene early and avoid fatal overdoses under a new proposal.

The Alcohol, Tobacco and Other Drug Association, a peak body representing organisations in the alcohol and drug sector, has put forward a proposal for a two-year trial of peer-administered naloxone.

Hospitals and emergency services workers already use the drug to treat heroin overdoses.

But programs overseas have been prescribing the opioid antagonist to drug users and people close to them – potential overdose witnesses – for a number of years.

The association, along with drug user support group the Canberra Alliance for Harm Minimisation and Advocacy, has called for a two-year pilot program.

The program would train about 200 people in naloxone administration and overdose management.

The association has estimated the cost of such a program at $200,000. It would be the first such program in Australia, but more than 50 similar projects are operating in the United States.

According to the association's proposal, the program would seek to "reduce and prevent opioid overdoses in the ACT by conducting a peer-led program that includes an evaluated trial of naloxone administration".

Health Minister Katy Gallagher was hesitant about supporting the proposal before being more thoroughly briefed.

"As Minister for Health I have not received any representations about any such trial," she said.

"Whilst I understand the positive motivations from CAHMA around this proposal, I would need to take some advice from ACT Health, [the Department of Justice and Community Safety] and the ACT Government Solicitor before I could comment further on the proposal."

Canberra Alliance for Harm Minimisation and Advocacy manager Nicole Wiggins said the participants would ideally include drug users and their families. "A lot of these programs overseas include families and friends, so to include just heroin users would defeat the purpose a bit, or be a missed opportunity," she said.

The concept has been controversial overseas because of liability concerns about non-medical personnel administering the drug.

Ms Wiggins said there had been a push for such a trial 10 years ago, but momentum faded with the onset of the heroin drought and a fall in the number of fatal overdoses.

But an increase in prescription opioid abuse put the proposal back on the agenda.

FOCUS: Page 28

Canberra Times 11/12/10 p.3.

Overdose antidote scheme proposed

By Bianca Hall

ACT Health is investigating a trial program that would allow the families and friends of heroin and opiate users to resuscitate them in the event of an overdose.

During the height of Australia's heroin glut of 1998-2001, an estimated 1000 Australian lives were lost to overdose each year.

But drug and health workers say while heroin use rates are dropping in Australia, opiate use – including pharmaceutical opiate prescriptions – continues to be widespread.

Family Drug Support founder Tony Trimington said, "The deaths have still been running at the rate of about 400 a year and we have evidence that heroin is on the rise again."

Mr Trimington's son Damien died of a heroin overdose in a Sydney alley in 1997, aged 23.

"As a father who lost his son to an overdose I can say that to have a supply [of the anti-overdose drug Narcan] on the premises would save lives. I regard it as very important."

According to ACT Health figures, ambulance officers attended more than 120 heroin overdoses last year.

In Australia, only emergency personnel such as ambulance workers and paramedics are authorised to administer the anti-overdose drug nalaxone, commonly known by its brand name Narcan.

The proposal, which would be an Australian first, was put to ACT Health by the Alcohol Tobacco and Other Drug Association.

Association health worker Geoffrey Ward said, "It's a town with a lot of substance abuse issues across the board, really, but there was a spike in methamphetamine use that has settled down.

"We're now trending back to use of opiates."

If the association's proposal succeeds, an opiate user would be prescribed Narcan to be administered by a third party such as a housemate, partner or family member. That third party would be trained to administer the drug in the event of overdose.

Narcan works by blocking the brain receptors activated by opiates, instantly reversing an overdose. It is effective against heroin and prescription opiate overdoses.

In the United States, where a heroin or opiate user's peers can administer Narcan for them in 17 states, 1000 lives were saved in 2008, according to the *American Journal of Public Health*.

The association says it would be most beneficial for people recently released from prison, who are of high risk of overdose.

It says the initiative could be tried for 24 months for $200,000, including an external evaluation and the establishment of a peer-supported drug-user group to implement the program.

ACT Health spokeswoman Hasnah Scheding said the organisation was investigating whether there were legal barriers to introducing a pilot program and whether it had the support of local medical practitioners.

"Preliminary advice is that it is something that could potentially save lives and, if targeted well and supported by key groups locally, it may be a valuable addition to current drug overdose prevention interventions in the ACT," she said.

Working together for THN – ENAACT & NNRG

Drug and Alcohol REVIEW

Drug and Alcohol Review (July 2015), 34, 404–411
DOI: 10.1111/dar.12198

Working together: Expanding the availability of naloxone for peer administration to prevent opioid overdose deaths in the Australian Capital Territory and beyond

SIMON LENTON[1], PAUL DIETZE[2], ANNA OLSEN[3], NICOLE WIGGINS[4], DAVID McDONALD[5] & CARRIE FOWLIE[6]

[1]*National Drug Research Institute, Faculty of Health Sciences, Curtin University, Perth, Australia,* [2]*Centre for Population Health, Burnet Institute, Melbourne, Australia,* [3]*Kirby Institute, University of NSW, Sydney, Australia,* [4]*Canberra Alliance for Harm Minimisation and Advocacy, Canberra, Australia,* [5]*National Centre for Epidemiology and Population Health, The Australian National University, Canberra, Australia, and* [6]*Alcohol Tobacco and Other Drug Association ACT, Canberra, Australia*

