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Saving lives: Australian naloxone access model



Penington Institute is a not-for-profit organization that advances health and community safety by connecting substance use research to practical action. We support individuals and the wider community through research analysis, promotion of effective strategies, workforce education and public awareness activities. Penington Institute first formed two decades ago as Anex (now a program of Penington Institute) — a network of service providers working to prevent HIV/AIDS transmission related to unsafe injecting drug use. Since then, we have been focusing on linking emerging evidence bases with public health responses.

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Definitions and explanatory notes

Acronyms

ACT	Australian Capital Territory
AOD	Alcohol and Other Drug
BI	Brief Intervention
COPE	Community Overdose Prevention and Education
I-ENAACT	Implementing Expanded Naloxone Availability in the ACT
MME	Morphine Milligram Equivalents
NSP	Needle and Syringe Program
NSW	New South Wales
OEND	Overdose Education and Naloxone Distribution
OMT	Opioid Maintenance Therapy
ORTHN	Overdose Response and Take-Home Naloxone
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PWID	People Who Inject Drugs
PWUD	People Who Use Drugs
SIF	Supervised Injecting Facility
TGA	Therapeutic Goods Administration
THN	Take-Home Naloxone
WA	Western Australia

Key terms

Scheduling refers to the Australian Therapeutic Goods Administration's classification system for poisons and medicines. Medicines are grouped into schedules according to the level of regulatory control regarding their availability that is deemed appropriate. This is done to protect public health and safety by limiting access to substances that are dangerous. The schedules relevant to this report are Schedules 2 through 4 as well as Schedule 8 (the Schedule 1 category is not currently in use in Australia).

Schedule 2 medicines can only be stocked by pharmacies, though are available from the shelves and no contact with a pharmacist is required to purchase it.

Schedule 3 is also known as available 'over-the-counter'. S3 medicines are available from pharmacies and require an interaction with a pharmacist (where advice can be given and the appropriateness of the medicine assessed) for a patient to access it.

Schedule 4 medicines are available through pharmacies, though require a prescription to access.

Schedule 8 refers to a Controlled Drug. Many S8 substances (including pharmaceutical opioids like oxycodone and fentanyl) are listed under the Pharmaceutical Benefits Advisory Committee (PBAC) and so are available via prescription.

Opioid Maintenance Therapy or OMT, also known as opioid substitution or replacement therapy, is a pharmacotherapeutic treatment for people who misuse opioids. It works by replacing opioids such as heroin with longer lasting opioid medications such as methadone or buprenorphine, allowing them to cease using other opioids while mitigating unpleasant withdrawal symptoms.

High dose refers to the strength of dosage for opioids. This is measured as Morphine Milligram Equivalents (MMEs). The US Centre for Disease Control (CDC) has issued guidelines recommending that doctors avoid prescribing above 90MME per day. This report defines 'high dose' as 90MME or greater per day. However, it should be noted that taking opioids at lower doses can still cause or contribute to an overdose, especially if other risk factors (such as concurrent use of other depressants such as alcohol or benzodiazepines) are present.

Poly-drug use refers to using multiple drugs (including alcohol) concurrently. When used together, some drugs increase the effects of each, as in the case of opioids and alcohol, putting the person at greater risk of overdose. Poly-drug use is detected in the majority of Australian overdose deaths.

Executive Summary

Opioid overdose represents a significant and ongoing problem for Australia's public health. Naloxone, a medication that reverses the effects of opioids, is an important means of responding to the harms associated with opioid overdose (including death). Penington Institute has examined international take-home naloxone (THN) programs to inform the development of a model for the Australian context. These programs distribute the life-saving drug naloxone to people likely to witness an opioid overdose, usually free-of-charge. Such programs generally form part of broader strategies aimed at reducing the harms associated with opioids, especially overdose. A comparative analysis of six international programs allows for an assessment of various approaches that could be applied in the Australian context. This report details Penington Institute's findings in the following areas:

- distribution of THN in international programs;
- recent changes to naloxone access in Australia;
- current programs providing overdose prevention (including THN) in Australia;
- barriers and challenges for THN distribution in Australia.

The report then proposes a model for a national THN program for Australia to adopt as part of a national public health response to growing rates of opioid overdose.

INTERNATIONAL PROGRAMS

Penington institute has examined six programs currently distributing THN to key populations in five countries. Three are national programs (Norway, Scotland and Wales) and three are large-scale state or provincial programs (Massachusetts in the USA and British Columbia and Ontario in Canada). These comprise a range of models, interventions, and engagement practices designed to reduce the burden of overdose death in populations at-risk of opioid overdose. Lessons are drawn from each and this has shaped the model for an Australian program proposed in this report.

OVERDOSE IN AUSTRALIA

Overdose is a growing public health risk in Australia. Currently, the number of Australians that die of overdose per year is greater than those lost in the road toll.¹ Not since the 'heroin scourge' of the late 1990s, have opioids accounted for such a high number of deaths in Australia. What has changed since then is that pharmaceutical opioids now account for the majority of fatal opioid overdoses (approximately 70% compared to 30% for heroin).² This presents new challenges for Australia in effectively responding to overdose, as the population of people misusing prescription opioids comprises a different demographic than those traditionally represented in overdose deaths: people who inject heroin.

¹ Penington Institute (2018) 'Australia's Annual Overdose Report 2018':

<http://www.penington.org.au/australias-annual-overdose-report-2018/>

² ABS (2017) 'Drug-Induced Deaths in Australia: A changing story', Australian Bureau of Statistics.

NALOXONE IN AUSTRALIA

Naloxone has been used in Australia in emergency settings for decades.³ While naloxone is theoretically available for access via prescription or over-the-counter, in practice naloxone remains largely out-of-reach for those at-risk of opioid overdose. The significant cost of purchasing naloxone over-the-counter and the onerous process of accessing it via prescription, serve as barriers for those most likely to benefit from facilitated access to the medicine.

There are several trials and small programs that provide THN to at-risk populations currently operating in Australia. However, these arrangements are highly bespoke and remain limited in scalability. To properly address rising rates of fatal overdose, it is imperative that Australia include large-scale distribution of THN as part of a broader response to overdose, its causes and associated harms.

Currently, naloxone is only available in single dose ampoules and a pre-loaded five-dose syringe. Both require injection to administer. Intra-nasal formulations (a more user-friendly format administered through the nose) are available in several international settings and should be made available in the Australian program.

THE PROPOSED MODEL

The model proposed in this report makes take-home naloxone available free-of-charge to those who need it – people at risk of overdose and people likely to witness overdose (people using opioids, their friends and family members). The proposed model does not reform current means of accessing naloxone (over-the-counter and via prescription), rather, it targets populations who experience a high-risk of overdose with free naloxone. Populations who experience high risk include:

- people who inject or use drugs (PWID/PWUD);
- those with past or current opioid use;
- people recently treated for overdose;
- people newly released from incarceration;
- people who have had a recent period of abstinence.

To effectively target these populations, the program will make THN available from a range of settings already accessed by at-risk groups. The agencies authorised to distribute THN through the program will be:

- Needle and Syringe Programs (primary and secondary);
- select community agencies (that work with at-risk clients including outreach and homelessness services);
- custodial facilities (including remand and youth justice centres);
- drug treatment facilities and programs;
- pharmacies (including pharmacies that provide Opioid Maintenance Therapy);
- emergency departments.

³ ANEX (2012) Australian Drug Policy: Lifesavers – access to naloxone to reduce opioid overdose-related deaths and morbidity', Penington Institute: <http://www.penington.org.au/wp-content/uploads/2014/04/Australian-Drug-Policy-Lifesavers-access-to-naloxone-to-reduce-opioid-overdose-related-deaths-and-morbidity.pdf>.

Staff at these facilities will be trained and credentialed to provide overdose prevention education (including administering naloxone) and authorised to supply THN directly to clients free-of-charge and without a prescription. Training for clients will be flexible and tailored to the differing needs of population sub-groups.

While a THN program is an important means of mitigating the risks and harms of overdose, there remains an ongoing role for GPs and other doctors who prescribe opioids to engage patients in discussions about overdose risk and naloxone as an option for managing this.

The report is divided into the following sections:

- Section 1 – International naloxone programs
- Section 2 – Background and context in Australia
- Section 3 – Proposed model

Introduction

There is a growing international crisis of opioid overdose. The number of deaths attributable to drug overdose has increased significantly in many parts of the world over the last twenty years. North America and parts of Europe have seen dramatic increases in overdose deaths, with the US Centers for Disease Control and Prevention (CDC) estimating that there were 72,000 fatal overdoses in 2017 in the US; more than 190 per day.

Opioids — substances derived from or mimicking opium — are responsible for the majority of overdose deaths. This is because opioids depress the central nervous system including the respiratory system, slowing a person's breathing and possibly stopping it altogether. In Australia, the illicit opioid heroin has traditionally accounted for most overdose deaths. However, prescription and pharmaceutical opioids have surpassed heroin in terms of overdose mortality, accounting for approximately 70% of fatal opioid overdoses⁴.

While Australia's experience of the opioid epidemic has not been as severe as elsewhere (i.e. the US and Canada), rates of overdose mortality have increased steadily since 2000. The Australia Bureau of Statistics recorded 1,808 overdose deaths in 2016; the highest in twenty years and provisional data indicates further increases in 2017.⁵ Currently in Australia, the death toll from overdose exceeds the number of people killed in road accidents.⁶

Not all overdoses are fatal, however, and non-fatal overdose also carry terrible consequences. Non-fatal opioid overdose involves the brain being deprived of oxygen, which can result in a range of harms and morbidities (generally termed 'hypoxic brain injury').

One critical response to this international pattern has been increasing the availability of the overdose-reversing drug naloxone. When administered to a person experiencing an opioid overdose, naloxone reverses the effects of the opioid, restoring their respiratory system and buying time for emergency services to arrive and treatment to be administered. A remarkable medicine, naloxone has very few side effects and no capacity for misuse. Naloxone has been used for treating opioid overdose for decades, though its use has traditionally been restricted to medical settings.

In 2014, the World Health Organization (WHO) issued guidelines recommending that people likely to witness an opioid overdose, including people who use opioids, their friends and family, be given access to naloxone and training in its use so they can respond in the event of an overdose where a medical response is not available.⁷

Like adrenalin for those with severe allergies and glucagon for diabetics, naloxone can act as an emergency medicine when put in the hands of those likely to experience or witness an overdose. As such, several countries have developed and implemented Take-Home Naloxone (THN) programs. These supply free naloxone kits to populations at risk of overdose. While a few small-scale versions of these programs are currently operating in Australia, these are localised, service small areas and are currently not scalable.

⁴ ABS (2017).

⁵ Ibid.

⁶ Penington Institute (2018).

⁷ WHO (2014) 'Community management of opioid overdose', World Health Organisation: http://www.who.int/substance_abuse/publications/management_opioid_overdose/en/

Naloxone is not a panacea for the issue of opioid overdose: it does not address the underlying causes of overdose and therefore cannot be relied upon to reduce the harms of overdose alone. The administration of naloxone is useful within an emergency context; other, non-emergency responses and systemic reforms are needed to reduce the harms associated with opioid overdose. The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) recommends the following:

- monitoring opioid prescription practices;
- curbing inappropriate opioid prescribing;
- curbing inappropriate over-the-counter-sales of opioids;⁸
- increasing the rate of treatment for opioid dependence;
- ensuring OMT is available and accessible;
- raising awareness about opioid overdose;
- linking those who are vulnerable to relevant services; and
- maximising the role of needle and syringe programs.⁹

The purpose of this report is to propose a model for large-scale distribution of Take-Home Naloxone (THN) to priority populations in Australia. However, Penington Institute also supports government action in the areas identified by EMCDDA. While THN is not a silver-bullet, it should form part of efforts to address overdose mortality as an ongoing issue of public health, alongside other innovations such as reforming ineffective drug policies; increasing the availability of appropriate treatment; and adequately funding evidence-based harm reduction initiatives such as Needle and Syringe Programs (NSPs).

In preparing this report, Penington Institute conducted desk-based examinations of several THN programs from around the world. The report examines programs operating in the Canadian provinces of Ontario and British Columbia, and the US state of Massachusetts; as well as national programs in Scotland, Wales and Norway.

