

An overview of take-home naloxone programs in Australia

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Abstract

Introduction and Aims

Take-home naloxone (THN) programs commenced in Australia in 2012 in the Australian Capital Territory and programs now operate in five Australian jurisdictions. The purpose of this paper is to record the progress of THN programs in Australia, to provide a resource for others wanting to start THN projects, and provide a tool for policy makers and others considering expansion of THN programs in this country and elsewhere.

Design and Methods

Key stakeholders with principal responsibility for identified THN programs operating in Australia provided descriptions of program development, implementation and characteristics. Short summaries of known THN programs from each jurisdiction are provided along with a table detailing program characteristics and outcomes.

Results

Data collected across current Australian THN programs suggest that to-date over 2500 Australians at risk of overdose have been trained and provided naloxone. Evaluation data from four programs recorded 146 overdose reversals involving naloxone that was given by THN participants.

Discussion and conclusions

Peer drug user groups currently play a central role in the development, delivery and scale-up of THN in Australia. Health professionals who work with people who use illicit opioids are increasingly taking part as AOD-related health agencies have recognised the opportunity for THN provision through interactions with their clients. Australia has made rapid progress in removing regulatory barriers to naloxone since the initiation of the first THN program in 2012. However, logistical and economic barriers remain and further work is needed to expand access to this life-saving medication.

Key words: take-home naloxone, opioid overdose, overdose response

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Introduction

In Australia, as elsewhere, the expansion of take-home naloxone (THN) programs through peer outreach services [1-3] and health services [4], is increasingly recognised as an important part of the response to escalating rates of opioid overdose mortality [5]. A crucial support for the expansion of these programs has been evaluative studies demonstrating the effectiveness [6-10] and cost effectiveness [11-14] of THN.

Beyond evidence building, evaluation research is an important mechanism behind the uptake of policy and practice initiatives and the diffusion of innovations seen in other jurisdictions [15]. Seminal with regard to the expansion of THN programs in Australia [see 16] and worldwide [8] was the US study by Wheeler and colleagues, which detailed the number of programs, people trained and recorded overdose reversals associated with these programs [17]. On a smaller scale, we have collated similar data for the THN programs developed in Australian jurisdictions over the past five years. The documentation of examples of program innovation and change is helpful in supporting new initiatives: by sharing experiences and materials, proposed projects do not have to ‘reinvent the wheel’.

The sharing of program information and documentation of Australian initiatives has been facilitated by the Naloxone National Reference Group (NNRG) [18], which is auspiced by the Centre for Research Excellence into Injecting Drug Use and grew out of Australia’s first THN project implemented in the capital city (Implementing Expanded Naloxone Availability in the Australian Capital Territory (I-ENAACT) [3]. The purpose of our paper is to: record the progress of THN programs in Australia, provide a resource for others wanting to start

THN projects, and provide a tool for policy makers and others considering expansion of THN programs in this country and elsewhere.

A shifting landscape

The development and implementation of THN programs in Australia has been affected by changing naloxone availability, insecure funding and policy change. Early THN programs relied on prescription of the drug to individual participants by a General Practitioner (GP). In February 2016, naloxone was rescheduled to make it available ‘over-the-counter’ (OTC) in pharmacies in Australia without a prescription (but supplied only by a pharmacist), although it can still be supplied via a prescription to enable a subsidised purchase price under Australia's Pharmaceutical Benefits Scheme (PBS) [19].

Shortly after the reschedule of naloxone came into effect, the pre-loaded naloxone product that had, for some three years, been the mainstay product distributed by THN programs in Australia became unavailable as the manufacturers ceased production [19]. This disruption of supply meant that, depending on stock, some of the programs reverted to distribution of naloxone ampoules. This continued until a multi-dose pre-filled product (comprising 5 x 400mcg doses in a single syringe) designed for use by people without formal medical training was granted a temporary supply approval by the Australian Therapeutic Goods Administration on 21 November 2016, in response to a lack of suitable product being available in Australia.