Abstract

Issue. *Since the mid-1990s, there have been calls to make naloxone, a prescription-only medicine in many countries, available to heroin and other opioid users and their peers and family members to prevent overdose deaths.* ***Context.*** *In Australia there were calls for a trial of peer naloxone in 2000, yet at the end of that year, heroin availability and harm rapidly declined, and a trial did not proceed. In other countries, a number of peer naloxone programs have been successfully implemented. Although a controlled trial had not been conducted, evidence of program implementation demonstrated that trained injecting drug-using peers and others could successfully administer naloxone to reverse heroin overdose, with few, if any, adverse effects.* ***Approach.*** *In 2009 Australian drug researchers advocated the broader availability of naloxone for peer administration in cases of opioid overdose. Industrious local advocacy and program development work by a number of stakeholders, notably by the Canberra Alliance for Harm Minimisation and Advocacy, a drug user organisation, contributed to the rollout of Australia's first prescription naloxone program in the Australian Capital Territory (ACT). Over the subsequent 18 months, prescription naloxone programs were commenced in four other Australian states.* ***Implications.*** *The development of Australia's first take-home naloxone program in the ACT has been an 'ice-breaker' for development of other Australian programs. Issues to be addressed to facilitate future scale-up of naloxone programs concern scheduling and cost, legal protections for lay administration, prescribing as a barrier to scale-up; intranasal administration, administration by service providers and collaboration between stakeholders.* [Lenton S, Dietze P, Olsen A, Wiggins N, McDonald D, Fowlie C. Working together: Expanding the availability of naloxone for peer administration to prevent opioid overdose deaths in the Australian Capital Territory and beyond. *Drug Alcohol Rev* 2015;34:404–11]

Key words: opioid overdose, naloxone, peer, policy, Australia.

Introduction

Naloxone is an opioid antagonist drug that reverses the effects of heroin and other opioid drugs. It does not cause intoxication. It has been used for over 40 years in emergency medicine and anaesthesia [1]. Naloxone is listed on the Australian Pharmaceutical Benefits Scheme as an S4 medication and as such is currently only available by prescription in Australia [2,3].

In the mid-1990s, calls were made to make naloxone available to opioid (typically heroin) users and their peers and family members to prevent overdose deaths through 'take-home' naloxone programs [4,5]. Such programs have now been implemented in many countries, including the UK, the USA, Canada, Germany, Georgia, Russia, Spain, Norway, Afghanistan, China, Kazakhstan, Tajikistan and Vietnam [6,7]. Naloxone has been available across the counter in Italy since 1995

Simon Lenton PhD, MPsych(clin), Professor, Paul Dietze PhD, BSc (hons), Professor, Anna Olsen PhD, BSc/BA (hons), Dr, Nicole Wiggins Ms, David McDonald BA, DipSocWk, MA, GradDipPopInHealth, FPHAA, Mr, Carrie Fowlie Ms. Correspondence to Professor Simon Lenton, National Drug Research Institute, Faculty of Health Sciences, Curtin University, GPO Box U1987, Perth, WA 6845, Australia. Tel: +61 8 92661603; Fax: +61 8 92661611; E-mail: s.lenton@curtin.edu.au

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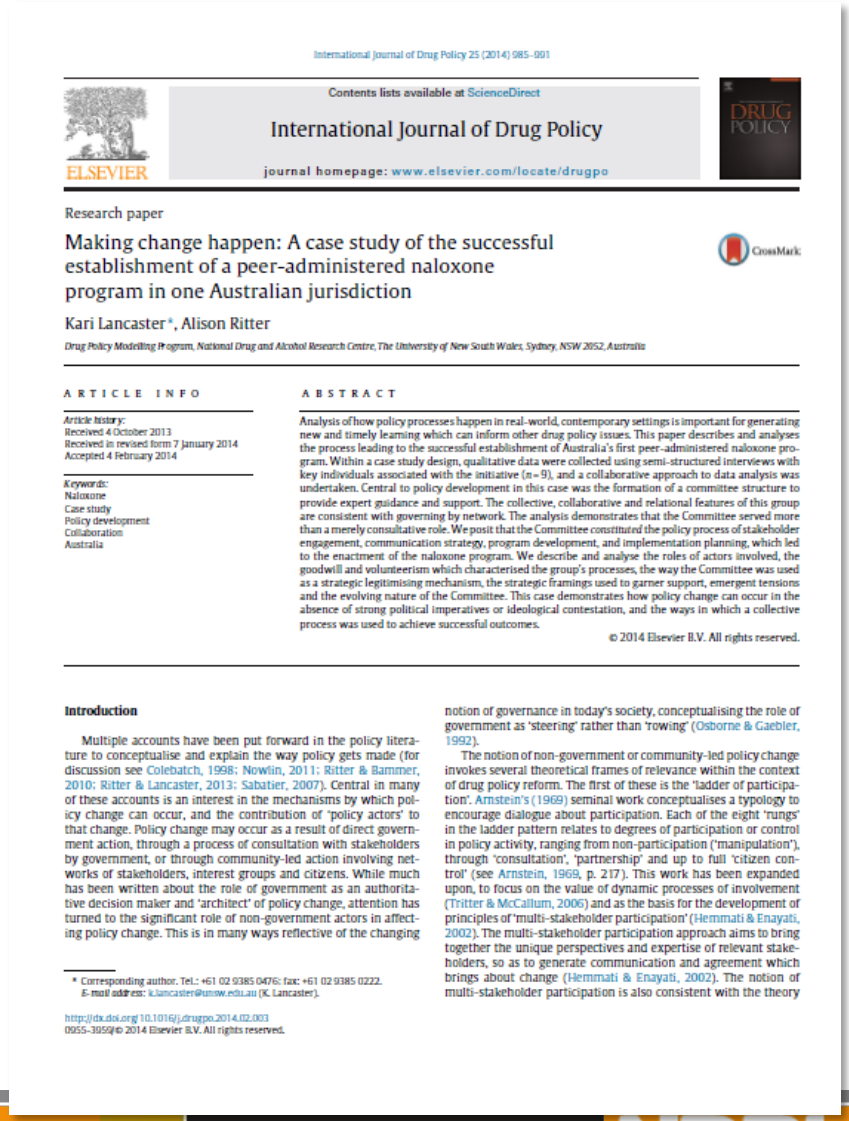