Penington Institute also held three focus groups with:

1. Staff from Victorian Needle and Syringe Programs;
2. People at risk of overdose;
3. Staff from a service treating people misusing prescription medicines.

Follow-up interviews and discussions were held with representatives from international THN programs:

Ontario, Canada

- Chris Harold – Manager, Addiction and Substances Policy and Programs, Ministry of Health and Long-Term Care.
- Margo Warren – Manager, Priority Policy, Ministry of Health and Long-Term Care.
- Ken English – Senior Program consultant, Ministry of Health and Long-Term Care.
- Elizabeth Foster – Program Analyst, Ministry of Health and Long-Term Care.

⁸ Australia recently rescheduled medications containing low doses of codeine, meaning from February 2018, opioids were no longer available over-the-counter in Australia. See: <https://www.tga.gov.au/codeine-info-hub>

⁹ EMCDDA (2016) 'Preventing opioid overdose deaths with take-home naloxone', Luxembourg: Publications Office of the European Union.

- Glenn McAuley – Lead Pharmacist, Ontario Public Drug Programs Division, Ministry of Health and Long-Term Care.
- Steve Parker – Senior Policy and Programs Adviser, Addictions and Substances Unit, Ministry of Health and Long-Term Care.
- Victory Lall – Policy Development Officer, The Works Needle Exchange, Toronto Public Health.

British Columbia, Canada

- Professor Jane Buxton – Professor of Epidemiology, University of British Columbia and BC Centre for Disease Control.
- Emily Ogborn-Hill – Operations Coordinator, Harm Reduction Program, BC Centre for Disease Control.

Norway

- Desiree Madah-Amiri – Research Fellow, Norwegian Centre for Addiction Research, University of Oslo.

Scotland

- Lee Barnsdale – Information Services Division, Scotland.
- Kirsten Horsburgh – National Naloxone Program Coordinator, Government of Scotland.

Wales

- Rhian Hills – Senior Policy Manager, Substance Misuse Policy, Welsh Government.

Part One – International naloxone distribution programs

Several countries and settings around the world have implemented Take-Home Naloxone (THN) programs as a response to rising rates of overdose. Programs vary in many respects: from large national programs to small, localised pilots; some distribute naloxone to anyone who requests it and others limit this to a highly select populations; some programs offer multiple formulations of naloxone (injectable and intra-nasal) whereas others are restricted to one type.

Despite these differences, THN programs share the aim of reducing the harms arising from opioid overdose by providing THN as an emergency response medicine to those likely to experience or witness an overdose. Patterns and characteristics of drug use vary dramatically across contexts, so there is no such thing as a perfect or universally appropriate model for THN distribution. Any program providing THN needs to cater to the specific needs of the populations it serves, while also adhering to the laws and regulations relevant to the context in which it operates.

This report examines six large-scale naloxone programs operating in five countries. They were selected based on size, diversity and the availability of information such as published evaluations. The programs examined in this report are:

- Scotland
- Wales
- Norway
- Massachusetts, US
- British Columbia, Canada
- Ontario, Canada

Table 1 (below) lists various innovations in THN distribution from the programs examined in this report. Not all will be suited to the Australian context, though they illustrate the range of possibilities to consider for an Australian THN program. Following this, each of the international programs examined for this report are described in further detail.

Table 1: Key innovations from international Take-Home Naloxone programs

Feature	Description	Benefit	Contexts used
Patient Group Directives	Protocols allowing named practitioners to dispense w/o prescriptions or medical supervision	Increases number of staff authorised to dispense	Scotland, Wales, Massachusetts
Overdose Response Sites	Temporary site that functions as a temporary NSP, SIF and naloxone distribution point	Allows for coordinated response to localised spikes in overdose	British Columbia, Ontario
Nasal atomiser adaptors ¹	Adaptors attached to pre-loaded syringes of naloxone (Prenoxad) to convert it for intra-nasal use	Injectable formulations can be adapted for intra-nasal use	Norway
THN distribution through peer outreach (Naloxone Outreach on Wednesdays (NOW) van)	Weekly mobile outreach that provides training and THN in high-risk areas.	Delivers naloxone kits and training to people rather than requiring them to attend training sessions	Ontario
Pharmacies as distribution points	THN available from pharmacies	Having pharmacies distribute THN increases coverage of naloxone programs	Scotland, Ontario, British Columbia
Emergency departments	THN available from EDs	Those receiving treatment for overdose at emergency departments provided with THN	Ontario, British Columbia
Pain Management Clinics	THN available from pain management clinics	Having THN available from pain management clinics captures those taking prescription opioids for pain	Ontario, British Columbia, Norway

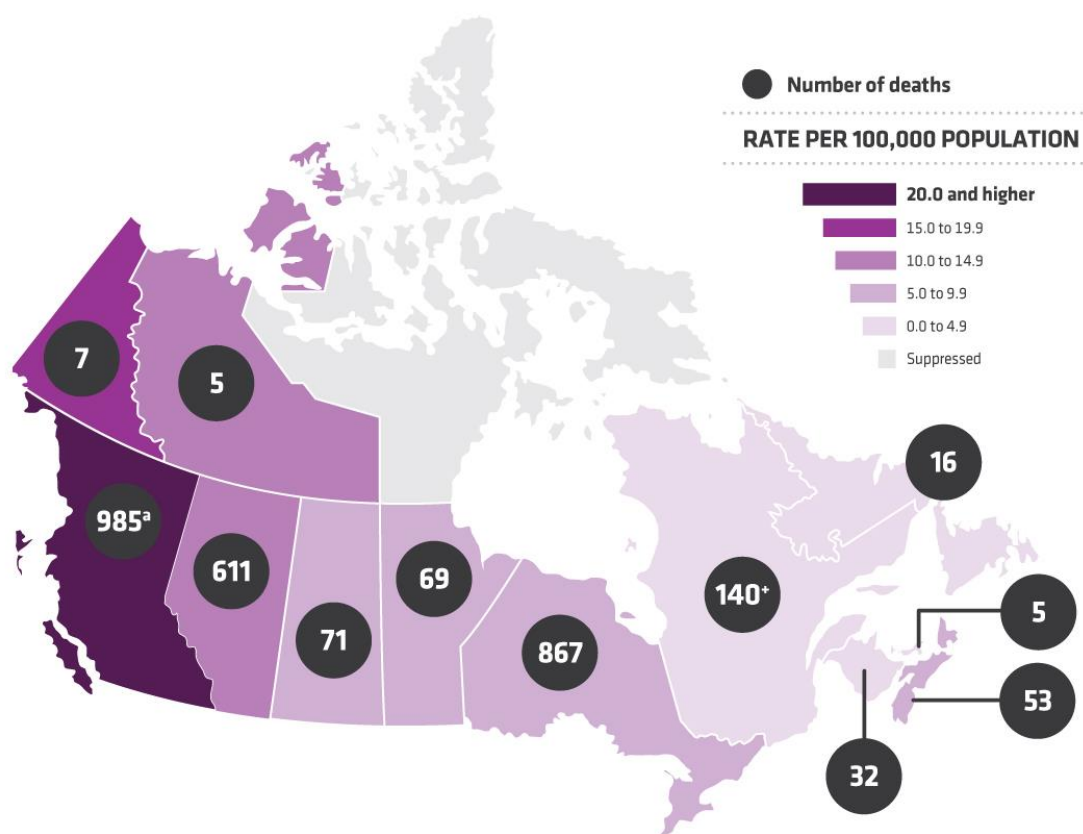
¹Injectable formulations contain higher volume of liquid than built for purpose intra-nasal units. This means a lot of liquid must be absorbed through the nasal mucosa for a full dose to be administered. This is likely to be less effective than a true intra-nasal unit.

Table 2: International innovations for responding to overdose (other than THN)

Feature	Description	Benefit	Contexts used
Supervised Injecting Facilities (SIF)	Supervised rooms where drug users can safely consume drugs. Also distribute harm reduction supplies including naloxone	Reduces overdose and associated harms, links users to health and support services	Norway, Ontario, British Columbia
Overdose phone app	App alerting people carrying naloxone of nearby overdoses	Allows people carrying naloxone to be notified of nearby overdoses in real-time	British Columbia
First responders carrying naloxone	Police cars and fire trucks carry naloxone in addition to paramedics	Gives all first responders naloxone to administer when an overdose is encountered	Ontario, British Columbia, Massachusetts (partial)
Opioid Maintenance Therapy	Use of methadone or buprenorphine to treat opioid addiction	Proven to reduce the risk of opioid overdose	Ontario, British Columbia, Massachusetts, Scotland, Wales, Norway
Facility Overdose Response Box (FORB)	A first aid kit for overdose that organisations that work with people at risk of overdose can install.	Makes emergency naloxone available in agencies that work with populations at risk.	British Columbia

Canada

In 2016, Canada recorded 2,816 deaths from apparent opioid overdose, and while more recent statistics are provisional, there were at least 1,460 deaths caused by opioid overdose from January to June 2017.¹⁰ Canada does not have a national naloxone distribution program, though the federal government's responses to the crisis include rescheduling naloxone to make it available without a prescription and issuing exemptions for clinics to operate supervised injecting facilities (which also distribute THN) in several cities.



^a British Columbia reports unintentional deaths related to all illicit drugs including, but not limited to, opioids.
⁺ Expected to rise











































































Number of overdose deaths in Canada in 2016. Source: Health Canada: <https://www.canada.ca/en/public-health/services/publications/healthy-living/apparent-opioid-related-deaths-report-2016.html>

Beyond rescheduling, how naloxone is distributed has been left up to the provinces with each responding to rising rates of overdose in its own way. The largest THN programs operate in the provinces of British Columbia, Ontario and Quebec, though all Canadian provinces now have programs distributing naloxone free of charge to those at risk of opioid overdose.

¹⁰ Government of Canada (2017) 'National report: Apparent opioid-related deaths in Canada': <https://www.canada.ca/en/public-health/services/publications/healthy-living/apparent-opioid-related-deaths-report-2016-2017-december.html>

The below table represents the availability of naloxone in Canada as of November 2017. Note that New Brunswick, Prince Edward Island and Newfoundland and Labrador have since introduced THN programs of varying size.

ACCESS TO NALOXONE ACROSS CANADA

	Free Take-Home Naloxone Kits				Emergency naloxone available through first responders	Naloxone available for purchase at pharmacies
	Distributed through pharmacies		Distributed through other sites			
	Available for all	Restricted eligibility	Available for all	Restricted eligibility		
British Columbia	 ³					
Alberta						
Saskatchewan				 ¹		
Manitoba		 ¹		 ¹		
Ontario	 ²					
Quebec	 ³					
New Brunswick						
Nova Scotia						
Prince Edward Island						
Newfoundland and Labrador						
Northwest Territories						
Yukon						
Nunavut						

✓ Available P Pending i Insufficient information available ✗ Not available in the province of territory

Ontario

In 2016, Ontario recorded the second highest number (867) of overdose deaths in Canada. The Ontario THN program was established in 2013, making it one of the oldest in Canada. The Ontario case study is worthy of consideration for the following reasons:

- Canada shares several geographic, political and social features with Australia (such as nationally subsidized healthcare, and large rural expanses), which provide key points of comparison and extrapolation;
- The Ontario model is extensive and wide-reaching, having undergone several expansions since its implementation;
- The Ontario model is sophisticated; it is comprised by three separate programs and operates across a range of distribution points;
- Nasal naloxone, which is not yet available in Australia, forms a key component of Ontario's program.

Ontario's Take-Home Naloxone Program

Ontario's Take-Home Naloxone (THN) Program comprises of three separate programs:

- The Ontario Naloxone Program (ONP);
- The Ontario Naloxone Program for Pharmacists (ONPP);
- The Provincial Correctional Facilities Take Home Naloxone Program.

Each program covers different (though overlapping) sites of contact with those at risk of overdose. This ensures widespread coverage and accessibility of THN. Importantly, those at risk of opioid overdose do not comprise a singular discrete group, rather, those at risk of opioid overdose are a diverse population with a range of differing needs, levels of engagement and health literacy.

Initially, THN was distributed through a single program— the ONP — which provided THN kits to clients of selected Needle and Syringe Programs (NSPs) free of charge. Following the national rescheduling of naloxone in 2016, the Ontario Naloxone Program for Pharmacists (ONPP) was launched. This rapidly expanded the availability of THN across the province.

