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Policy Analysis paper

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

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Conflict of interest

All authors are members of the Implementing-Expanding Naloxone Availability in the ACT (I-ENAACT) committee. PD and SL have been advocating for wider availability of naloxone in Australia for more than 10 years and, like all the authors, have been centrally involved in many of the Australian events described in this paper. PD is the recipient of funds from an untied educational grant from Reckitt Benckiser awarded to the National Drug and Alcohol Research Centre used in the post-marketing surveillance of Suboxone in Australia.

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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, 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 (CAHMA), a drug user organisation, contributed to the rollout of Australia's first prescription naloxone program in the Australian Capital Territory (ACT). Over the subsequent 18mths 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.

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, 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 U.K., the U.S., 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 [8] and in November 2010 Scotland became the first country internationally to roll out a national Take-home Naloxone program, which was funded for 5 million pounds over 2 years [9]. Accumulating international evidence from these programs shows that the provision of take-home naloxone, with appropriate training, to people who come into contact with people who use opioids (including friends, family, service providers) can lead to successful opioid overdose reversals and that it is a remarkably safe intervention with few, if any, adverse effects [e.g. 9, 10, 11-19]. In the US alone, as of 2010, there had been over 53,000 kits containing naloxone distributed through 188 programs across 16 US states with 10,171 reported overdose reversals incorporating naloxone administration [20].

Observational studies have shown declines in overdose mortality subsequent to implementation of take-home naloxone programs in Chicago [14, 21, 22], New York [23] and San Francisco [24], but these studies could not control for other potential explanations of these effects. An interrupted time series analysis of 19 geographically distinct cities and towns in Massachusetts found lower opioid related overdose death rates in locations where programs of Overdose Education incorporating Naloxone Distribution (OEND) had been implemented with more than 100 enrolments per 100,000 population (OR =0.54), compared to control communities where no such programs existed, but just failed to find a significant difference between high-dose (> 100 enrolments in OEND per 100,000 population) and low-dose (≤ 100 enrolments in OEND per 100,000 population) interventions [25]. Importantly, the naloxone programs effects were not evident for other types of acute deaths such as road traffic accidents thus demonstrating specificity of effect to overdose outcomes. Analysis of a recent cost

effectiveness model concluded that naloxone administration by trained lay persons is likely to reduce overdose death rates, and is highly cost-effective even under very conservative assumptions [26]. These findings suggest that take-home naloxone is an effective addition to other overdose prevention strategies and the US FDA has recently been considering extending access to naloxone outside of conventional medical settings [27, 28].

Opioid Overdoses in Australia

In Australia, deaths from heroin and other opioids among people aged between 15 and 54 years peaked at 1116 deaths in 1999, a rate of 10.19 deaths per 100,000 Australians. This rapidly declined to 386 deaths in this age range in 2001, a rate of 3.46 per 100,000 persons [29]. Despite this decline, overdoses involving heroin or other opioids continue to account for most illicit drug related deaths in this country [30]. In 2009, 563 Australians aged between 15 and 54 years died from accidental opioid overdose, a rate of 4.59 deaths per 100,000, up from 3.04 deaths per 100,000 in 2007. Most of these deaths related to the injection of heroin, although deaths from pharmaceutical opioid misuse appear to be rising [29]. Heroin is still the drug of choice among the majority of people surveyed who inject drugs in Australia [31].

This continued opioid related mortality led to the revival of the idea of take-home naloxone in the Australian academic literature [2, 3]. Although the rates of opioid related mortality remain below those of the heroin ‘glut’ of the late 1990s [32], these articles reasoned that it was timely to start to develop take-home naloxone programs in this country, which could be scaled-up over time if and when overdose mortality continued to increase. The aim of this paper is to document recent Australian developments in implementing take-home naloxone, particularly in the ACT, to reflect on key elements of the processes involved in establishing the ACT program, and consider issues associated with future scale up of take-home naloxone in Australia. Central to the success of the developments in the ACT and elsewhere has been co-operative effort of stakeholders across a range of sectors *working together* toward the shared goal of improving access to take-home naloxone to prevent overdose morbidity and mortality.