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Research paper

Making change happen: A case study of the successful establishment of a peer-administered naloxone program in one Australian jurisdiction

Kari Lancaster*, Alison Ritter

Drug Policy Modelling Program, National Drug and Alcohol Research Centre, The University of New South Wales, Sydney, NSW 2052, Australia

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ABSTRACT

Analysis of how policy processes happen in real-world, contemporary settings is important for generating new and timely learning which can inform other drug policy issues. This paper describes and analyses the process leading to the successful establishment of Australia's first peer-administered naloxone program. Within a case study design, qualitative data were collected using semi-structured interviews with key individuals associated with the initiative (n = 9), and a collaborative approach to data analysis was undertaken. Central to policy development in this case was the formation of a committee structure to provide expert guidance and support. The collective, collaborative and relational features of this group are consistent with governing by network. The analysis demonstrates that the Committee served more than a merely consultative role. We posit that the Committee constituted the policy process of stakeholder engagement, communication strategy, program development, and implementation planning, which led to the enactment of the naloxone program. We describe and analyse the roles of actors involved, the goodwill and volunteerism which characterised the group's processes, the way the Committee was used as a strategic legitimising mechanism, the strategic framings used to garner support, emergent tensions and the evolving nature of the Committee. This case demonstrates how policy change can occur in the absence of strong political imperatives or ideological contestation, and the ways in which a collective process was used to achieve successful outcomes.

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Introduction

Multiple accounts have been put forward in the policy literature to conceptualise and explain the way policy gets made (for discussion see Colebatch, 1998; Nowlin, 2011; Ritter & Bammer, 2010; Ritter & Lancaster, 2013; Sabatier, 2007). Central in many of these accounts is an interest in the mechanisms by which policy change can occur, and the contribution of 'policy actors' to that change. Policy change may occur as a result of direct government action, through a process of consultation with stakeholders by government, or through community-led action involving networks of stakeholders, interest groups and citizens. While much has been written about the role of government as an authoritative decision maker and 'architect' of policy change, attention has turned to the significant role of non-government actors in affecting policy change. This is in many ways reflective of the changing notion of governance in today's society, conceptualising the role of government as 'steering' rather than 'rowing' (Osborne & Gaebler, 1992).

The notion of non-government or community-led policy change invokes several theoretical frames of relevance within the context of drug policy reform. The first of these is the 'ladder of participation'. Arnstein's (1969) seminal work conceptualises a typology to encourage dialogue about participation. Each of the eight 'rungs' in the ladder pattern relates to degrees of participation or control in policy activity, ranging from non-participation ("manipulation"), through 'consultation', 'partnership' and up to full 'citizen control' (see Arnstein, 1969, p. 217). This work has been expanded upon, to focus on the value of dynamic processes of involvement (Tritter & McCallum, 2006) and as the basis for the development of principles of 'multi-stakeholder participation' (Hemmati & Enayati, 2002). The multi-stakeholder participation approach aims to bring together the unique perspectives and expertise of relevant stakeholders, so as to generate communication and agreement which brings about change (Hemmati & Enayati, 2002). The notion of multi-stakeholder participation is also consistent with the theory

* Corresponding author. Tel.: +61 02 9385 0476; fax: +61 02 9385 0222.
E-mail address: k.lancaster@unsw.edu.au (K. Lancaster).

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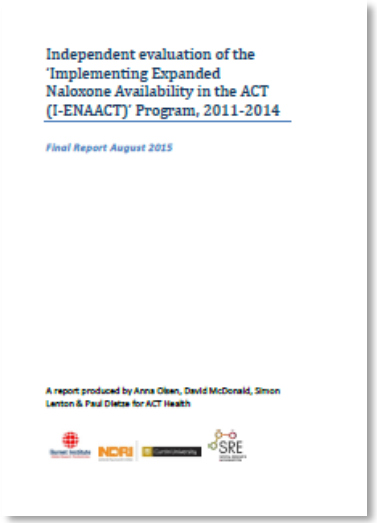
Australian THN Programs

By mid 2017

- April 2012 ACT Implementing Expanding Naloxone Availability in the A.C.T (I-ENAACT) program commenced. CAHMA + ACT Health. Evaluation: 200+ Trained & provided THN. 113 followed up 57 reversals reported (Olsen, MacDonald, Lenton, Dietze, 2015)
  Overall 543 trained to June 2017


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

Final Report August 2015

A report produced by Anna Olsen, David McDonald, Simon Lenton & Paul Dietze for ACT Health