The Ontario Naloxone Program (ONP)

In 2013, the ONP was launched in response to growing numbers of overdose deaths in the province and across the nation. Initially, pre-assembled naloxone kits purchased by the Ontario government were distributed to 22 eligible NSPs. Each kit contained two single-dose glass ampoules of naloxone, syringes, needles and other paraphernalia such as alcohol swabs and gloves. Kits were provided along with training in how to recognise an opioid overdose, administer naloxone, and other appropriate responses (call emergency services, stay with the person until they arrive, etc.).

The ONP was incorporated into Ontario's network of 36 Public Health Units (PHUs) in 2016 and the list of agencies authorised to dispense naloxone was expanded. PHUs are publicly-funded health agencies providing coordinated health services to specific areas. Several PHUs operate harm reduction services (such as NSPs) on site. For example, Toronto Public Health is the PHU servicing the Toronto area, which operates an NSP and Supervised Injecting Facility (SIF) called 'The Works'.

In addition to NSPs, six types of agencies were authorised to distribute THN through the ONP: homeless shelters, outreach services, withdrawal services, drop-in centres, community health centres (including Aboriginal Health Services) and 'overdose prevention sites'.¹¹ These secondary agencies are coordinated through a 'hub-and-spoke' model. For example, The Works in Toronto distributes harm reduction supplies to 52 agencies in the local area. Of these, 38 have been contracted and trained by The Works to distribute naloxone kits.

Currently, the ONP only distributes kits containing intra-nasal naloxone, though due to client demand, kits containing injectable naloxone will soon be available.

Key features of the ONP:

- Free naloxone kits are provided to key or at-risk populations through Needle and Syringe Programs, community health centres and other agencies;
- Requesting a kit through an agency is anonymous with no ID or other verification necessary;

¹¹ 'Overdose Prevention Sites are 'hotspots' for overdose, where a temporary or 'pop-up' service can be established to dispense safe injecting equipment and other harm reduction services including naloxone.

- The ONP only provides intra-nasal naloxone, though aims to also provide injectable forms soon;
- The ONP operates through Ontario's 36 Public Health Units, which coordinate networks of distributions points;
- PHUs are funded to provide training, capacity building and implementation development to local contracted agencies in their area;
- Currently, a kit obtained through the ONP contains:
 - 1 hard case;
 - 2 doses Narcan® nasal spray (4mg/0.1ml);
 - 1 pair non-latex gloves;
 - 1 card that identifies the person who is trained to give the naloxone;
 - 1 insert with instructions (English and French).

Ontario Naloxone Program for Pharmacists (ONPP)

The Ontario Naloxone Program for Pharmacists was launched in June 2016 following the rescheduling of naloxone from Schedule 3 (prescription-only) to Schedule 2 ('over-the-counter'). This saw a rapid expansion of the number of distribution points for free naloxone kits in Ontario.

The ONPP makes free THN kits available through community pharmacies¹² to anyone who requests one and has a valid Ontario Health card. This includes a person who believes they are likely to witness an overdose such as a friend or family of an opioid user. Pharmacists supply a kit and can provide training to the person in how to administer naloxone, as well as other information regarding how to correctly identify and respond to an overdose.

Currently, kits provided through the ONPP only contain injectable naloxone (ampoules and syringes). The Ontario government plans to make kits containing intra-nasal naloxone available through the ONPP to provide clients with more choice.

Participation in the ONPP is voluntary. However, pharmacies are not required to sign-up to the ONPP; any Ontario pharmacy can begin ordering naloxone kits and claim the cost upon dispensation. For dispensing a naloxone kit with training, the pharmacy will be reimbursed \$70 which covers the kit (\$35), the training (\$25) and a dispensing fee (\$10). For dispensing a kit without training, the pharmacy is reimbursed \$45.

Pharmacists participating in the ONPP are encouraged to provide training and education to any client who requests a naloxone kit, though training is not mandatory. Health Canada has stipulated that training should cover more than just administration, addressing how to identify an opioid overdose, the importance of contacting emergency services, and the importance of CPR and how to administer it.

There are an estimated 4,400 community pharmacies in Ontario and approximately 3,000 of them are currently participating in the ONPP. Of these, more than 600 belong to large companies (Shoppers Drug Mart and Rexall). Both companies have mandated that all their Ontario stores participate in the ONPP.

¹² A 'community pharmacy' is any pharmacy that is not located within a hospital setting.

Key features of the ONPP are:

- The ONPP distributes pre-assembled THN kits containing injectable naloxone from participating pharmacies;
- Kits can be accessed through the ONPP by any Ontarian who requests one and presents a valid Ontario Health card;
- All pharmacies in Ontario are eligible, though participation is voluntary;
- Training a client in naloxone administration is optional. No standardized training for pharmacists is available, though the Ontario Pharmacists Association has produced an online training module for pharmacists;
- THN kits obtained through the ONPP contain:
 - 1 hard case;
 - 2 (0.4mg/1 ml) vials or ampoules of naloxone;
 - 2 safety engineered syringes with 25g, 1" needles attached;
 - 2 devices known as 'snappers' for opening ampoules;
 - 1 pair non-latex gloves;
 - 1 card that identifies the person who is trained to administer naloxone.

The Provincial Correctional Facilities Take-Home Naloxone Program

The correctional facilities program was launched in 2016. Senior government public servants initially rejected a proposal for dispensing naloxone to newly-released inmates, though this was overruled by the Minister for Health and Long-Term Care.

Inmates who use opioids or are at risk of overdose are identified upon entry to a correctional facility and offered participation in the program. Staff at the correctional facility provide training in the administration of naloxone and a THN kit is included in an inmate's discharge bag upon release.

The kit also contains a wallet card with a phone number to a service that locates the nearest THN site. All parole and probation officers in Ontario also carry these wallet cards to dispense to their clients.

Key characteristics of the correctional facilities program are:

- All 26 correctional facilities in Ontario participate in the program;
- The population targeted is newly released inmates who have a history of opioid use and/or have identified themselves as at risk of overdosing on opioids;
- Access is through the correctional facility;
- Training in naloxone administration is delivered by correctional facility staff prior to release. Upon release, the former inmate is provided with one free naloxone kit;
- Correctional facilities participating in this program only provide intra-nasal naloxone.

Other distribution points

The primary distribution points for THN kits in Ontario are Needle and Syringe Programs, pharmacies and correctional facilities. However, through the expansion of the ONP, free naloxone kits are also available through homeless shelters, outreach organisations, community health centres and withdrawal management services.

Many PHU's also operate outreach services which can dispense naloxone and train clients in its administration. These mobile units provide training and THN kits either to specific locations upon request, or along standardised weekly routes.

Recently, THN kits were made available through emergency departments in Ontario. The Ontario government has also made naloxone available to police and fire services that volunteer to carry kits, however, these are not kit distribution points. These emergency services carry kits to administer when an overdose is encountered, but the kits are not dispensed.

In January 2018, THN kits were made available from Supervised Injecting Facilities and Overdose Prevention Sites (temporary 'hotspot' response sites providing NSP and SIF services). Ontario currently has three permanent SIFs.

Key outputs:

ONP:

- 36,211 kits dispensed (up to January 2018);
- 54 primary (hub) sites; no accurate data is available on total number of distribution sites;
- Only intra-nasal naloxone available (though plans to include injectable have been announced).

ONPP:

- 67,500 kits dispensed (up to December 2017);
- Approximately 3,000 pharmacies participating across province;
- Only injectable naloxone available (though plans to change this have been announced).

Provincial Correctional Facilities THN Program:

- 2,200 kits dispensed (up to November 2017);
- All 26 correctional facilities in Ontario participating;
- Only intra-nasal naloxone.

Challenges for Ontario

The Ontario program demonstrates several key strengths, such as coverage that is both extensive and targeted, multiple integrated distribution sites, and high-levels of access across the program. However, there are some ongoing challenges;

- Gaps in service coverage remain, particularly in rural areas of Ontario. Different Public Health Units have different levels of capacity for a range of reasons including lower levels of infrastructure, geographic isolation, fewer services available and differences in funding levels.
- In the early stages of the program, some kits had to be assembled on-site by staff. This resulted in a degree of kit variation, leading to complaints from regular clients. Kits have now been standardised across the THN program.
- Training uptake and consistency presents an ongoing challenge. There is no standardised training program, so levels and quality of training vary between agencies.

- Obtaining a kit through the ONPP requires a person to have a valid Ontario Health card. This constitutes an access barrier for non-Ontarians and people who have difficulty maintaining possessions, such as those experiencing homelessness.
- The cost of intra-nasal naloxone is prohibitive. A pack containing two units of intra-nasal costs \$145, compared to between \$10-35 per ampoule. Public funding for intra-nasal units was identified as a contested issue in negotiations between stakeholders.

British Columbia

The province of British Columbia (BC) has been hit hard by the opioid overdose crisis affecting Canada and many other countries around the globe. BC is Canada's third most populous province behind Quebec and Ontario, yet recorded the highest number of overdose deaths (985) in the nation in 2016. In the first half of 2017, 798 deaths were recorded indicating that increases are continuing.

BC's THN program is more streamlined than Ontario's: there is no tier system and the program is overseen directly by the BC Centre for Disease Control (BCCDC).¹³

Pilot Program

In 2012, amid growing rates of overdose deaths and the increasing availability of the powerful synthetic opioid fentanyl, British Columbia's government convened a Governmental Joint Task Force on Overdose and authorised the BC Centre for Disease Control (BCCDC) to pilot a publicly-funded THN program.

The pilot ran in two of BC's Health Authorities: Vancouver Coastal and Interior. It supplied overdose prevention training and a free Take-Home Naloxone kit to people using opioids at six participating sites. These sites comprised existing health units or community agencies partnered with healthcare providers housing drug treatment centres, needle and syringe programs and specialist community health services.¹⁴ At the time, naloxone was classified as a prescription-only medication in Canada so naloxone was restricted to people currently using opioids.

Within the first year, the pilot program dispensed 995 kits, trained more than 400 people in overdose prevention and recorded 30 overdose reversals using training and kits acquired through the pilot.¹⁵ The early successes of the program resulted in expansion of the program being fast-tracked. By December 2013, all BC Health Authorities were participating in the pilot.

Following a positive evaluation in 2014, the BCCDC approved the expansion of the pilot into a formal, province-wide THN program.¹⁶

BC's Take-Home Naloxone program

The BC THN provides naloxone kits free-of-charge to people at risk of opioid overdose and those likely to witness an opioid overdose. Clients are trained in overdose prevention including how to administer naloxone prior to kits being issued. The BCCDC have produced a standardised training program (including a downloadable app) for both service providers and clients.¹⁷

While the British Columbia Harm Reduction Program (based at the BCCDC) oversees the THN, management and coordination of supply has been devolved to BC's Regional Health Authorities. These are publicly funded health providers servicing BC's five regional districts: Fraser, Interior, North, Vancouver Coastal and Vancouver Island.

¹³ Banjo et al (2014) 'A quantitative and qualitative evaluation of the British Columbia Take-Home Naloxone program' *CMAJ Open*, vol. 2(3): 153-63.

¹⁴ Ibid.

¹⁵ Toward the Heart (2013) 'Take Home Naloxone Program: Nine month review': <http://towardtheheart.com/ezine/4/bcs-take-home-naloxone-program-update>

¹⁶ Toward the Heart (2017) 'The History of Take Home Naloxone in British Columbia': <http://towardtheheart.com/assets/uploads/1498515378JnqUKldhS4FXyCAWviFs9tIMlrPw3x1hyJvNuXI.pdf>

¹⁷ See <http://towardtheheart.com/>. The BC College of Pharmacists have also produced naloxone training resources: <http://www.bcpharmacists.org/naloxone>

Latest estimates show that in December 2017 BC had a total of 1,563 active distribution points. The rapid expansion of the number and type of organisations eligible to participate means that THN kits are now available in BC via medical facilities including emergency departments, community health organisations (including Aboriginal health and HIV/AIDS centres), homeless shelters, pharmacies, harm reduction organisations, addiction treatment clinics, pain management clinics, counselling services, community services such as youth drop-in centres and BC's nine Supervised Injecting Facilities (SIF) as well as temporary Overdose Prevention Sites.