On 1 April 2017, the multi-dose pre-filled product was listed as a subsidised medicine under the PBS which capped the maximum price at \$38.80 (rather than the product manufacturer's price of \$73.52) for a customer with a prescription. The drug is currently available for

approximately \$6 for individuals with a concession card (Government card that provides access to subsidised health services and medicines). Naloxone can be prescribed by a nurse practitioner as well as a physician [20].

Method

Authors Dwyer and Olsen wrote to key stakeholders with principal responsibility for the THN programs operating in Australia and asked them to provide a short description of their program and populate a draft table (see Table 1) including program duration and features. Material was confirmed by keystakeholders from the relevant programs prior to submission. We provide short summaries from each jurisdiction and a table detailing program characteristics and outcomes.

The program summaries are presented in chronological order, starting with Australia's first THN program in the Australian Capital Territory (ACT). In addition to these programs, we note that Drug and Alcohol Services South Australia (DASSA), SA Health implemented an 18-month pilot THN program commencing November 2012. At the time of writing there are no active operational THN programs in South Australia although DASSA continues to engage agencies and networks to build their capacity to provide clients with overdose prevention and response advice, including advice on naloxone administration. A program summary for THN in South Australia is not included in this paper.

Take-home naloxone in ACT 2012 to 2017

Australia's first THN program – the Implementing Expanded Naloxone Availability in the ACT (I-ENAACT) program – was initiated in April 2012 by the peer-based drug user group Canberra Alliance for Harm Minimisation and Advocacy (CAHMA), along with ACT

Health, the Alcohol Tobacco and Other Drug Association ACT (ATODA) and a multidisciplinary group of national stakeholders and experts [1, 3]. The initial program operated from April 2012 to December 2014. An evaluation conducted during this time recorded over 200 trained participants [3]. This seminal program laid the foundations for the training materials used in many Australian THN programs, as well as the evaluation framework and measures employed to assess programs across jurisdictions.

Funded by ACT Health, the program involved comprehensive opioid overdose management training and the prescription and supply of THN to eligible participants who are not health professionals [3]. Using a collaborative approach, the program was coordinated and delivered by CAHMA, with prescriptions provided by local GPs. The program involved one-hour training workshops for small groups of people (5-12 individuals) who have a history of opioid use. Participants were recruited primarily via word-of-mouth. The program provided education on the prevention and management of opioid overdose, including basic life support skills and the administration of naloxone. Participants were provided with an overdose kit including five doses of naloxone. A local pharmacy supplied the prescribed naloxone.

In another Australian first, 18 of these participants were inmates at the Alexander Maconochie Centre (Canberra's prison, which holds both sentenced prisoners and those on remand). During the evaluation period, 57 overdose reversals using program-issued naloxone were documented. All reversals were successful and no serious adverse events were reported [3].

In 2016, the ACT Government announced recurrent funding to continue the naloxone program through CAHMA for those at risk of opioid overdose. The program expanded to

include not only the original group-based program but opportunistic brief interventions (short one-on-one training) with naloxone supplied OTC, obviating the need for a prescription, as well as naloxone and opioid overdose information sessions for alcohol and other drug (AOD) workers. In the two years to June 2017, the CAHMA THN program has provided overdose management training to almost 500 individuals at risk of overdose (543 recorded workshop attendances, including people who attended training more than once), delivered 93 brief interventions to people at risk of overdose, and engaged 75 AOD workers. CAHMA and collaborators are currently exploring opportunities to embed opioid overdose education and THN as routine practice in the ACT AOD sector. CAHMA, ATODA and ACT Health are also working with community pharmacies to establish an OTC naloxone voucher pilot in which CAHMA clients would be able to access a pre-paid voucher for OTC naloxone.