As context, the ACT is located in the south east of the country and is an enclave within New South Wales, Australia’s most populous state. Canberra, the only city within the ACT, is the seat of the Australian national government. At 2,358 km² the ACT is the smallest self-

governing territory on mainland Australia, and has a population of some 383,000 out of Australia's total population of 23.2 million. [33]

The take-home naloxone program in the ACT

The accumulating international evidence of program implementation, effectiveness [e.g. 9-11, 13, 14, 17-19] and more recent cost-effectiveness [26, 34] summarised above has provided a foundation for industrious local advocacy and collaborations in program development and evaluation between Australian drug user organisations, clinicians, public servants, researchers and others. Subsequent to the 2009 calls for the establishment of take-home naloxone programs in this country [2, 3], community and sector stakeholders took a central role in moving forward. The Canberra Alliance for Harm Minimisation and Advocacy (CAHMA), a well-respected, active drug user group led the initiative in the ACT, by drafting a proposal for a peer naloxone program and submitted it to the ACT Government in October 2010. In the same month, the Australian independent non-profit organisation, Anex, put out a position paper on wider access to naloxone [35] and brought Dr Sarz Maxwell out from Chicago to give a keynote presentation on the wider distribution of naloxone [36] at their annual conference in Melbourne. While in Australia, Dr Maxwell met with various local stakeholders including the ACT Minister for Health and related officials and did a number of media interviews [e.g. 37, 38]. On December 1, 2010 a Symposium was held at the Australasian Professional Society on Alcohol and Drugs Annual Conference in the ACT, entitled *Increasing community access to naloxone to prevent opioid overdose deaths: lessons for Australia* that involved local and international stakeholders [22]. This coincided with supportive coverage about the ACT proposal in the ACT press [39].

Central to the establishment of the ACT take-home naloxone program was the public support for the proposal from the ACT Minister for Health, Ms Katy Gallaher MLA [e.g. 40] who subsequently became ACT Chief Minister [41]. The ACT Government had undertaken a comprehensive review process which contributed to the development of a number of proposals including a take-home naloxone program and a controversial recommendation to commence what would be Australia's first prison needle and syringe exchange in the Alexander Maconochie Centre, the ACT's prison [41-43]. Both the naloxone and the prison needle exchange [44] proposals were eventually endorsed by the government.

In February 2011 the Alcohol Tobacco & Other Drugs Association ACT (ATODA) worked to set up a consultative group (subsequently named the Expanding Naloxone Availability in the

ACT (ENAACT) committee) to provide expert guidance and support to key stakeholders in the development of a take-home naloxone program. Membership included representatives of: CAHMA, ATODA, ACT Health, the ACT Division of General Practice, Winnunga Nimmityjah Aboriginal Health Service, the ACT Ambulance Service, the Pharmacy Guild, , Family and Friends for Drug Law Reform, the Burnet Institute, and the National Drug Research Institute (NDRI). This co-operative inter-sectoral group worked well together to design the ACT Naloxone Program, as documented by Lancaster and Ritter [45]. An accompanying evaluation strategy and framework developed by the ENAACT Committee was subsequently funded by the ACT Health Directorate and auspiced by the two research institutes the NDRI and the Burnet Institute. The program was launched by the Chief Minister on December 16, 2011, with program materials developed by CAHMA, in consultation with ENAACT members over the period through until April 9, 2012 when the first program participants were trained. At the same time the ENAACT Committee changed its name to I-ENAACT (Implementing ENAACT).

The I-ENAACT program involves comprehensive overdose management training. Naloxone is prescribed and supplied to program participants who wish to obtain the drug and have a history of opioid use. It is intended that participants prescribed take-home naloxone will be administered it by a trained peer (usually a friend or family member) in the event of an opioid (primarily heroin) overdose. The initial program was to be conducted over a two-year year period with 200 participants [46]. The training is typically conducted in groups of around 10 opioid users and other potential overdose witnesses. Eligible participants who successfully complete the training are prescribed naloxone by a General Practitioner (GP) after completing a brief medical assessment and determination of the participant's knowledge and competence in overdose management and naloxone administration. The provision of the naloxone is funded by the ACT Health Directorate and the GP consultation is bulk billed to Medicare, so there is no personal cost to participants. The training program has been adapted from international models and is provided by CAHMA staff. Training involves: recognising opioid overdose; risk factors for opioid overdose; Basic Life Support; and responding to opioid overdose including resuscitation techniques, calling for an ambulance, administration of naloxone and post naloxone management. Participation in the evaluation is voluntary. The program evaluation incorporates pre-post training knowledge surveys (including questions based on earlier versions of the OOKS and the OOAS [47]) and follow-up interviews between

3 and 6 months after the education session and when participant's naloxone is used and they attend for replenishment.