Originally, kits provided through the THN contained two single dose ampoules of naloxone, though in 2016 this was increased to three. Currently, THN kits provided through the program contain:

- Three doses of naloxone (in either glass ampoules or vials);
- Three syringes and needles;
- Non-latex gloves;
- Snappers (for opening ampoules);
- Alcohol wipes;
- Information pack (in English and French)

Intra-nasal naloxone is not currently available through BC's THN program; however, intra-nasal formulations are available to purchase from pharmacies or other businesses that stock it.

Summary of outcomes

Since the beginning of the program:

- 85,845 kits have been distributed from 1,563 active distribution sites;
- 51,563 kits have been issued to new participants;
- 14,922 kits have been replacements or refills;
- 19,360 kits have been reported as being used to reverse an overdose.¹⁸

Expansions and additional information

The BC THN program has undergone significant reform and expansion since its inception in 2012. Below is a list of key changes brought in as part of both provincial and national responses to the overdose crisis:

- In April 2016, opioid overdose was declared a public health emergency by the BC Provincial Health Officer.¹⁹ This made way for certain special provisions such as the 'unscheduling' of 'emergency naloxone' in BC (see below);
- In 2016, the federal Minister for Health signed an interim order allowing intra-nasal naloxone to be imported from the USA for use in provincial THNs;
- In 2016, THN kits were made available from all hospital emergency departments in BC;
- As part of BC's broader response to the problem of drug misuse, Opioid Maintenance Therapy (OMT) is now covered by PharmaCare; BC's publicly-funded medication program;

¹⁸ BC Centre for Disease Control (2017) 'BC Take Home Naloxone Program', *Provincial Health Services*

Authority:

<http://towardtheheart.com/assets/uploads/1521426142Wdl7GEmGgOyEKaddaBywFzQysK9vj2zEtChhRL.pdf>

¹⁹ Toward the Heart (2017) 'The History of Take Home Naloxone in British Columbia':

<http://towardtheheart.com/assets/uploads/1498515378JnqUKldhS4FXyCAWviFs9tIMlrPw3x1hyJvNuXl.pdf>

- In 2016, BC Emergency Health Services changed their policy regarding police attendance suspected overdoses unless ongoing safety concerns are present;
- In 2016, the College of Physicians and Surgeons of BC altered their standards and guidelines for the safe prescribing of drugs to recommend physicians offer THN kits to all patients being prescribed opioids;
- In 2016, Health Canada — the body regulating therapeutic goods in Canada — changed the scheduling of naloxone to make it available from pharmacies without a prescription. The BC College of Pharmacists (the regulatory body for pharmaceutical medicines in BC) subsequently downgraded the status of ‘emergency naloxone’ to ‘unscheduled’. This means that no professional supervision is required for the purchase of naloxone; it is available to purchase from any vendor (petrol station, corner store, restaurant or bar) that chooses to stock it.
- At the beginning of the program, eligible sites were required to have a ‘prescriber’ on-site, though with the scheduling change (see above) this is no longer required;
- In 2016, BC’s correctional facilities were incorporated into the program: soon-to-be-released inmates who are at risk of overdose are trained in overdose prevention and receive a THN kit upon release;
- In 2017, the *Good Samaritan Act* was made law in Canada, meaning that anyone who calls emergency services to an overdose or who is at the scene of an overdose when emergency services arrive are immune for prosecution for possession of illicit substances;
- In 2017, the BC government committed \$322 million of funding over the next three years to the province’s THN program.

United Kingdom

In recent years, three of the four countries that make up the United Kingdom (UK) have implemented national naloxone distribution programs: Scotland, Wales and Northern Ireland. The UK has long had a drug-induced mortality rate higher than the European average. This currently sits at 60 per million population, nearly three times the European average of 21.²⁰

England is the only UK country without a national naloxone program. Naloxone is available by prescription and some Local Area Authorities run small naloxone distribution programs, however, availability, training and access vary significantly and access is neither coordinated nor reliable. While there have been several trials of naloxone distribution programs conducted in England, there is no indication that a national program is planned.

Scotland

Scotland has a very high rate of drug-related death; more than double the rest of the UK and possibly the highest in Europe.²¹ While rates of drug-related death have historically been higher in Scotland, they have seen marked increases in recent years. In 2015, the rate of drug-related deaths was 94 per million of population; it is now estimated to be 160 per million (which would make it the highest rate in Europe).²² In response to the increases in opioid-related overdose (and associated harms including death) a two-year pilot trialling naloxone distribution to opioid users was launched in Scotland in 2007.²³ In 2011, after a thorough evaluation of the pilot, the Scottish parliament approved the roll-out of a nation-wide program. This made Scotland the first country in the world to implement a naloxone distribution program at the national level.

As a national program, Scotland's National Naloxone Programme (NNP) provides key insights into what is involved in development and implementation of a large-scale naloxone distribution program and what preparatory work is required for such an undertaking.

Background

As stated, the rate of drug-related death in Scotland is exceptionally high at 160 per million in 2016.²⁴ It is estimated that Scotland has approximately 60,000 problem drug users, one third of whom receive Opioid Maintenance or Substitution Therapy (OMT/OST).²⁵ Data indicates that opioids were detected in 93% of drug-related deaths in Scotland in 2013, most of which were cases of overdose. In addition, opioid use and entry into a correctional facility have a significant correlation in

²⁰ EMCDDA (2017) 'United Kingdom: Country Drug Report 2017:

http://www.emcdda.europa.eu/countries/drug-reports/2017/united-kingdom/drug-harms_en

²¹ McAuley et al (2016) 'Engagement in a National Naloxone Programme among people who inject drugs', *Drug and Alcohol Dependence*, vol. 162: 236-40.

²² National Records of Scotland (2017) 'Drug-related deaths in Scotland in 2016', *National Statistics*: <https://www.nrscotland.gov.uk/files/statistics/drug-related-deaths/drd2016/16-drug-rel-deaths.pdf>

²³ McAuley et al (2016).

²⁴ National Records of Scotland (2016).

²⁵ McAuley et al (2016).

Scotland. One third of inmates tested positive to opioids upon entry²⁶ and half of those who die from opioid overdose have a history of incarceration.²⁷

The large population of drug users combined with the high prevalence of opioids in drug-related deaths made Scotland a prime environment for a national naloxone distribution program.

Pilot program

- Pilot targeted injectors and poly-drug users;
- Program had a strong emphasis on training ('train the trainers' model), which was offered to both clients and their friends/family;
- Pilot found a reduction in drug-related deaths among participants and that after training, clients were able to responsibly manage their naloxone supply and kit loss was rare.

In 2007, pilot naloxone distribution programs were launched in two Scottish districts; Lanarkshire and Greater Glasgow and Clyde (GGC). The rate of drug-related death in both districts were amongst the highest in Scotland at the time.²⁸ The population targeted by the pilot were those with a high risk of experiencing overdose (injecting and/or poly-drug use), though the pilots differed markedly in size. Where the Greater Glasgow and Clyde program recruited 300 participants, Lanarkshire recruited just 23. However, the trial in Lanarkshire employed a 'buddy system' whereby training was conducted with a participant and a close friend or family member, meaning the number of trainees was double the number of participants recruited.

The pilots adopted a 'train the trainers' model in which emergency medicine consultants trained local AOD workers in naloxone administration. This was then 'cascaded' to agency clients along with a THN kit. Naloxone is classified as a prescription-only medicine in Scotland, so a 'patient group direction' — a legal device that allows prescription-only medicines to be supplied without a prescription to the patient group — was utilised to address this restriction.

Evaluations of the pilot indicate that the rate of drug-related deaths decreased significantly for participants.²⁹ Encouragingly, the evaluation also found participants were able to responsibly manage their naloxone supply and kit loss was rare.

Following the first evaluation of the trial, the National Forum on Drug Related Deaths (an expert group commissioned by the Scottish government) recommended the pilot be extended across the country, while emphasising the need for continued evaluation.

National Naloxone Programme (NNP) structure

- THN available to people who use opioids, their friends and family from community outlets, correctional facilities and pharmacies; kits contain pre-loaded five-dose syringe;
- Distributors reimbursed £10 per kit distributed;
- Standardised training program implemented and supported by Naloxone Training Support Officers.

²⁶ McAuley et al (2016).

²⁷ McAuley et al (2012) 'From Evidence to policy: The Scottish national naloxone programme', *Drugs: education, prevention and policy*, vol. 19(4): 309-19.

²⁸ McAuley et al (2016).

²⁹ McAuley et al (2012).

Launched in April 2011, Scotland's National Naloxone Programme (NNP) provides overdose training and THN kits, to people who use opioids their friends and family. In addition, training and kits are also available to service workers who work with people at-risk of opioid overdose.

The Scottish government produced a nationally standardised training module for both workers and clients, including the creation of Naloxone Training Support Officer roles. The take-home kits available through the NNP contain a pre-loaded syringe containing the equivalent of five doses of naloxone, two needles, alcohol swabs and a patient information kit.

By January 2012, 13 of Scotland's 14 National Health Service (NHS) Boards — health administration bodies overseeing specific geographic districts — were participating in the NNP. All 14 Boards were participating by the end of 2012 and the NNP has undergone significant expansion since its inception.

Initially, the coordination of the NNP was centralised, though many aspects of its administration (such as funding) have since been devolved to district NHS Boards. The Information Services Division (ISD) was commissioned to monitor and analyse the program; the ISD releases evaluation reports annually.

The primary distribution points are community outlets (these are primarily specialist drug treatment centres but also include hostels, drop-in centres, needle and syringe exchanges, etc.) and correctional facilities (for at-risk inmates upon release). Distributors are reimbursed £10 per kit, covering the cost of the supplies. In 2015, a third avenue of access was added to the program, making THN available via community prescription. This made THN available from pharmacies free-of-charge upon receipt of a prescription (issued by a doctor, nurse, hospital pharmacy or on behalf of clients by a community organisation).

Key features

- Government funded national program; operating in all of Scotland's NHS Board areas;
- Rigorous data collection and monitoring; Scotland Information Services Division (ISD) commissioned to monitor program;
- Utilises a Patient Group Direction (see below) to override the prescription-only status of naloxone for program clients.

The Scottish National Naloxone Program has several features that distinguish it from other THN programs around the world, the first being that it is a national program.

Another notable feature is the level of data collection and monitoring. Many other Overdose Education and Naloxone Distribution (OEND) programs forgo rigorous data collection to decrease barriers of access. For example, while most programs track the number of kits distributed, few track whether these are a first supply or refill. Most programs collect some data using voluntary surveys, but the Scottish program mandates the collection of this information.

There are clearly benefits to each, as monitoring can pose significant barriers of access to vulnerable people wanting to access the program. On the other hand, the data collected allows for rich and nuanced analysis of the effectiveness and reach of the program.

Notably, the Scottish model has reduced other barriers to access. While naloxone remains a prescription-only medication in Scotland, several mechanisms have been implemented to overcome the barriers to access this creates. Namely, the availability of naloxone through community

prescription (obtainable through multiple sources) and the use of a Patient Group Direction (a mechanism allowing named services to dispense naloxone without a prescription).

Monitoring and evaluation

- Multiple evaluations, both commissioned and independent;
- Program 'reach' estimated as 345 kits per 1000 problem drug users;
- Access to naloxone has increased, though rates of participants carrying naloxone on their person has decreased;
- Overall effectiveness of program at reducing death estimated between 20 - 30%.

The rigorous collection of data from Scotland's NNP means that nuanced evaluation of the program is possible. By collecting data on who receives a kit and whether it is a first or repeat supply, the IDS can estimate the 'reach' of the program. This is calculated by isolating the number of 'first supply' kits (i.e. excluding refills and replacements) and comparing this number to the estimated number of problem drug users in Scotland. The latest estimate of reach is 345 new kits distributed per 1000 problem drug users. This latest reach estimate is the largest in the program's history.³⁰

This shows that while the program is well-administrated, operating effectively and expanding, there is still a considerable way to go in terms of coverage. In addition to the regular reporting by IDS, several independent evaluations of the NNP and the pilot programs have been conducted.