Take-home naloxone in New South Wales (NSW) 2012 to 2017

THN became available in NSW in July 2012 as part of the Overdose Prevention and Emergency Naloxone (OPEN) Project initiated by the Kirketon Road Centre (KRC) in partnership with the Langton (Drug and Alcohol) Centre – both inner Sydney health facilities of South Eastern Sydney Local Health District (SESLHD). Extensive consultation with the ACT group was undertaken during development, with the sharing of educational materials, clinical protocols and some of the evaluation methods to enable the collection of comparable data. The OPEN Project was the first Australian THN program hosted by clinical services, conducted using internal funds [4]. The lessons learned from the OPEN Project informed SESLHD's subsequent approach, including expanding the THN within SESLHD and facilitating its uptake by other NSW services.

The OPEN Project training session was delivered by trained health practitioners (health education officers, nurses), and was typically a small group activity of 30 to 45 minutes duration including information on opioid overdose, managing an emergency overdose situation including calling for ambulance assistance and basic life support measures, and use of naloxone. The Project incorporated a comprehensive evaluation from the outset [4] and ongoing process evaluation continues.

While evaluation data show positive feedback from OPEN participants, it was clear that to maximise THN uptake, delivery needed to be brief and flexible (e.g., in groups, individual training and in outreach settings). In 2014, SESLHD approved a standardised procedure for what is now called the 'Brief Intervention' (BI), describing the necessary clinical governance issues in delivering a 15-20 minute brief intervention. This is now offered to all clients at risk of opioid overdose across SESLHD AOD services and KRC. The intervention provides client education and information, naloxone supplies and an Overdose Prevention Kit free of charge to clients [21].

In January 2015, the Sydney Medically Supervised Injecting Centre (MSIC) introduced a THN program as part of its core business. While MSIC clients were initially trained at KRC, MSIC staff are now trained to deliver individual-level brief interventions of about 10-15 minutes' duration. Naloxone is now dispensed directly to MSIC clients by nursing staff, free of charge. Registered nurses are able to dispense naloxone to a client of the MSIC under a protocol approved by the Pharmaceutical Services Branch of the NSW Ministry of Health in November 2016 and is the only such authority in Australia.

At June 2017, it is estimated that 1000 people have received THN in NSW and 185 opioid overdoses have been successfully reversed (Table 1). In 2016, SESLHD, in partnership with a number of other local health districts/networks, consumer and academic groups, was awarded a NSW Health Translation Research Grant to develop, evaluate and roll out THN program access across NSW AOD services, primary Needle Syringe Programs and peer outreach services. The ‘one-stop’ model involves ‘free to the consumer’ THN provided by a range of health workers (nurses, allied health) without the need for doctor or pharmacist involvement, with harmonised approaches across services to minimise variation or confusion for consumers.

The BI developed by SESLHD in 2014 has now been adapted and incorporated by a number of other drug and alcohol services elsewhere in NSW. Its use in other policy or clinical guideline documents in this way serves as an example of ensuring a sustainable THN response. THN is also considered part of routine care planning for people entering and exiting opioid substitution treatment (OST) programs and has been incorporated into pending NSW Opioid Treatment Program guidelines. Future work involves establishing procedures for THN BIs to be available to individuals following overdose in a number of hospital Emergency Departments.

Take-home naloxone in Western Australia (WA) 2013 to 2017

Since 2013, the Western Australian Substance Users’ Association (WASUA), in collaboration with the Mental Health Commission (MHC), has been delivering a Peer Naloxone Education Program to consumers, family and friends and frontline AOD workers. The program provides education on the prevention and management of opioid overdose,

including basic life support skills and the administration of naloxone; and provides participants with two (400mcg) doses of naloxone on completion.

As of June 2017, the WA Peer Naloxone Education Project has provided training to 546 people and dispensed 283 naloxone kits. The Project has expanded to include targeted regional areas, along with providing the program at specific agencies with a high opioid-using client base. The initial 18 months of the project was evaluated by the National Drug Research Institute (NDRI) at Curtin University [2]. This evaluation concluded the WA project should be continued and expanded as it found that: the initial 153 participants substantially increased their knowledge about how to recognise and respond to an opioid overdose: there were 32 overdose reversals using peer-administered naloxone reported; and in all of these cases the person survived.