Other take-home naloxone programs in Australia

Elements of the I-ENAACT process have been described in detail elsewhere [46, 48, 49]. Importantly, the process has welcomed colleagues from other Australian jurisdictions involved in establishing take-home naloxone programs, to share experiences, knowledge, and training and evaluation materials, thereby attempting to minimise duplication of effort. This process, undertaken in a spirit of cooperation and collaboration, provided support for the implementation of the Overdose Prevention Education & Naloxone (OPEN) project [50] in Sydney, NSW that commenced almost concurrently with the ACT program in June 2012 and the prescription naloxone program at the Drug and Alcohol Services South Australia (DASSA) in Adelaide, SA [50] in November 2012. ENAACT is also directly connected to the take-home naloxone program established in Western Australia (WA) by the Drug and Alcohol Office of WA Health and the WA Substance Users Association (WASUA) which commenced operation in April 2013 on the back of considerations from their long-standing Overdose Strategy Group. In Victoria, take-home naloxone was integrated into the Victorian Drug Strategy in January 2013, with distribution commencing in August through collaborations between Harm Reduction Victoria and other agencies, notably Access Health and North Richmond Community Health. At the end of August the Victorian Minister for Human Services and Mental Health announced the funding of the Community Overdose Prevention and Education (COPE) program, an initiative to be led by Anex designed to increase access to take-home naloxone throughout the state.

There is no doubt that the work underpinning the ACT program establishment and network has harnessed momentum for establishing take-home naloxone in Australia. This has been further facilitated by academic presentations and media interviews by various stakeholders and by endorsements of take-home naloxone interventions by various peak bodies. With regards to the latter, at a national level, programs received support from the Australian Medical Association [51] and the Australian National Council on Drugs in [49]. Endorsement by such esteemed bodies provides governments a level of re-assurance, in addition to the evidence published in the academic literature, that moving forward on take-home naloxone is a successful, defensible public health initiative.

Reflecting on the Australian developments – theoretical aspects

There are a number of theoretical approaches to understanding the policy process and different aspects of this account of the commencement of take-home naloxone programs in Australia reflect these theories. Kingdon's 'multiple-streams' approach [52] explains how some policy ideas survive and others die, depending on the opening and closing of 'policy windows' and the influences of 'policy entrepreneurs', who can bring together three streams of activity: problems, policy and politics. In terms of this theory, the 2009 academic publications [2, 3], which reminded Australian stakeholders of opioid overdose as an ongoing problem, and the re-invigorated advocacy for the use of take-home naloxone as one additional policy response to that problem, was part of bringing together of Kingdon's problem and policy streams. The problem at hand was linked to the political stream when CAHMA and ATODA made their submissions to ACT Health, further bolstered by timing and an open policy window associated with the ACT government's consideration of new approaches to tackling drug-related harm. Sabatier's 'advocacy-coalition' framework focuses on the interaction between coalitions of advocates across institutions who share policy beliefs and operate within a shared policy subsystem [53]. Aspects of the interactions and industry among members of the ENAACT committee and other Australian naloxone advocates and stakeholders reflected these policy processes. Berry and Berry's 'policy diffusion' framework [54] accounts for variations in the adoption of policy innovations across different jurisdictions. The cascading development of take-home naloxone programs first in the ACT, then in (almost simultaneously) NSW, SA, WA, and Victoria, invokes this theoretical understanding. The theory of 'institutional rational-choice' [e.g. 55] explains how institutional rules affect behaviours of individuals who are viewed as rational actors motivated by self-interest. Aspects of the negotiations around the detail of the take-home naloxone processes within the I-ENAACT Committee reflected these considerations.

The 'enlightenment' model [56] explains how research can have an incremental impact on the belief systems of policy makers over time. Indeed the accruing research evidence of successful naloxone program implementation in the US and, to a lesser extent in Europe provided support for local Australian action at a governmental level. Finally, 'Punctuated-equilibrium' theory [57] attempts to explain why political processes typically produce stability and incrementalism, but sometimes also lead to discontinuous, abrupt change. At a macro level this theoretical approach provides insight into the hiatus in development and

implementation of peer naloxone programs in Australia due to the end of the ‘heroin glut’, and the subsequent developments in naloxone programs in the past 12 to 18 months.