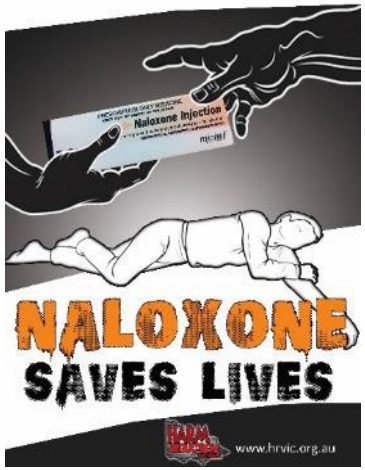
- NSW projects: commenced July 2012 with OPEN trial Kirketon Rd Centre and Langton Centre, service run, ongoing.
  Evaluation 83 trained, 35 followed up, 30 reversals (Chronister, Lintzeris, Jackson, Ivan, Dietze, Lenton, Kearley, van Beek. 2016). Now KRC, SESLHD, MSIC ISLHD. Across all NSW programs over 1000 trained and supplied THN, 175 anecdotal reversals reported.


Findings and lessons learnt from implementing Australia's first health service based take-home naloxone program

Australian THN Programs cont.

By mid 2017

- Jan 2013 Perth program commenced. Run by MHC & WASUA. May 2015 153 trained & provided THN under prescription 63 followed up 32 documented OD reversals (Nelson, Lenton Dietze, et al., 2016). By July 2017 283 opioid users trained & given THN.
- In Jan 2013 THN Integrated into the Victorian Drug Strategy, with distribution commencing in August through collaborations between Harm Reduction Victoria & other agencies. 27 reversals among 99 followed up To June 2015. As at July 2017 HRV reported 1072 trained & provided THN + approx. 400 workers trained. Approx. 143 additional reversals reported.
- Jan 2014 Small trial started in Qld via N. Metro Hospital & Health Service. Now NSP staff + opportunistic BI. To date 50+ participants trained & supplied THN. Some 5 Reversals.
- Across evaluations in Australia by July 2017 we had some 358 participants trained and formally followed up with 142 (40%) reversals using THN reported. There were over 2500 additional trainings & provision to PWID with 359 anecdotal reports of reversals.



National Naloxone Reference Group

- Formed in 2014(?)
- Auspiced by the Burnet's Centre for Research Excellence into Injecting Drug Use (CREDIU)
- Grew out of people involved in early programs following I-ENAACT.
- Now includes 20+ reps from all jurisdictions which have THN
- Multidisciplinary: drug user group representatives involved in THN delivery; federal, state and territory government bureaucrats; clinicians and researchers.
- Share program information, program materials, and evaluation materials and generally support each other.
- Co-ordinate and advocate (e.g. supporting rescheduling, new product availability such as Prenoxad® Nyxoid®)

International Evidence supporting THN was important

- Strong evidence that naloxone can be used safely by trained non-medical peers with many thousands of such overdose reversals having been reported (e.g. Mueller, Walley, et al, 2015)
- Existing research had provided suggestive observational evidence that THN programs can significantly decrease overdose death rates at a community level with decreases in overdose death rates coincident on program implementation
- Walley et al (2013) find a significant difference in death rates between cities and towns where THN programs have, or have not been implemented
- Cost-effectiveness: Naloxone distribution to heroin users is likely to reduce overdose deaths, would increase QALYs and be highly cost effective, even under markedly conservative assumptions (Coffin & Sullivan, 2013)
- 2014 endorsement of expansion of THN programs by WHO
- Training family members in overdose management and naloxone administration is effective (Williams, Marsden & Strang et al 2014, Bagley et al., 2015)

Rescheduling and availability

- Feb 1 2016 Rescheduling - Dual listing S3 & S4
- Rescheduling application made by Angelo Priccolo, community pharmacist in Melbourne
- NNRG members made submissions supporting rescheduling.
- The TGA reported that there were 96 submissions all supporting rescheduling.
- The TGA's reasons for the recommendation incl:
  - naloxone is well tolerated life-saving medicine with minimal adverse effects
  - benefits outweigh the risks; and
  - "Overseas experience and the outcomes of a program conducted in ACT show that easier availability of naloxone will likely decrease the proportion of opioid overdoses that result in fatality"
- But cost-effective access through existing programs not helped by rescheduling:
  - Under S3 dispensing must involve a pharmacist and be in a pharmacy

Perspectives

Australia reschedules naloxone for opioid overdose

The Therapeutic Goods Administration has changed naloxone scheduling to make it available over the counter

On 24 November 2015, the Therapeutic Goods Administration (TGA) announced its final decision to place "naloxone when used for the treatment of opioid overdose" on Schedule 3, thereby allowing over-the-counter (OTC) purchase.[1] This measure came into effect on 1 February 2016, making Australia the second country, after Italy (in 1995), to have naloxone formally available OTC.