The WA Peer Naloxone Project was expanded to include pre-release prisoners in Acacia prison, Australia's first formal prison-based THN program where prisoners can receive naloxone on release. Under the scheme that commenced in 2016, prisoners receive their naloxone as part of their discharge kit so they have it when they leave the prison. In 2016, Next Step Drug and Alcohol Services (a government agency) commenced prescribing and dispensing naloxone to OST clients. In addition, various Western Australian services have consulted with MHC to consider how they can implement naloxone programs or provide education and access to naloxone.

With changes to naloxone scheduling allowing pharmacists to dispense naloxone OTC [20], pharmacists were identified as a key stakeholder in the provision of naloxone education and in promotion of naloxone education and access to pharmacotherapy clients [22]. The

Workforce Development Branch at the MHC has been collaborating with pharmacist organisations to develop and deliver training and resources to assist with naloxone dispensing, although the number of naloxone kits dispensed through this program is not known.

The MHC has developed the *Recognising and Responding to Amphetamine Intoxication/Toxicity & Opioid Overdose* package, including an audio-visual resource, trainer guide and fact sheets and a Naloxone Brief Education Tool. The resource, developed with extensive input from drug user representatives and clinical experts, is aimed at providing comprehensive information to those who wish to deliver education and training to prevent and manage opioid overdose. It includes opioid overdose scenarios depicting signs and symptoms of overdose, along with appropriate responses to overdose including basic life support and the administration of naloxone. The printable Brief Education Tool has been adapted from the Opioid Overdose Knowledge Scale (OOKS) [23]; and frontline workers can utilise the Brief Education Tool along with the opioid audio-visual scenarios to provide opportunistic education sessions, prior to facilitating naloxone access. Since September 2016 MHC's Workforce Development Branch has trained over 150 frontline workers with the *Recognising and Responding to Opioid Overdose* component of the package.

Take-home naloxone in Victoria 2013 to 2017

Programs to provide opioid consumers with THN commenced in Victoria in August 2013. The first THN workshop was delivered by Victoria's drug user organisation, Harm Reduction Victoria (HRVic), in collaboration with Access Health, one of six specialist drug-related primary health services in Melbourne. Since 2013, direct distribution of THN has expanded to HRVic-delivered THN programs in other specialist drug-related primary health services

and NSPs. Several of these services also now provide opportunistic individual BIs and naloxone with service users.

The HRVic-led THN program has been designed and delivered by a HRVic peer educator. The program model is similar to the CAHMA model in the ACT. The collaborating services recruit participants for training, host the group training sessions and provide access to a GP for prescription of naloxone. Upon satisfactory completion of training, a GP writes a prescription for each program participant. Service staff take the prescriptions to a local pharmacy and return to the service with the naloxone. Program participants are then provided with naloxone and associated equipment (see Table 1). The HRVic peer educator now also opportunistically conducts brief (15-20 minute) individual training sessions after which naloxone is provided.

The HRVic-led THN initiatives were independently evaluated over 18 months by researchers at Victoria University and the Burnet Institute. Select evaluation findings are reported elsewhere [24, 25]. To June 2017, 1072 people have been trained by the HRVic peer educator, with 295 successful reversals reported (this figure includes evaluation data and anecdotal reports to HRVic and collaborating services).

Complementing the HRVic-led direct distribution THN program, the Community Overdose Prevention and Education (COPE) program initiated by the Pennington Institute runs as a parallel strategy in Victoria. The COPE program conducts group sessions to train frontline workers, including NSP workers, AOD workers and other community workers (e.g., housing, welfare) in THN. Workers are trained in how to prevent, recognise and respond to opioid overdose, including using naloxone in order that they may then provide this training to people

at risk of opioid overdose and potential overdose witnesses. There are written supporting materials for health professionals and community members, including procedures for conducting brief interventions on overdose recognition, response and reversal with naloxone, available in the COPE section of the Pennington Institute website (www.pennington.org.au).