Naloxone program rollout and scale-up issues

If take-home naloxone programs in Australia are going to be scaled up to a level where population impacts on rates of opioid overdose related fatalities can be determined, certain challenges will need to be met. These include:

(i) *Scheduling and cost.* In Australia currently available naloxone products are prescription-only medication under Schedule 4. If these products were to be re-scheduled to S3 to make them available across the counter, they would no longer be covered by Pharmaceutical Benefits Scheme (PBS) and the cost per dose is likely to increase significantly. The cost of naloxone is currently listed (exclusive of dispensing fee) as \$16.64 per 400 microgram/ml minijet® distributed by UCB Australia. But under the PBS consumers can get up to 5 minijets® for \$36.50 or \$5.50 on concession. Most naloxone programs in Australia provide a minimum of 2 x minijets® per kit, but the cost of these is currently borne by the program, rather than the recipient which is unlikely be the case if programs were scaled up. It is imperative that cost factors are not a barrier to those of low incomes, and programs that provide to them, getting access to naloxone. However, it may be the case that in future there could be a range of naloxone products available, for example some in an injectable form, others in an intranasal form. Although all products should be available to those of low income at the lowest possible cost, there is no reason why each these products should be identically scheduled or under the same pricing structure.

(ii) *Administration to third parties in an overdose emergency.* Naloxone 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, this can be covered under Good Samaritan laws that exist across Australian jurisdictions, although coverage is not perfect. For example, in both ACT and NSW [58, 59] such laws exclude persons under the influence of a drug. Despite this, advice provided by government solicitors to authorities in at least one Australian jurisdiction where peer naloxone programs now operate have suggested it would be extremely unlikely that legal action would be pursued against someone trying to save a life with naloxone.

(iii) *Prescribing as a potential barrier to scale-up.* In some US states legislative or regulatory steps have been taken to allow approved program trainers, who are not licensed medical personnel, to dispense naloxone rescue kits to participants who have successfully completed

brief training. [e.g. 22, 60]. These laws or regulations allow the distribution of a prescription medication under a standing order from a licensed medical director prescriber.

(iv) *Naloxone for Intranasal administration.* Intranasal (IN) naloxone, has advantages over intramuscular (IM) 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 [12, 61, 62]. While a number of US programs have been using the IN administration ‘off-label’ since 2006, naloxone is not approved by the Australian Therapeutic Goods Administration (TGA) for intranasal use. Furthermore, the currently commercially available IM form is at a lower concentration (0.4 mg/ml) than that used in conjunction with an atomiser device for IN use in the US (2.0 mg/2ml) [63]. To allow widespread IN use, an application would need to be made to the TGA for a higher concentration naloxone product suitable for that mode of delivery.

(v) *Naloxone for service provider administration.* There is an obvious case for providing training and naloxone to service providers who are likely to witness overdoses as part of their employment. These include, but are not limited to, peer outreach workers, needle exchange staff, drug treatment workers, staff at shelters and other emergency accommodation services, and indeed, police and other emergency services workers. In Australia, such staff are expressing a need for naloxone training, but they cannot be provided naloxone under the current prescription model. Particularly now that IM injection practice associated with the use of an adrenaline auto-injector [64] has been adopted as part of First AID training courses in this country (I. Jacobs, personal communication, 27/01/2014), a mechanism for supplying naloxone to workers needs to be identified.

(vi) *Alliance of drug user groups, clinicians and others.* In Australia, as elsewhere, drug user groups have been central to the advocacy for and development of take-home naloxone programs. These programs have also been characterised by drug users, clinicians, public servants, service agencies, peak bodies, researchers and others working together to achieve a common goal. As the expansion of naloxone provision continues, it needs to embrace a variety of forms, depending on the setting. These will range from drug user-led group settings, to one-on-one sessions between client and clinician and everything in between. Future developments in this area must continue to be characterised by ongoing respectful sharing of specialist knowledge between drug user representatives, clinicians and others, for the full life-saving potential of this intervention to be realised.

Conclusion

In this paper we have argued that the clinical and biological evidence that naloxone can reverse the effects of opioid overdose has been supplemented by evidence that naloxone can be used safely by trained non-medical peers and overdose bystanders (with many thousands of overdose reversals now reported). Further, a growing body of ecological studies of increasing sophistication suggests that take-home naloxone programs save lives and are cost-effective. This evidence has supported the careful rollout and evaluation of programs in this country. Importantly, the call has been for take-home naloxone to be implemented *in addition to*, rather than *instead of*, other existing evidence based strategies for reducing the risk of opioid overdose, most importantly increasing access to opioid substitution treatment. The development of Australia's first take-home naloxone program in the ACT has been an 'ice-breaker' for the development of other Australian programs. If take-home naloxone programs continue to be shown to be safe and contribute to overdose reversals in this country, a scaling up to a level where macro, population level impacts on overdose rates can be determined is warranted.

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