An evaluation by McAuley et al surveyed approximately 5,000 Scottish people who inject drugs (PWID) across two periods: the program's launch in 2011/12 and two years later in 2013/14.³¹ Results from the survey showed that the proportion of those surveyed that had been prescribed naloxone increased from 8% in 2011/12 to 32% in 2013/14. This indicates a significant increase in rates of accessing naloxone. However, the proportion of participants that actively carried naloxone decreased significantly from 16% in the first survey period to just 5% in the second.

Given the proportion of participants receiving naloxone from either a correctional setting or community outlet remained statistically consistent, this may indicate a decreased level of naloxone carriage. While the authors of the evaluation were reluctant to make a concrete conclusion, clearly increased access does not automatically result in increased carriage. Such detailed findings are only possible with robust and effective systems of monitoring and evaluation in place.

Another evaluation by Bird et al examined kits distributed to recently-exited inmates of correctional facilities. The study demonstrated that the THN provision was associated with a 36% reduction in the proportion of prison-release opioid deaths (within four weeks of release).³² For those recently exiting either prison or discharged from hospital, the NNP is associated with a 22% decrease in opioid-related deaths within four weeks of exit. Overall, Bird et al estimate the effectiveness of the NNP in reducing opioid-related deaths at 20% at the lowest confidence interval, and possible as high as 30%.

³⁰ Ibid.

³¹ McAuley et al (2016).

³² Bird et al (2015) 'Effectiveness of Scotland's National Naloxone Programme for reducing opioid-related deaths: a before (2006-10) versus after (2011-13) comparison', *Addiction*, vol. 111: 883-91.

The latest evaluative data show that a total of 37,609 naloxone kits were distributed from the beginning of the program in 2011 to the latest reporting period (November 2017).³³ 8,159 kits were distributed in the 2016/17 reporting period; 6,497 from community outlets, 700 in correctional facilities and 962 via community prescriptions. Of those kits distributed in 2016/17, 48% of them were repeat supplies (refills), a quarter (25%) of which were reported due to use of previous kit. 3,386 (or 41%) of 2016/17 kits were a first supply to an individual.

Conclusion

The Scottish model represents an instructive case study for the Australian setting. First, the benefits of implementing rigorous systems monitoring and data collection are clear. Second, the Scottish emphasis on training demonstrates the benefits of developing a nationally standardised training module. Third, the Scottish model provides important insights into what work is required for the development and implementation of a national program.

McAuley et al (2012) have detailed the journey ‘from evidence to policy’ in the Scottish case.³⁴ The authors identify three areas of work that were critical to the successful roll-out of Scotland’s national program:

- Gathering evidence (including evaluation of pilot programs);
- Strong advocacy from health, welfare, and drug and alcohol sectors, and;
- Legislative reform.

The authors note that the latter is particularly important, as this ensures that the development and implementation of the program takes place within an existing legislative framework designed to support it rather than requiring legislation to retroactively ‘catch up’.

³³ Ibid.

³⁴ McAuley et al (2012).

Wales

Like many countries, drug-related deaths in Wales have been steadily increasing in recent decades. In 1993, there were 33 drug-related deaths in Wales compared to 132 in 2009, with an 18% increase occurring between 2008/09.³⁵ There are an estimated 25,767 opioid users in Wales, and approximately 10,588 opioid injectors who are in contact with Welsh needle and syringe programs.³⁶

In 2009, Wales initiated a pilot THN as a demonstration project. Like Scotland, the rigorous monitoring and data collection allowed for highly detailed evaluations.

Demonstration project

- Pilot program implemented in selected drug treatment centres and needle and syringe programs;
- Evaluation showed 10% of kits distributed were used in response to an overdose;
- Participants were more likely to respond to an overdose, had better knowledge of appropriate responses and were more likely to access treatment.

Following on from Scotland, Wales implemented a national Take-Home Naloxone (THN) program in 2011. As in Scotland, the implementation of the national program was preceded by a pilot or demonstration project, initiated in 2009, to determine the effectiveness and feasibility of a national program. The demonstration project was approved as part of the Welsh Assembly Government's new strategy for tackling substance misuse 'Working Together to Reduce Harm'.³⁷

In the demonstration project, training in overdose recognition and response (including administering naloxone) was provided to opioid users, their friends and family. The training took place in a single session that lasted an hour and was conducted by staff at drug treatment centres and community service agencies. For a control group, the project also monitored the clients of similar services not participating in the trial. This allowed for comparative analysis of the effectiveness of overdose training including distribution of THN as a clinical intervention.

For those in the naloxone group, kits were provided upon completion of the training. Kits were only provided to people who used opioids (friends and family who completed the training but were not themselves opioid consumers did not receive a kit). Kits contained a single ampoule (one dose) of naloxone and two syringes, two needles and alcohol swabs. Over 600 clients (plus friends and family) were trained as part of the demonstration project.³⁸

An evaluation of the project commissioned by the Welsh Assembly Government found that 10% of kits were reported as being used to respond to an overdose.³⁹ Also reported was a variety of positive outcomes for participants in the naloxone group including increased knowledge and confidence,

³⁵ Bennet and Holloway (2011) 'Evaluation of the Take Home Naloxone Demonstration Project: Full Report', Welsh Assembly Government.

³⁶ Substance Misuse Programme (2017) 'Harm reduction Database Wales: Take Home naloxone 2016-17', *Public Health Wales*.

³⁷ Welsh Assembly Government (2008) 'Working Together to Reduce Harm 2008-18': [http://www2.nphs.wales.nhs.uk:8080/SubstanceMisuseDocs.nsf/\(\\$All\)/6361D5806F16EEDD80257C5B005AC8AF/\\$File/Working%20Together%20to%20Reduce%20Harm%20-%20SM%20Strategy%202008-2018.pdf?OpenElement](http://www2.nphs.wales.nhs.uk:8080/SubstanceMisuseDocs.nsf/($All)/6361D5806F16EEDD80257C5B005AC8AF/$File/Working%20Together%20to%20Reduce%20Harm%20-%20SM%20Strategy%202008-2018.pdf?OpenElement)

³⁸ Bennet and Holloway (2011).

³⁹ Ibid.

effective administration of naloxone in witnessed overdose events, and increased willingness to administer naloxone in the event of witnessing an overdose.

The naloxone group were also more likely to respond to an overdose appropriately, such as using the recovery position, administering CPR and calling an ambulance.⁴⁰ Members of the training group were also better able to distinguish between effective and ineffective responses to overdose (such as injecting the person with milk or salt water).

The evaluation also identified an increase in enrolment in addiction treatment in participants from the naloxone group. While this was not an identified aim of the program or the evaluation, it indicates additional benefits to the training components of THN programs

This result potentially indicates some additional benefits to THN programs. Participating in programs increases participants' contact with health organisations, enables conversations about drug use to be held and accurate information to be shared. This suggests naloxone distribution programs may have harm reduction functions beyond just reversing overdose.

After the evaluation of the demonstration project, the Welsh Assembly Government approved the full implementation of the THNP across Wales.

Take-Home Naloxone Programme structure

- National program; expanded to all Welsh NHS Board areas;
- Kits contained two pre-loaded syringes of naloxone (equivalent of 10 doses);
- Three of six correctional facilities currently participating; work to include five more underway.

The structure of the Welsh Take-Home Naloxone Programme (THNP) is very similar to that of the demonstration project, albeit expanded to all NHS Board regions in Wales. There are a few changes of note. First, kits now contain two pre-loaded, five-dose syringes. It is unusual amongst THN programs for a single kit to contain 10 standard doses, though due to concerns about fentanyl this was seen as prudent. The other significant change is that family or friends of an opioid user are now able to access free naloxone kits through the program.

Naloxone is available through the THNP via needle and syringe programs, detoxification centres, drug treatment services and community health services. Three of Wales' six prisons are currently participating in the THNP. Just as in Scotland, inmates at risk of opioid overdose are trained in overdose prevention and use of naloxone and are issued a kit upon their release. Since the last reporting period, work has been undertaken to establish naloxone distribution in the three remaining prisons in Wales in addition to two correctional facilities just over the Wales-England border that house several Welsh inmates.

In total, there are 54 naloxone access points operating in Wales. Information about clients who access naloxone is collected and is monitored and analysed by the Harm Reduction Database (HRD). As in Scotland, data collection is rigorous compared to other programs, including tracking the number of first supply and refill kits.

⁴⁰ Ibid.

Key outcomes

- 15,037 naloxone kits distributed since beginning of pilot program;
- 1,654 overdose events in which kit was used reported;
- In 80% of these, kit was used to administer naloxone to a third party.

Since the beginning of the demonstration project, 15,037 naloxone kits have been distributed through the THNP (data up to December 2017). Just over half of these (7,627) were distributed to new individuals, with the remainder (7,410) distributed as resupply for used, lost or expired kits.⁴¹ The number of kits supplied during 2016-17 was 4,487, representing a 40% increase on the previous year. Approximately 20% of kits distributed were distributed to friends, family members or carers of or professionals working with someone at risk of opioid poisoning.

Since the start of the demonstration project in 2009, 1,654 overdose events in which THN was used have been reported by participants.⁴² Fewer than 1% of these involved a fatality. Most administrations of naloxone occurred within a private residence, and in 80% of cases, naloxone was administered to a third party rather than the owner of the kit.

Prior to the THNP, naloxone could only be supplied by a medical doctor in Wales. While the THNP circumvented this, in 2015 the Welsh government enacted legislative changes meaning that naloxone can now be supplied by organisations providing drug treatment services, increasing the number of sites able to participate in the THNP.

A note on Good Samaritan laws in the UK

In 2015 the *Social Action, Responsibility and Heroism Act* was brought into law in England and Wales. This provides protection in cases of alleged negligence when the action causing injury was done attempting to assist to save someone's life. As the UK does not recognise a legal duty to assist, a person cannot be held liable for failing to assist.

The Act protects those whose alleged negligence or breach of duty occurs when the person is acting for the benefit of society or its members; where the person's actions demonstrate a predominantly responsible approach toward protecting the safety or interests of others; or when carried out in an act of heroism. It is unknown whether this Act has been utilised in a case of naloxone administration.

Scotland does not have a dedicated Good Samaritan law. As with the rest of the UK, there is no duty to act in Scotland and laws pertaining to negligence are the same as those in the UK.

Norway

According to the 2017 statistics from the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), approximately 13,977 people who use opioids were classed as high-risk in 2017. High-risk drug use in the Norwegian context has historically been linked to injecting drug use, predominantly heroin.⁴³

⁴¹ Substance Misuse Programme (2017).

⁴² Ibid.

⁴³ EMCDDA (2017) 'Norway – Country drug report', European Monitoring Centre for Drugs and Drug Addiction: http://www.emcdda.europa.eu/countries/drug-reports/2017/norway/drug-use_en.

Despite having a robust system in place for people who inject drugs, with 60% of people who use opioids in treatment (OMT), opioid overdose mortality has remained a major concern in Norway.⁴⁴ In 2014, Norway's rate of drug-induced mortality was amongst the highest in Europe (75.6 drug-related deaths per million adult inhabitants against a European average of 20.3).⁴⁵

Norwegian Drug Policy and the National Overdose Prevention Strategy

Norwegian drug policy has a strong harm reduction focus. This is based on five key health promotion and prevention principles:

1. Prevention and early intervention;
2. Coordination – services working together;
3. Greater competence and better quality of services;
4. Help for those with severe dependency – reducing the number of overdose fatalities;
5. Efforts aimed at next-of-kin and at reducing harm to third parties.⁴⁶

In 2014, responding to a high number of fatal opioid overdoses, the Norwegian Ministry of Health implemented a 5-year national overdose prevention strategy.⁴⁷ Working towards a 'Vision Zero' for overdose deaths, the main goal of this overdose strategy was to reduce the number of overdose fatalities by facilitating life-saving emergency medical aid following an overdose.⁴⁸

The overdose strategy identified six key areas of focus in the work towards this goal:

1. User/peer empowerment;
2. Reducing the number of overdoses, including non-fatal overdoses;
3. Reducing serious harm to health because of overdoses;
4. Improved follow-up after non-fatal overdoses;
5. Improved assessment of suicide risk and suicide prevention measures in the context of overdoses;
6. Improved public services to next of kin and close friends following the death of a loved-one from an overdose.