Background

With much recent media focus on problems due to crystalline methamphetamine use in Australia, few may be aware that deaths from opioid overdose have been increasing over recent years.[2] Following the "heroin drought" of late 2000, accidental deaths from heroin and other opioids among Australians aged 15–54 years dropped from 1116 deaths in 1999 (10.19 deaths per 100 000 population) to 386 deaths in 2001 (3.46 deaths per 100 000 population). However, opioid-related deaths have been rising steadily since 2007 — the most recent confirmed data indicate that 617 Australians aged 15–54 years died in 2011 (4.95 deaths per 100 000 population). Estimates for 2012 and 2013 suggest that this trend continues.[2]

Take-home naloxone (THN) programs are designed to help manage opioid overdose events in the pre-hospital setting.[3] These programs involve training potential overdose witnesses (typically opioid users, and their friends and families) in overdose response (including naloxone administration), and then prescribing and distributing naloxone to potential overdose victims for later use in an overdose situation. Training typically includes education on risk factors for opioid overdose, signs of opioid overdose, basic life support and overdose response, including resuscitation techniques, calling for an ambulance, administration of naloxone, and post-naloxone management. Training addresses the possibility of rebound opioid toxicity due to the relatively short half-life of naloxone (mean, 60 min; range, 30–80 min)[4] compared with many opioids and the need to monitor the person and administer another dose of naloxone if required. However, the evidence indicates that rebound toxicity is rare.[5] To date, naloxone kits provided to trainees in Australian THN programs have typically comprised between 2 and 5 minijets of naloxone 400 µg/mL plus intramuscular needles, swabs, gloves and instructional materials.

Reports on THN programs, including successful reversals with few adverse effects, emerged in the late 1990s and

"We recommend … regulatory changes that allow current THN programs to dispense naloxone directly to their clients"

Simon R Lenton PhD, MPsych(Clin), MPsych[1]
Paul M Dietze PhD[2]
Marianne Jauncey BMed, MPH(Hons), FAFPHM[3]
1 National Drug Research Institute, Curtin University, Perth, WA.
2 Burnet Institute, Melbourne, VIC.
3 Sydney Medically Supervised Injecting Centre, Sydney, NSW.
s.lenton@curtin.edu.au

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programs have expanded since that time. A survey of programs in the United States in 2010 found that, since 1996, 53 000 kits containing naloxone were distributed through 188 programs across 16 US states, and naloxone was administered in over 10 000 successful overdose reversals.[6] In November 2010, Scotland became the first jurisdiction to implement a national THN program[7]; however, like most current programs, this program involves prescription. Many advocates of THN programs have called for better access to naloxone by making it available OTC.[8] To our knowledge, only Italy and some US states have naloxone available OTC (the US has inconsistent policy across state pharmacy boards, and at least one pharmacy chain in the US recently began offering naloxone OTC),[9] and recent initiatives will further expand OTC naloxone availability in the US.[10] There are no published accounts of the extent and consequences of naloxone use in Italy.

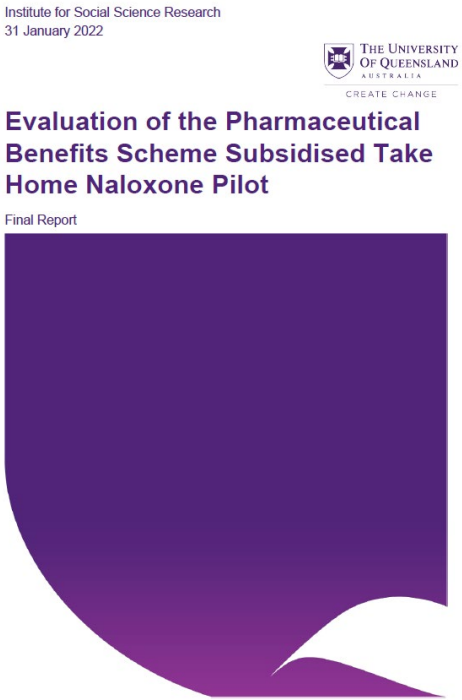
Timely naloxone administration is crucial for preventing morbidity and mortality associated with opioid overdose. Wider access, through making the drug available OTC, is a positive step towards reducing morbidity and mortality.[11]

The TGA's decision

The TGA's decision creates a new listing for OTC naloxone, under Schedule 3, while keeping the original listing under Schedule 4 (requiring prescription). This dual system means that the drug will be government-subsidised, but only when on prescription. The decision was made in response to a Melbourne community pharmacist's rescheduling application, which resulted in 96 individual submissions to the TGA in the subsequent consultation process. According to the TGA, all submissions supported the proposal to down-schedule naloxone; the main points were that: making it OTC will remove barriers to access; naloxone is safe and has no effect on anyone without opioids in their system; and it has little to no misuse potential. The TGA's reasons for the recommendation included that: naloxone is a well tolerated life-saving medicine with minimal adverse effects, and the benefits outweigh the risks; and overseas experience and the outcomes of a program conducted in the Australian Capital Territory[12] show that easier availability of naloxone will likely decrease the proportion of opioid overdoses that result in fatality. The TGA further suggested that OTC naloxone would need to be supplied with full and clear instructions for use, understandable by lay people (rather than only for trained health care professionals, as is currently the case),

The federal government takes up the cause

- 2017 closed door briefing of Australian National Advisory Council on Alcohol and other Drugs (ANACAD) and Commonwealth Department Health and Aged Care Recommending:
  - OD Prevention and THN be a priority
  - BI and Health Worker credentialling to ↑ access
  - Commonwealth Funding for THN Co-ordination
  - Fast tracking of Intra Nasal forms into Australia
  - New mechanisms for fast tracking supply
- Feb 2019 Fed Health Minister announced free naloxone pilot in 3 states (SA, NSW, WA) $2M over 2yrs.
- Pilot evaluation (Salom et al., 2021) concluded a success in terms if distribution and ODs reversed
- July 2022 the program was expanded nationally meaning that naloxone is technically available at no cost to the consumer across the country
- Actually, earlier, free naloxone was available at state level, and still more work to be done to reach all, but overall, a welcome development