The COPE strategy does not involve direct provision of THN. Commencing in February 2014, COPE has trained approximately 600 health and community workers in metropolitan and regional areas of Victoria (to June 2017). These trained professionals have, in turn, provided opioid overdose recognition and response (including naloxone administration) training to an estimated 610 people at risk of opioid overdose. Among this group, an estimated 583 received either naloxone or a prescription for naloxone.

Most recently, in February 2017 the Victorian government announced a Naloxone Subsidy Initiative. This initiative provides additional funding to select organisations in six ‘overdose hotspots’ across Melbourne to subsidise the cost of naloxone and thereby increase access and availability for people who use opioids [26]. As is occurring in the ACT, several Victorian services are working with community pharmacies to establish OTC naloxone voucher arrangements to enable clients to access a pre-paid voucher for OTC naloxone.

Take-home naloxone in Queensland 2014 to 2017

The Queensland Department of Health, in response to a series of overdose deaths (related to diverted fentanyl), developed an overdose prevention strategy which included a naloxone training and distribution project. A pilot program began at Brisbane’s Biala Community Health Centre Clinic in January 2014. Biala has an opioid treatment clinic, a withdrawal management clinic and an active primary NSP. A weekly one-hour training session focused

on reducing the risk of overdose, recognising the features of overdose, responding to an overdose and giving naloxone by injection. At the end of the session, a prescription for five pre-filled naloxone syringes was issued. Two local pharmacies agreed to hold naloxone in stock. In three months, 12 people received training. The pilot was judged a partial success, providing proof of concept for THN delivery. Participants rated the training as effective, although the small number of people accessing the training was disappointing.

It was determined that a fixed one-hour training schedule was not the best way to scale up the provision of THN. Instead, a 10-minute BI was developed for delivery by NSP staff. This could be delivered opportunistically, or whenever the topic of overdose was raised at the NSP counter. Materials developed by the Metro North Alcohol and Drug Information Service, now available in some NSPs, include a two-page FAQ about naloxone, a flyer promoting THN training and a wallet-sized overdose card. Anecdotally there have been several successful reversals, and at least two people have returned to Biala for repeat THN prescriptions.

The Queensland Injectors Health Network (QuIHN), is a government-funded state-wide welfare organisation providing information, support and withdrawal management for illicit drug users and others affected by illicit drug use. QuIHN also offers opportunistic naloxone training and prescriptions through its NSP in Bowen Hills, Brisbane, though uptake has again been limited. Across Queensland generally, there has been slow uptake of THN. Efforts to promote take-home naloxone awareness and training continue. Finally, the provision of THN to people presenting to Emergency Departments following opioid overdose has been recommended after a local Mortality Review meeting. It is hoped this approach will be implemented across the Hospital and Health Services and then state-wide.

[TABLE 1 ABOUT HERE]

Discussion

Main findings

The data presented in this paper show that THN naloxone programs currently operate in at least five Australian jurisdictions, mainly through community services (primarily peer drug user groups and NSPs) but also in some specialised drug services (e.g., drug treatment services, supervised consumption facilities), other specialised health services (such as Aboriginal medical services) and at least two custodial institutions. Most of the programs offer small group THN training workshops, although increasingly the opportunity and need for individual and opportunistic training and provision has been met by the development of BIs.

Two of the programs receive specific funding for the THN programs from governments while the rest are funded internally. Although federal government funding has been received through research granting bodies for a small number of THN-related projects, the Federal Government to date has not been a direct funder of THN initiatives in Australia. The majority of health-related funding is distributed by the state and territories in Australia. However the Federal Government has been briefed on THN developments and has a potential role to play in national leadership around THN.

Overall, our review suggests that in excess of 2500 Australians at risk of overdose have been trained and provided naloxone through THN programs. However, program implementation data are incomplete and so this figure is likely a significant underestimate. Evaluation data from four programs recorded 146 overdose reversals undertaken by THN participants using

naloxone. This number of recorded overdoses was derived from a total of 358 participants formally followed-up 3-6 months post training – suggesting 41% of trained participants used their naloxone to help revive someone during that time period. There are a further 484 anecdotal reports of overdose reversals involving THN collated in this review. These reports derive from informal client and program trainee feedback recorded by service staff and naloxone trainers.