A key aim for the Norwegian strategy is empowering people at risk of overdose with skills to make life-saving actions. Acknowledging that a substantial proportion of overdoses are witnessed by others who use opioids, the overdose prevention strategy stressed the need to support people who use drugs by providing them with training in life-saving first aid (termed 'buddy rescue'), and ensuring access to naloxone.⁴⁹

Up until 2014, the ambulance service was the only service carrying and administering naloxone outside of supervised injecting facilities and emergency treatment. Naloxone is available in Norway

⁴⁴ Madah-Amiri et al (2017) 'Rapid widespread distribution of intranasal naloxone for overdose prevention', *Drug and Alcohol Dependence*, vol. 173: 17-23.

⁴⁵ EMCDDA (2017).

⁴⁶ EMCDDA (2012) 'Annual report to the European Monitoring Centre for Drugs and Drug Addiction – The drug situation in Norway', *The European Monitoring Centre for Drugs and Drug Addiction*: http://www.emcdda.europa.eu/system/files/publications/768/Norway_NR2012_443577.pdf.

⁴⁷ Norwegian Directorate of Health (2014) 'National overdose Strategy 2014-2017', Government of Norway: <https://helsedirektoratet.no/Lists/Publikasjoner/Attachments/145/National-overdose-strategy-2014-2017-IS-0418EN.pdf>.

⁴⁸ Ibid.

⁴⁹ Ibid.

from pharmacies, though is scheduled as a prescription-only medication. However, the Norwegian Medicines Agency has since issued a waiver to allow intra-nasal naloxone to be distributed without individual prescription.

Norway's Take-Home Naloxone program

According to the EMCDDA, there's been 5500 overdose deaths in Norway since 1977 and approximately 260 people dies of an overdose each year.⁵⁰ Most of these deaths are related to the consumption of illicit opioids (mainly heroin) in combination with benzodiazepines. In March 2014, the Ministry of Health and Care Services issued a recommendation for the implementation of a trial naloxone distribution project. The Norwegian Centre for Addiction Research (SERAF) at the University of Oslo was contracted to design and monitor the project and the pilot was rolled out in Norway's two largest cities, Oslo and Bergen, which account for approximately 40% of drug-induced deaths.⁵¹

The pilot, which is wholly funded and coordinated by the Norwegian Government, provides intra-nasal naloxone available free of charge at multiple community facilities across Oslo and Bergen.⁵²

The project utilised a "train-the-trainer model" which saw a total of 511 staff of low-threshold facilities — homeless shelters, drop-in centres, harm reduction centres and the safe injecting facility in Oslo —trained in overdose prevention and response. After receiving training, participating sites cascade the training to clients and distribute naloxone without requiring referral, prescription or payment.⁵³ Training was made available to all staff regardless of position or educational background. The program's primary goal was to facilitate rapid, widespread access to naloxone, particularly for high-risk groups outside formal drug treatment.

The decision to only distribute intra-nasal naloxone was made on the basis that it is more user-friendly than injectable formulations. However, at the time the program was initiated intra-nasal naloxone was not available in Norway. Norway began importing a pre-filled syringe formulation and commissioned local drug manufacturing company Den Norske Eterfabrikken to remove the label and needle and replace the latter with a nasal atomiser. The Norwegian government also commissioned the design and development of an intra-nasal device to be manufactured in Norway. However, the production of this new device has been delayed and the program is still using imported and adapted pre-loaded syringe units.

This device was then distributed to participating organisations by the Norwegian Centre for Addiction Research. The kits by the program included the pre-loaded syringe, nasal atomiser and a breathing mask, Instructions and pictorial information. While the unit is a prefilled syringe suitable for use in injections, no needles are provided in the kits.⁵⁴ The lack of a needle in the kit meant that there was no need for individuals to acquire a prescription for the medicine.

In the next stage of the pilot program, naloxone training sessions were made available to anyone interested, especially those who were likely to witness an overdose. All training was performed by

⁵⁰ EMCDDA (2017).

⁵¹ SERAF (2018) 'Take-Home Naloxone – Norway', *The Norwegian Centre for Addiction Research*: <http://stoppoverdoser.no/steder/>.

⁵² Madah-Amiri et al (2016) 'The use of public health infrastructure the best strategy for national and large-scale naloxone distribution programmes', *Addiction*, vol. 111(7): 1309-10.

⁵³ Ibid.

⁵⁴ Madah-Amiri et al (2017).

facility employees who had undertaken the initial training. The target population were high risk groups (injecting and poly drug). Other groups who were likely to witness an overdose, such as family support organisations, police, security staff were also trained in the use nasal naloxone. Clients were instructed to administer 0.4mg/0.4ml of naloxone in each nostril and give rescue breathes while awaiting response. Information on ongoing care, aftercare, side-effects including potential withdrawal symptoms and risk for future overdoses was provided.

Outcome of the pilot project

By using existing facilities for training and distribution points, the pilot project assured continuous access and widespread distribution of naloxone within a short time-frame. From July 2014 until December 2015, 2056 THN kits were distributed from approximately 20 participating facilities. Furthermore, four out of ten people who received naloxone came back for a refill kit and 277 successful overdose reversals were reported during that time. The widespread distribution of naloxone supports the feasibility of adopting take home naloxone programs as a mainstream public health intervention.

Nation-wide expansion and implementation

Between 2016 and 2017, the Norwegian take home naloxone program was rolled out in 11 additional cities. Since the expansion, more than 4000 intra-nasal naloxone spray devices have been distributed and there are now 73 key access points across the country.⁵⁵ Where the trial targeted at-risk opioid users outside of treatment, distribution has been expanded into formal treatment populations.⁵⁶

In 2017, the Norwegian Institute for Public Health (FHI) conducted a street-based survey, interviewing 495 high risk drug users in seven Norwegian cities. Data from the survey revealed that 51% of participants had received training in how to administer naloxone nasal spray. Moreover, 38% of participants were carrying naloxone nasal spray at the time of the interview. Almost half of the participants (n=211) reported to have used naloxone nasal spray while witnessing an overdose.⁵⁷ Findings from this survey further support the pilot projects success in assuring widespread distribution and uptake of intra-nasal naloxone in Norway.

Massachusetts

Deaths by opioid overdose have been steadily increasing in the US state of Massachusetts since the 1990s. Research conducted by the Massachusetts Government revealed several troubling trends:

- Those with a history of incarceration are 120 times more likely to die of an overdose than those without;
- People with a history of homelessness are 30 times more likely to die of an overdose and one in 25 adults in Massachusetts has experienced homelessness;
- People with mental illness were six times more likely to die of an overdose and one-in-four people aged 11 or over were identified as having a serious mental illness;

⁵⁵ SERAF (2018).

⁵⁶ Clausen (2017) 'Naloxone update: Norway', *European Monitoring Centre for Drugs and Drug Addiction*: <http://www.emcdda.europa.eu/system/files/attachments/6228/Naloxone%20update%202017%20in%20Norway%20-%20Thomas%20Clausen%2C%20Norway.pdf> en.

⁵⁷ Norsk Folkehelse Institutt (2017) 'Narkotikabruk paa gateplan I syv Norske byer 2017' Oslo, Norway <https://www.fhi.no/ml/rusmidler-og-avhengighet/narkotikabruk-pa-gateplan-i-syv-norske-byer-2017/>.

- More than a third of deaths among women giving birth between 2011-15 were opioid overdoses;
- 1.1 million people were prescribed opioids for an extended period (longer than three months).⁵⁸

In response to increasing mortality rates in the early 2000s, harm reduction activists began informally distributing naloxone to opioid users to circumvent longstanding government and bureaucratic resistance.⁵⁹ However, upon recording 660 opioid related mortalities in 2006 — the highest number in the state's history — the City of Boston's Health Department approved a trial THN program. Operating out of two established NSPs, the trial trained potential overdose witnesses in overdose education including naloxone administration. Upon completion, participants were dispensed a kit containing two pre-filled, 2mg/2ml syringes and two nasal atomiser adaptors.⁶⁰

In 2007, following an evaluation of the Boston trial, the program was unanimously approved and extended to additional sites in Boston and the nearby district of Cambridge. To address concerns regarding legal liability, the City of Boston classified all staff at organisations offering THN as 'special employees' of the city, assuming legal liability for all actions taken by staff in the administration of naloxone.

Aware of these developments, in 2007 the Massachusetts Department of Public Health (MDPH) established a strategic plan to address increasing rates of overdose deaths in the state. This included expanded access to Opioid Maintenance Therapy (OMT), adding an additional four sites to the Boston/Cambridge THN program, and the state's medical director issuing a standing order allowing non-medical staff to distribute naloxone.

At the beginning of the program, provision of THN was restricted to agencies that had pre-existing contracts with the Office of HIV/AIDS and the Bureau of Substance Addiction Services (BSAS) to provide needle exchange services. By 2011, eight agencies were providing THN (in addition to partner agencies) across 12 communities as well as one state-wide organisation that worked with substance abuse treatment programs to provide THN.

Massachusetts' Overdose Education and Naloxone Distribution (OEND) program

The Massachusetts OEND program provides overdose training and naloxone from NSPs, HIV education centres, drop-in centres, addiction treatment programs, emergency and primary healthcare settings, community health organisations and support groups for opioid users (such as Narcotics Anonymous), their friends and family.

In addition to the OEND program, Massachusetts implemented several other reforms to increase access to naloxone outside of the program. This included several changes to state prescribing laws, such as:

- Allowing nurses, pharmacists and physician's assistants to prescribe naloxone;

⁵⁸ Massachusetts Department of Public Health (2017) 'Data Brief: An Assessment of Opioid-related Overdoses in Massachusetts 2011-2015': <https://www.mass.gov/files/documents/2017/08/31/data-brief-chapter-55-aug-2017.pdf>.

⁵⁹ Walley et al (2013) 'Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis', *BMJ*: 364.

⁶⁰ Harm Reduction Coalition, 'Massachusetts OEND': <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/naloxone-program-case-studies/massachusetts-oend/>.

- Issuing a standing order allowing approved pharmacies to provide naloxone without a prescription;
- Approving overdose education and naloxone administration programs to help ensure training quality among agency staff.

Outside of Massachusetts' program, naloxone can be accessed from a pharmacy over-the-counter or via prescription. Currently, and in contrast to Australia, it is cheaper to access naloxone without a prescription, so long as the person attends a pharmacy with a standing order from the Government of Massachusetts to provide naloxone free of charge (updated list [is at https://www.mass.gov/files/documents/2017/01/sw/pharmacies-so-naloxone.pdf](https://www.mass.gov/files/documents/2017/01/sw/pharmacies-so-naloxone.pdf)). Massachusetts state insurance program MassHealth covers the cost of naloxone dispensed via standing order.