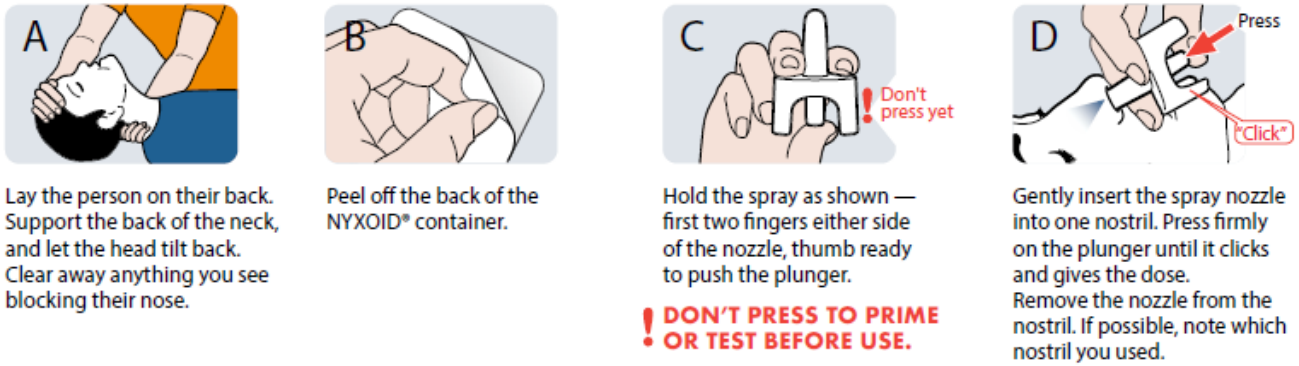


Intranasal Naloxone – A game changer

- While there had been a number of pre-poaded intramuscular forms of Naloxone in addition to syringes and ampoules, IN opened-up naloxone to a wider range of settings and potential consumers
- Significantly, early Australian work by Dietze et al., demonstrated the effectiveness and utility of IN products.
- In November 2019 the intranasal naloxone spray (Nyxoid®) was listed on the PBS making it an alternative to existing intramuscular preparations for consumers.
- Preferred by many because of the ease of using, no needlestick risk, and the concomitant simpler training

- **D** Check for **DANGER**
- **R** Check for **RESPONSE**
- **S** **SEND** for help
- **A** Clear and open **AIRWAY**
- **B** Check for **BREATHING**
- **N** Give **NALOXONE**
- **C** Commence **CPR**
- **D** Use **DEFIBRILLATOR** if available

Each nasal spray contains **one dose only.**



A — Lay the person on their back. Support the back of the neck, and let the head tilt back. Clear away anything you see blocking their nose.

B — Peel off the back of the NYXOID® container.

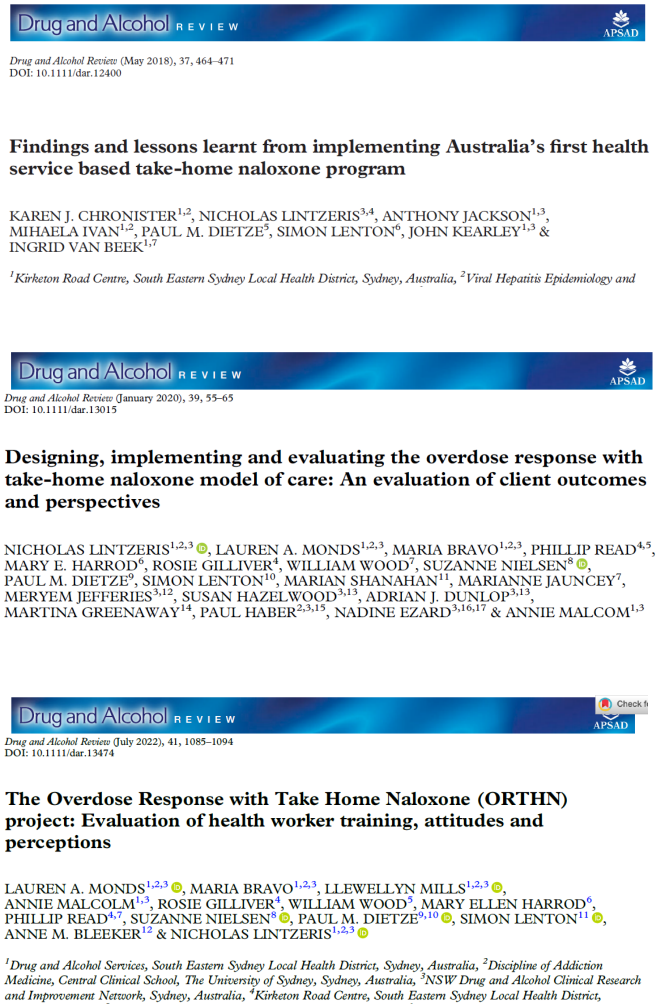
C — Hold the spray as shown — first two fingers either side of the nozzle, thumb ready to push the plunger.

! DON'T PRESS TO PRIME OR TEST BEFORE USE.

D — Gently insert the spray nozzle into one nostril. Press firmly on the plunger until it clicks and gives the dose. Remove the nozzle from the nostril. If possible, note which nostril you used.

Drug Treatment Agencies

- One of the early THN programs in Australia targeted people who use opioids attending alcohol and other drug (AOD) treatment, needle and syringe programs (NSP) and related health services targeting people who inject drugs in NSW
- Based on UK models with 60 min group workshop training was then reduced to brief intervention.
- the ORTHN project enabled supply directly to consumers attending AOD services, NSPs and primary health care services targeting PWIDs.
- involved completion of a training program, and assessment of competency of the worker to safely deliver THN interventions which has continued as an online credentialling model for health workers across NSW.