While all programs began in metropolitan areas, three now have regional components of various sizes. Peer drug user groups continue to play a central role in the development, delivery and scale-up of THN in Australia, and health professionals who work with people who use illicit opioids are increasingly taking part as AOD-related health agencies have recognised the opportunity for THN provision through interactions with their clients.

Most THN programs target people at risk of overdose from illicit opioid use, who in the social context of illicit drug use, are also those most likely to witness an overdose amongst their peers. THN programs are yet to target regular or dependent users of pharmaceutical opioids but we are aware that these are under development. National and international trends in overdose deaths [27, 28] suggest that this group should also receive overdose training and THN.

Although many AOD workers have also sought and been provided overdose training through THN programs, current medico-legal requirements associated with prescription access have meant the provision of naloxone has been limited to people with a history of opioid use. Training family members and friends in overdose prevention and naloxone administration, which has been a feature of programs internationally [e.g., 29, 30], has not been a major

feature of Australian programs. OTC naloxone access through pharmacy provides avenues for new non-prescription models of THN. Together, these changes will likely increase access to naloxone for other potential overdose witnesses as well as people who use opioids. Nevertheless, people who use illicit opioids such as heroin remain most likely to witness an overdose and should not be neglected as THN programs evolve.

Limitations

There are a number of limitations to our review. The data rely on self-report of program coordinators and others and, apart from the few published evaluations [2-4], the data do not include standardised methods or active follow-up with participants to explore use of naloxone by program participants. As a consequence, numbers trained and numbers of reversals are likely to be under-reported.

However, because of the NNRG and the relatively small number of people involved in the THN ‘community’ in Australia, we can be confident that we have accessed information on most THN programs in Australia, with information supplied by key informants who are able to provide the best currently-available data on these programs. Information on the people accessing naloxone OTC through pharmacy sales, or the pharmacies supplying OTC naloxone are not included in this summary; feedback from the different jurisdictions suggests that naloxone uptake through this route has been slow [31], which was not helped by supply uncertainty due to changes in product availability nationally, as described above.

Prescription and non-prescription models

A major issue for THN programs, especially those which are run out of community services or groups such as peer-based drug user organisations is that, despite rescheduling, there

remain access and cost barriers. Many of those at risk of overdose are people from marginalised and economically disadvantaged groups in the community such as people who inject drugs [19]. The requirement for accessing naloxone as a prescribed medicine through a doctor or OTC via a pharmacist remains a logistical and economic (where services cover the costs of naloxone from internal funds) barrier for most community THN programs. At least one peer drug user group, WASUA in WA, has a nurse practitioner to prescribe naloxone as part of their service, however most rely on GPs, whose time and availability is variable. While expansion of access through OTC pharmacy sales is a welcome development, the cost, even under PBS subsidy, remains a barrier for many of the people most at risk of overdose.

Australia has made rapid progress in removing regulatory barriers to naloxone since the initiation of the first THN program in 2012. However, secondary distribution, an important mechanism for getting naloxone into the hands of the most hard-to-reach PWID is not easily possible under existing regulations. In other countries, health authorities have put in place delegation provisions that allow approved programs which meet designated training and other criteria to dispense/provide naloxone to their clients [32, 33]. Until recently there has not been a mechanism to do this in Australia, although recent regulatory developments look promising in this regard (see NSW above).

Current joint state, territory and commonwealth government initiatives aim to establish a national approach to the assessment and conferral of scheduled medicines authorities for the unregistered health professions, potentially enabling a national framework for an expanded range of service providers involved in THN supply. In the meantime, the distribution of naloxone by nurses and allied health staff (without doctor or pharmacist involvement) in some drug and alcohol agencies and NSP services has commenced in NSW as described

above. If this model proves to be feasible, it is hoped that it will provide a template for similar programs elsewhere in Australia.

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