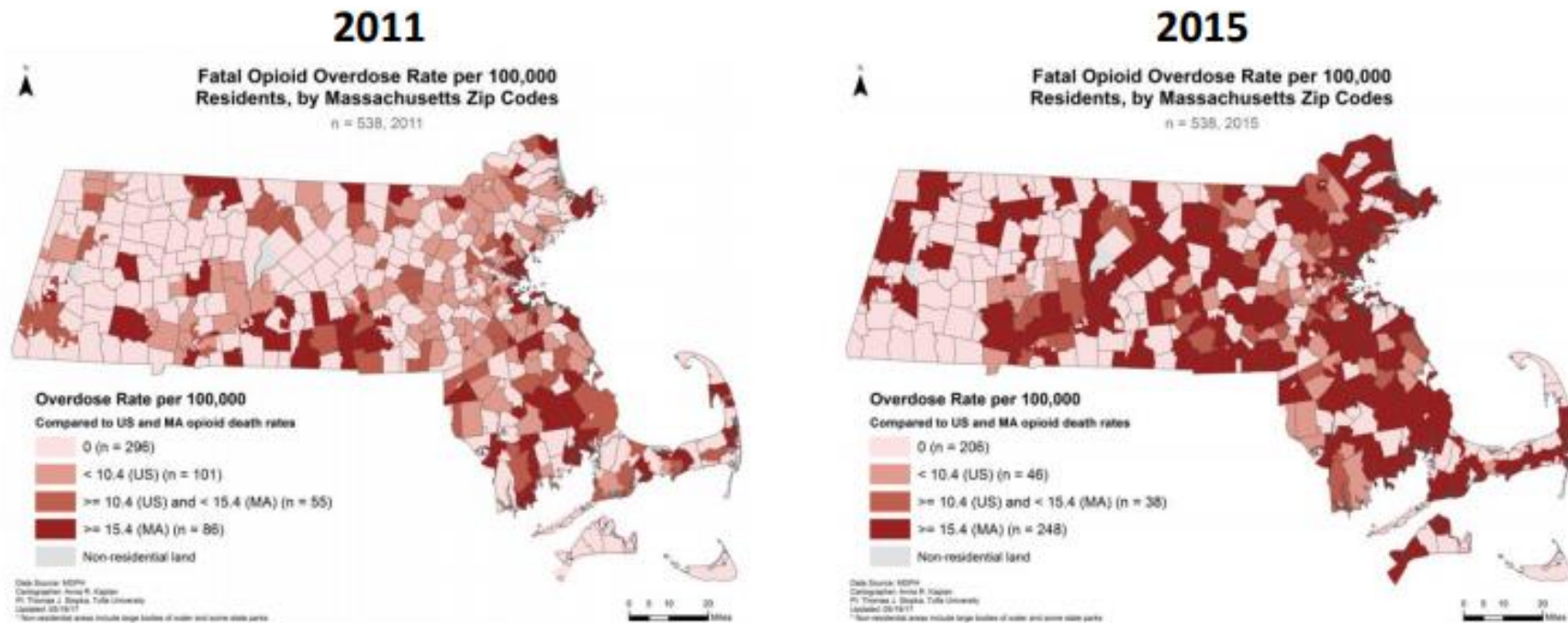
The Massachusetts program has some interesting features. First, it is relatively small for a state-wide program (compared to those in BC and Ontario). However, it has been supplemented by other reforms, such as the state-wide standing orders allowing pharmacies to issue naloxone without a prescription, and by expanding the professions able to issue a naloxone prescription.

In addition, local municipal bodies and state entities (i.e. police or fire departments) can purchase naloxone in bulk through the State Office of Pharmacy Services at a subsidised cost negotiated between MDPH and the pharmaceutical wholesaler.

While Massachusetts is a relatively early adopter of community naloxone distribution, the continued growth in fatal overdose demonstrates that such programs are not a panacea to the problem of overdose. The most recent data indicates that the annual overdose mortality rate had risen to over 2,107 in 2016.

The graph below demonstrates the increase in fatal overdose from 2011 to 2016:

Increasing and Spreading Opioid-Related Overdose Death Rates in Massachusetts from 2011 to 2015¹



Source: Massachusetts Department of Public Health, 'Data brief: An assessment of opioid related overdose in Massachusetts in 2011-2015', Commonwealth of Massachusetts.

Key features of Massachusetts Take-Home Naloxone program

- State-funded;
- Supported by state health insurance program (MassHealth);
- Intra-nasal naloxone only;
- Operating from community outlets (NSPs, HIV organisations, homeless shelters, drop-in centres, outreach and addiction support groups), emergency departments, detoxification centres, drug treatment programs and primary healthcare providers;
- Kits contain two pre-filled 2mg/2ml syringes and two mucosal atomisers for intra-nasal administration;
- Participants are enrolled anonymously using an easy to remember identification code;

Part Two – The Australian Context

This section of the report outlines details of the Australian context, including patterns of opioid use in Australia, the current means of accessing naloxone in Australia, current efforts at THN distribution, and Australia's national drug strategy and other relevant governmental frameworks. This section also includes the results from three focus groups that Penington Institute held in the course of researching this report.

Opioid use and overdose in Australia

Opioids have a long history in Australia; both of use and attempts at regulation. Australia's efforts to control opioid use mirror those of other Western countries: focusing heavily on supply reduction and being limited in their effectiveness.

Prior to a sharp drop in heroin availability in the early 2000s, rates of heroin consumption and related harms (including death) were very high in Australia.⁶¹ The number of drug-induced deaths peaked in 1999 at 1,740.⁶² While the mortality rate dropped considerably after that (colloquially referred to as a 'heroin drought'), the number of overdose deaths involving opioids has risen again since then. In 2016, the number of drug-related fatalities in Australia exceeded the 1999 peak with 1,808 drug-induced deaths recorded that year. The majority of these were attributed to opioid overdose.⁶³

What has changed significantly since the 1990s is the number of opioid overdose deaths caused by pharmaceutical opioids as opposed to heroin. In the 1990s, fatal opioid overdoses were predominantly caused by heroin, albeit often in combination with other drugs such as alcohol and benzodiazepines (termed 'poly-drug use').⁶⁴ While poly-drug use is still the norm, pharmaceutical opioids such as oxycodone, codeine, methadone and fentanyl now account for approximately 70% of fatal opioid overdoses. This increase in the role of pharmaceutical opioids in overdose deaths is

⁶¹ Degenhardt, et al (2006) 'The "lessons" of the Australian "heroin shortage"', *Substance Abuse Treatment, Prevention, and Policy*, vol. 1(11): 1-7.

⁶² ABS (2017).

⁶³ Ibid.

⁶⁴ Ibid.

mirrored in international trends.⁶⁵ This trend is matched by increases in the prescribing of opioids. In Australia, prescriptions for opioids have risen from 10 million per year in 2009 to 14 million today.⁶⁶

This contrasts starkly against the stereotypes that proliferate about substance misuse and overdose. These phenomena are strongly associated with people who inject drugs (PWID), a group both highly stigmatized and marginal. A common misconception about overdose is that only those who use illicit drugs like heroin are vulnerable to it. Other factors that contribute to this are the belief that prescription medicines are not dangerous and that people who misuse prescription medications often minimize their dependence or may not be aware of it.

These trends are not isolated to Australia: other parts of the world, particularly Europe and North America, are seeing significant increases in their rates of overdose (and associated harms). In 2017, the US recorded more than 72,000 fatal overdoses.⁶⁷ While the Australian experience has not been as severe as this, preliminary data from 2016 indicate that Australia's drug-induced mortality rate continues to rise.⁶⁸ Demonstrably, Australia requires effective ways of responding to rising rates of opioid use as well as ways of reducing the immediate harms of overdose. Getting naloxone into the hands of those at-risk of or likely to witness an overdose is a crucial means of reducing those harms.

While a program distributing THN to key populations will go some way to achieving this, many people misusing pharmaceutical opioids access those opioids via a prescription obtained from their doctor. This interaction is an important opportunity for engaging patients about the risks opioids carry including overdose and what patients can do to mitigate these risks including being prescribed naloxone.

Opioids – illicit, prescription or diverted?

Where the illicit opioid heroin once accounted for most overdose deaths in Australia, it now represents approximately 30%. Heroin remains a significant contributor to drug-related mortality and it is essential that people who use heroin have access to THN. In countries like Scotland and Wales where heroin remains the main cause of overdoses, THN provision has focused heavily on services accessed by PWID such as NSPs and OMT providers. However, pharmaceutical opioids account for 70% of opioid overdose deaths in Australia, and the model must be tailored to suit this environment.

Use of pharmaceutical opioids can be broken down into two primary categories: prescription and diverted. The former involves a person using medications that have been prescribed to them, while the latter involves pharmaceutical opioids that have been diverted from their intended medical use. While toxicology can differentiate between illicit and pharmaceutical opioids, it cannot distinguish prescription from diverted opioids. However, research has shown that increases in the rate of fatal opioid overdose correlate to increases in opioid prescribing, indicating that the rate of deaths involving pharmaceutical opioids (whether prescription or diverted) is determined primarily by the

⁶⁵ Rudd et al (2016) 'Increases in drug and opioid overdose deaths – United States, 2000–2014', *Morbidity and Mortality Weekly Report*, Centre for Disease Control.

⁶⁶ TGA (2018) 'Prescription strong (Schedule 8) opioids use and misuse in Australia – Options for a regulatory response – Consultation paper', Therapeutic Goods Administration, Department of Health, Government of Australia.

⁶⁷ National Institute on Drug Abuse (2018) 'Overdose death rates', *Centers for Disease Control and Prevention*: <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>

⁶⁸ Pennington Institute (2018) 'Australia's Annual Overdose Report 2018', Pennington Institute.

rate of opioid prescription.⁶⁹ This suggests that the most effective way to reduce deaths involving pharmaceutical opioids is to curb the rate at which they are prescribed.

While evidence suggests that there is a level of mixed use — where people are using both prescription and illicit opioids—and there are many shared risk factors (e.g. concurrent use of CNS depressants such as alcohol or benzodiazepines), the needs of people misusing prescription opioids are different to PWID.⁷⁰ For example, people dependent on prescribed opioids may not engage with services like NSPs and may also be unaware of overdose and risk factors that contribute to this.

This highlights the importance of routine screening for risk-factors and the provision of non-judgmental care to all people who may be at risk of an opioid overdose. Australia has a significant population of people who use opioids in a variety of contexts and for a variety of reasons. Both the program itself and the promotion and awareness raising activities must be tailored to address the specific needs of these divergent populations (as well as the cross-over that occurs between them).

Risk-factors for opioid overdose

Not everyone who uses opioids requires Take-Home Naloxone. For example, someone occasionally taking low-dose codeine for headaches is not at sufficient risk of overdose to justify receiving THN.⁷¹ Those most at-risk of overdose are people who use or inject drugs (PWUD or PWID) and those prescribed high doses of opioids.⁷² Risk of overdose among PWID/PWUD increases significantly following a recent period of abstinence or a recent overdose. In fact, an overdose in the last 12 months is the single most reliable predictor of overdose risk.⁷³

Given the higher risk amongst PWID, it is troubling that this cohort is not well serviced by current means of accessing naloxone. The cost of over-the-counter naloxone in Australia is prohibitive and while obtaining naloxone via prescription is much cheaper, the process of getting prescription can be onerous for this group. Programs distributing THN elsewhere have all included mechanisms to target this population specifically.

For those using prescribed opioids, risk of overdose increases for those on high doses (>90 MME per day) or who are using opioids long-term (longer than 3 months). Research among chronic non-cancer pain patients showed that risk of overdose doubles for those receiving 50 MME per day compared to 20MME or less, and for those receiving 100 MME per day or greater, overdose risk was 9.5 times higher.⁷⁴

Other risk factors for opioid overdose are being unaware of signs and symptoms of overdose, underestimating risk, and taking concurrent Central Nervous System (CNS) depressant medications

⁶⁹ Roxburgh et al (2017) 'Trends in heroin and pharmaceutical opioid overdose deaths in Australia' *Drug and Alcohol Dependence*, vol. 179: 291-8.

⁷⁰ ABS (2017) 'Drug Induced Deaths in Australia: A changing story', *Australian Bureau of Statistics*: <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/3303.0~2016~Main%20Features~Drug%20Induced%20Deaths%20in%20Australia~6>.

⁷¹ Low-dose codeine products have recently been rescheduled in Australia from S3 to S4, meaning they are now only available with a prescription.

⁷² Opioid doses are measured in Morphine Milligram Equivalents (MMEs). In 2016, the US Centre for Disease Control recommended that doctors should avoid prescribing opioids at levels that exceed 90 MMEs per day, or justify why such a high dose is necessary. See TGA (2018).

⁷³ Cauderella et al (2016) 'Non-fatal overdose as a risk factor for subsequent fatal overdose among people who inject drugs', *Drug and Alcohol Dependence*, vol. 164(1): 51-5.

⁷⁴ Dunn et al (2010) 'Overdose and prescribed opioids: Associations among chronic non-cancer pain patients', *Annals of Internal Medicine*, vol. 152(2): 85-92.

(such as benzodiazepines) or alcohol. Additional risk-factors include comorbidities such as poor mental health, histories of substance misuse, physical ailments and chronic pain.⁷⁵

Those with a history of opioid use who are incarcerated also experience significantly increased risk of opioid overdose upon exiting incarceration.⁷⁶

Real-time prescription monitoring

Real-time prescription monitoring (RTPM) is a system designed to track prescriptions as they are issued. The main purpose of RTPM is to prevent the practice of ‘doctor-shopping’ – the practice of visiting multiple doctors to obtain prescriptions for a particular medicine from each (usually for drugs to which people may become addicted, such as sedatives or analgesics). There have been multiple coronial inquests that have called for the introduction of a national real-time prescription monitoring system in Australia to address this practice.