Drug and Alcohol REVIEW

Drug and Alcohol Review (May 2018), 37, 464–471
DOI: 10.1111/dar.12400

Findings and lessons learnt from implementing Australia's first health service based take-home naloxone program

KAREN J. CHRONISTER[1,2], NICHOLAS LINTZERIS[3,4], ANTHONY JACKSON[1,3], MIHAELA IVAN[1,2], PAUL M. DIETZE[5], SIMON LENTON[6], JOHN KEARLEY[1,3] & INGRID VAN BEEK[1,7]

[1]*Kirketon Road Centre, South Eastern Sydney Local Health District, Sydney, Australia,* [2]*Viral Hepatitis Epidemiology and*

Drug and Alcohol REVIEW

Drug and Alcohol Review (January 2020), 39, 55–65
DOI: 10.1111/dar.13015

Designing, implementing and evaluating the overdose response with take-home naloxone model of care: An evaluation of client outcomes and perspectives

NICHOLAS LINTZERIS[1,2,3], LAUREN A. MONDS[1,2,3], MARIA BRAVO[1,2,3], PHILLIP READ[4,5], MARY E. HARROD[6], ROSIE GILLIVER[4], WILLIAM WOOD[7], SUZANNE NIELSEN[8], PAUL M. DIETZE[9], SIMON LENTON[10], MARIAN SHANAHAN[11], MARIANNE JAUNCEY[7], MERYEM JEFFERIES[3,12], SUSAN HAZELWOOD[3,13], ADRIAN J. DUNLOP[3,13], MARTINA GREENAWAY[14], PAUL HABER[2,3,15], NADINE EZARD[3,16,17] & ANNIE MALCOM[1,3]

Drug and Alcohol REVIEW

Drug and Alcohol Review (July 2022), 41, 1085–1094
DOI: 10.1111/dar.13474

The Overdose Response with Take Home Naloxone (ORTHN) project: Evaluation of health worker training, attitudes and perceptions

LAUREN A. MONDS[1,2,3], MARIA BRAVO[1,2,3], LLEWELLYN MILLS[1,2,3], ANNIE MALCOLM[1,3], ROSIE GILLIVER[4], WILLIAM WOOD[5], MARY ELLEN HARROD[6], PHILLIP READ[4,7], SUZANNE NIELSEN[8], PAUL M. DIETZE[9,10], SIMON LENTON[11], ANNE M. BLEEKER[12] & NICHOLAS LINTZERIS[1,2,3]

[1]*Drug and Alcohol Services, South Eastern Sydney Local Health District, Sydney, Australia,* [2]*Discipline of Addiction Medicine, Central Clinical School, The University of Sydney, Sydney, Australia,* [3]*NSW Drug and Alcohol Clinical Research and Improvement Network, Sydney, Australia,* [4]*Kirketon Road Centre, South Eastern Sydney Local Health District,*

Community Pharmacies

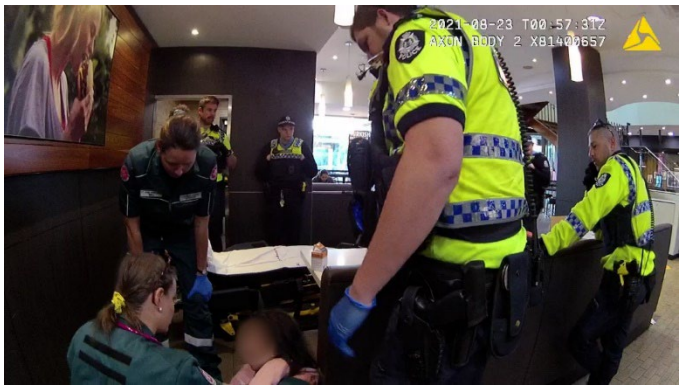
- Community pharmacies are an obvious place to enhance naloxone availability, not only for people who inject drugs, but also for prescription opioid patients.
- Considerable work was done in Australia to:
  - Identify the barriers to greater pharmacy involvement in naloxone distribution (Lai Joyce Chun et al., 2019; Nielsen et al., 2016; Nielsen & Olsen, 2021; Olsen et al., 2019)
  - Developing innovative ways, in partnership with the pharmacy profession to engage pharmacy in this (Moullin et al., 2023; Moullin et al., 2024).

Bendigo residents set to access 'lifesaving' overdose reversal drug, naloxone, free of charge

Bendigo Advertiser, July 6 2022

Police carrying naloxone and saving lives

- Western Australian Police Force Naloxone pilot Jul 2021-July 2022 [1st in Southern Hemisphere]
- 447 police officers trained in OD management and naloxone administration
- Evaluation (Agramunt & Lenton 2024)
- Willingness to administer naloxone pre (66%) post (99%)
- 20% witnessed an OD in the 6mo after training and 70% of these used naloxone to reverse the overdose
- Well received, improved management of OD, lives saved,
- 'Changed the conversation' between police and PWID
- Naloxone training and kits rolled out state-wide.
- Police elsewhere in Australia keen to run similar programs



*"[…] I **can only see a benefit for it** and **I'm really grateful** that myself and my team … were invited to be part of the pilot, because… **it's really been very…very positive** … for my staff when you can actually go somewhere and **do something good,** because a lot of policing these days is…is quite negative and we...we don't get that **good feeling** sometimes after being in a job."*

The West Australian for 190 years

WA News | Health | Police | State Politics

WA Police give Naloxone to cops across the State after trial ends with lifesaving treatment given to dozens

Shannon Hampton | The West Australian
Mon, 14 August 2023 3:34PM

Shannon Hampton

WA Police is expanding a landmark program that gives officers training to administer a lifesaving drug to opioid overdose victims – the first of its kind in the southern hemisphere – to police across the State.

The expansion follows a 12-month trial that was rolled out in Perth and Bunbury where police were given

Ambulance Leave Behind Programs

- Since September 2021, St John Ambulance Western Australia (SJWA) paramedics, ambulance officers and volunteers when they attended an overdose scene and treat the patient, they are then able to distribute naloxone to others at the scene to help manage subsequent overdose events.
- An evaluation (Agramunt & Lenton, 2023) concluded that the training was high quality and the program feasible.
- Consequently, the pilot was extended state-wide into routine SJWA care protocols.
- A subsequent pre-post evaluation using ambulance attendance data concluded that the scheme did not result in fewer overdose attendances for overdoses, but more patients were discharged at the scene without detrimentally affecting subsequent survival rates (Tohira et al., 2024).
- We understand that since this pilot in WA, other states are exploring similar schemes

Descriptive before-and-after study of the introduction of a 'Leave Behind' take-home naloxone dispensing/distribution program by the ambulance service in Western Australia

Paramedicine
1–11
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Sage

Hideo Tohira[1,2], Rudolph Brits[3], Simon Lenton[4], Seraina Agramunt[4], Deon Brink[1], Curtis Naylor[3], Jason Belcher[3], Stephen Ball[1,3] and Judith Finn[1,2,3]

Abstract

Objective: To describe changes observed in case characteristics and patient outcomes before and after ambulance service participation in a 'Leave Behind' take-home naloxone (THN) dispensing/distribution program.

Methods: This before-and-after study included emergency ambulance attendances for patients experiencing an opioid overdose one year before 1 October 2021 (pre-participation phase: 1 October 2020–30 September 2021) when St John Western Australia (SJWA) participated in the THN program and those one year after the date (post-participation phase: 1 October 2021–30 September 2022).

Results: There were 945 and 1240 opioid overdoses among 221,451 and 222,480 emergency ambulance attendances in the pre- and post-participation phases (0.43% vs 0.56%, $p < 0.001$). The number of ambulance attendances for overdose in the post-participation phase was not significantly different from that predicted based on the ambulance attendances in the pre-participation phase. No statistically significant differences in patient age, sex, and geographical location were identified between the two phases. Compared to the pre-participation phase, more patients had naloxone administered prior to ambulance arrival (10.7% vs 15.1%, $p = 0.003$), and more patients were discharged at the scene (21.2% vs 29.8%, $p < 0.001$) in the post-participation phase. No difference was found in mortality within one day (3.4% in the pre-participation phase vs 3.5% in the post-participation phase, $p = 0.30$).

Conclusions: After implementation of a 'Leave Behind' take-home naloxone dispensing/distribution program, more patients had naloxone administered prior to ambulance arrival, and the likelihood of discharging a patient at the scene significantly increased without affecting patient survival rates.

Prescribed Opioids Patients

- In Australia, people who are prescribed opioids represent a substantial proportion of opioid overdose deaths (Roxburgh et al., 2017)
- Chronic pain patients prescribed LT opioids are open to an offer of naloxone but knowledge re naloxone and OD are low (Nielsen et al., 2018)
- Despite this only 2% of patients at risk are offered it (Salom et al., 2021)
- Major issue is lack of appropriate resources targeted at this group. Recent co-design projects have been done with this group (e.g. Moullin et al, 2024)

Other Australian THN programs:

- Hospital Emergency Departments
- Postal THN programs

Some themes associated with the expansion of THN in Australia

- The central role of drug user representative in kick starting & maintenance.
- Pilot, evaluate & diffuse … rather than wait for perfect policy.
- Science addressing barriers and supporting expansion of naloxone.

Future challenges:

- Fentanyls and Nitazenes
- Synthetic opioids in party drugs

Expanding Naloxone availability

- 1990's calls for wider availability of naloxone
- 2000 Heroin 'drought' / shortage + increased concern re meth
- 2009 Opioid overdoses increasing – call for wider availability of naloxone
- 2012 CAHMA in ACT begins program, closely followed by NSW, WA, SA, Qld and Vic
- Evaluations showed viability, knowledge improvement and lives saved, scale-up?
- 2014 WHO endorsed making naloxone more widely available
- 2014(?) National Naloxone Reference Group (NNRG) established
- 2016 TGA rescheduled (OTC + script) after evaluations & strong sector advocacy
- 2019 the intranasal naloxone spray (Nyxoid®) available and listed on PBS in Nov.
- 2019 - 2021 Federal PBS subsidised THN pilot in SA, NSW and WA
- November 2019 PBS Listing and availability of intranasal spray (Nyxoid®)
- 2022 UQ Federal pilot evaluation recommends free naloxone nationally
- July 2022 made available for free nationally
- Themes: Across sector co-operation and support e.g. NNRG
  Pilot, evaluate & diffuse … rather than wait for perfect policy
  Expansion into new settings & target groups
  Science addressing barriers & evaluating pilots