At the time of writing, a national RTPM is not likely to be implemented soon. However, MyHealthRecord — a national online digital health record — will make tracking the medicines an individual is prescribed easier. Currently, Tasmania is the only state with a RTPM system in place, though the Victorian government intends to begin implementation of an RTPM system in 2018. While RTPM may address the practice of attending multiple doctors to receive multiple prescriptions for the same medication (colloquially referred to as ‘doctor-shopping’), it should be noted that this is a practice engaged in by a minority of people. Findings from the Victorian Coroners Court show that in overdose deaths involving pharmaceutical drugs, seven out of 10 had only attended one General Practitioner.⁷⁷

Further, international evaluations of the effects of RTPMs on rates of overdose show mixed results.⁷⁸ Clearly, what is needed is systemic reform of the means through which opioids are accessed as well as increased investment in treatment and support.

Focus groups

Penington institute conducted three focus groups for this report. These were designed to draw upon the expertise of various groups of people living or working in the opioid use space. Each focus group was conducted with a specific population: AOD workers (primarily staff from NSPs); NSP clients; and staff from an AOD treatment service specializing in misuse of prescription medications.

While the questions asked were tailored to each group, all participants were invited to discuss naloxone, its benefits, who they thought needed it and what they considered the most effective means of distribution. The staff were asked about their own perspectives and invited to comment on the perspectives and experiences of the clients they worked with.

⁷⁵ Park et al (2016) ‘Understanding risk factors for opioid overdose in clinical populations to inform treatment and policy’, *Journal of Addiction Medicine*, vol. 10(6): 369-81.

⁷⁶ Merrall et al (2010) ‘Meta-analysis of drug-related deaths soon after release from prison’, *Addiction*, vol. 105(9): 1545-54.

⁷⁷ ABC News (2017) ‘Opioid prescription crisis: Everyday Aussies, not ‘doctor shoppers’, at heart of crisis, experts say’: <http://www.abc.net.au/news/2017-11-21/doctor-shoppers-not-at-heart-of-prescription-opioid-crisis/9167606>

⁷⁸ Finley et al (2017) ‘Evaluating the impact of a prescription drug monitoring program implementation: a scoping review’, *BMC Health Services Research*, vol. 17: 420.

The focus groups were held to include the perspectives of those most affected by the changes proposed in this model: people at-risk of opioid overdose and those who work with them. We chose to conduct a focus group with staff from the service specializing in misuse of prescription medicines as we assumed clients of this service would be unwilling to discuss these issues with us in a group setting. This assumption was confirmed by staff at this service who cited a powerful reluctance amongst their clients to discuss overdose generally, as well as high levels of concern about their privacy.

Common themes emerging from all groups included support for a national program, the necessity of the program providing naloxone free to consumers, the need for increased public awareness about overdose, and the need for the program to engage, prioritize and utilize peers.

Staff

The focus groups held with staff shared many common themes, though diverged on a few key issues. The staff from NSPs and agencies servicing PWID reported high levels of familiarity with the term naloxone, though the degree of accurate knowledge varied considerably. Interestingly, the brand name 'Narcan' was consistently the most familiar among clients, though understanding that naloxone was the active ingredient of Narcan was significantly lower. This finding was replicated in the client focus group. However, staff from the service specializing in the misuse of prescription medicines reported very low levels of awareness among their clients:

Low, very low. And most people don't seem to understand what it is if you say naloxone or Narcan. They might have heard the word "Narcan" but generally they don't know what that is. And understanding that it [naloxone] is available is, it's just unheard of.

This was understood as being the case for several reasons: the association of overdose with people who inject drugs; a lack of awareness about overdose, particularly risk factors; an inability to recognize the signs of overdose; and a tendency to minimize their patterns of opioid use and risk.

If they're using medications, there's no connection of it [overdose] being a real risk for them. A lot of them don't even know they've overdosed, they just wake up.

However, while low awareness or mixed levels of understanding were cited, the biggest barrier cited by all staff (and many people who use drugs) was low levels of awareness about naloxone amongst doctors coupled with an unwillingness to prescribe it. Both AOD and NSP staff reported difficulty in locating general practitioners (GPs) willing to prescribe naloxone. One AOD service staff member had recently called a GP on behalf of her client to get naloxone prescribed and was refused. Another spoke of the disappointment about naloxone remaining inaccessible despite changes increasing its availability as a take-home medicine:

About two years ago people got really excited about naloxone and certainly, as workers, we were excited about talking to people about it. And then we just found it so hard to access. No GPs would prescribe it. I had encouraged a few clients to get a prescription for it and being refused was a terrible experience for them. Really stigmatising.

Another issue regularly raised was the need for increased social salience of overdose as a public health issue. This was expressed as support for a public awareness campaign focusing on information about naloxone and how it can be accessed.

Staff anticipated numerous barriers to getting naloxone into the hands of people that needed it. One was accessibility in rural areas, where many people struggle to access safer injecting equipment and healthcare generally. Regulatory barriers, engagement of those misusing prescription or diverted opioids, and engaging hard-to-reach groups such as CALD and ATSI people were other anticipated barriers. As one staff member said:

The translation of information into other languages is a no-brainer but has it happened? I know it's not just a matter of straight translation, it's about making the information and the services culturally appropriate and accessible too, but it just has to happen.

We asked staff participants to name three things essential to an Australian THN program. The most common answers were:

- Naloxone must be free;
- Increased public awareness as well as targeted information for priority populations;
- Removing doctors as the sole gate-keepers for naloxone access.

Clients

Clients from the NSP were quite familiar with the term naloxone and highly familiar with the term 'Narcan'. However, levels of understanding about what these were and what they did were mixed. Upon hearing the word 'naloxone', several clients assumed we were talking about Suboxone, a combination of buprenorphine and naloxone used in opioid maintenance therapy (OMT). It was only after we said 'Narcan' that he understood what was being discussed:

P1: When we think of Narcan, we obviously think of bringing someone out when they've dropped but when we think of naloxone, we think of an ingredient in Suboxone. That's what a lot of boys in jail think.

P2: But Narcan, that's like Pulp Fiction.

One client had a strong understanding of naloxone because he had done the training, and carried the kit on him at all times. He had twice used it to revive peers, and once a peer had used it to revive him. After that, he had ceased using heroin, though still carried the kit with him:

No one drops on my watch. I don't care if it kills your high, no more of my mates are dying with me around.

Several participants who had not completed the training expressed anxiety about having to respond to an overdose, though said training would help them feel more confident:

P1: I don't know, I've never done it, I'd have a heart attack if someone dropped in front of me. I'd flip out I reckon.

I: Do you think training would help with that?

P1: Oh yeah, exactly. You wouldn't want to drop in front of me coz you'd be screwed, but if I'd been trained I'd be better but right now, I got no idea what to do.

Clients also confirmed reports of reluctance among doctors to prescribe naloxone, with several having been refused, even after explaining they had been trained in naloxone administration. They

also emphasized the importance of accessibility and were wary of a one-size-fits-all model or of the training only being held at inconvenient times or locations:

It's [the training] only 10 minutes but when you're in the game, especially if you're coming in crook, ten minutes is ten minutes. I know that if I'm rough, I don't feel like kicking around for 10 minutes. I want to get my pack and get on.

Instead, they suggested tailoring the program to local contexts:

If I'm coming here [the NSP] I want to get on, so I don't know if I'd want to do the training then. But I go to breakfasts they put on up at [local community centre] where I hang around for a couple of hours. I'd definitely do it there.

One participant, who had received naloxone several times, cited the importance of consistency of kit contents. The first time he had done the training he received pre-loaded single-dose syringes (minijets), the second time ampoules and most recently, a pre-loaded five-dose syringe. This made feeling confident about the training he had received difficult.

That's no good, you know? I've been trained with one, and then next time I get something else. That spins me out a bit.

Several participants who were recently released from correctional facilities said they wished to see naloxone training be available in custodial facilities:

P1: I heard some of this stuff years ago, but I been back in jail, just got out three weeks ago, not even. So, I don't know nothing now. They need to run it in the joint so people can be updated.

P2: Yeah, I got out two weeks ago. It needs to be part of pre-release.

When asked how they had heard about naloxone and where they received their information from, all participants said peers. One participant, who had never heard of naloxone before that day, said she had found out about naloxone from the participant who always carried his kit with him.

He told me about it. I wouldn't do it otherwise, but I know [participant's name] and trust him, so I know it's worth doing if he says so.

Several participants reported anxiety or wariness about carrying and administering naloxone, and all reported stories of people failing to respond to overdose:

There's other things [contributing to wariness about naloxone] too, you know. When a mate of mine dropped he was with two blokes on parole and they did the bolt. They took off and left the front door open. Did the bolt because they didn't want to get in any shit.

Even though the group considered leaving the scene of an overdose a bad thing, they also sympathised with people wanting to avoid being implicated in another person's overdose. When asked what it would take to get people to stay at the scene of an overdose and respond, the group answered that it was about empowerment and encouraging people to take responsibility:

I: What is going to be the thing that gets you into training, that gets you in the program, on board carrying naloxone and willing to use it?

P1: Just finding out how easy it is and, you know, being told that you can do this, that you can save someone's life.

P2: You'd get a lot of brownie points for bringing someone 'round.

P3: Not just that, you can be proud of yourself too, proud that you were brave enough to stick around.

P1: Yeah. That'd be an amazing feeling; they'd be dead otherwise.

Another echoed this, saying it was important how naloxone was framed and what was emphasised in the training:

That's it, they need to tell people they can be a hero, a real fuckin' gun. I've never been told I can do anything, so being told I can save my mate's or my partner's life, I mean, who wouldn't want to?

Demonstrably, how the training and THN is framed will have a significant effect on how and whether it is accessed. Emphasising empowerment and responsibility may help encourage people in at-risk populations to participate in a THN program and to bring about a broader shift in how people understand overdose: as something that can and should be responded to, and as something they are empowered to respond to. Generating an ethic of care about overdose will be an important part of the program's success.

When asked what the three essential components of a national THN program were, the most common answers from the NSP clients were:

- Naloxone being free;
- The program being flexible and accommodating of their needs and preferences;
- Increased awareness and the provision of accurate and non-stigmatising information through channels that are accessible to them (bus stops, advertising in NSPs and peers-led knowledge transfer).

The focus groups revealed widespread support for making THN more available in Australia. However, several barriers to achieving this were also highlighted, including difficulty engaging hard-to-reach populations, getting doctors — and GPs in particular — to prescribe, and difficulty accessing naloxone in rural areas.

Naloxone in Australia

Naloxone has been used in Australia in emergency settings for decades. While naloxone has technically been available by prescription for several decades, this has been rare and it has remained highly inaccessible. In 2013, a structured program for prescribing naloxone was introduced, however, many access barriers remain. In 2016, naloxone was rescheduled to Schedule 3 (S3) making it available from a pharmacist ('over-the-counter') *as well as* via prescription. Despite easing restrictions on access, several barriers remain meaning naloxone is not readily accessed by those who need it.

To address this lack of accessing, naloxone distribution programs need to address several barriers of access that currently exist.

Lack of demand for naloxone

As yet, there has been no large-scale awareness campaign targeting people at-risk or potential witnesses of overdose. As the focus groups demonstrated, knowledge of naloxone amongst at-risk populations is mixed.⁷⁹ Limited knowledge of naloxone constitutes a significant barrier to generating demand for it, which consequently determines the level of uptake. This, along with several other factors such as limited opportunities to access naloxone and people underestimating the risks of overdose, constitute an ongoing barrier to widespread adoption and uptake of naloxone as a take home medicine.

Addressing the gaps in awareness and knowledge of naloxone across risk groups is a necessary step to drive up demand for naloxone among priority populations. Making naloxone readily available is essential; ensuring the target population to obtain and carry it understand its importance is crucial for a successful Australian THN program. As such, Penington Institute makes recommendations for awareness raising activities (see Part Three of report).

Scheduling

As with any other medicine, there are a range of restrictions and standards relating to access, distribution and storage attached to naloxone. A medicine's 'scheduling' determines the regulatory conditions attached to it, such as who is authorised to sell it. Scheduling is determined by a country's regulatory body for medicines and therapeutic goods (the Therapeutic Goods Administration or TGA in Australia). Such bodies consider a range of factors, such as demand, cost and risks associated with the medicine (such as the potential for iatrogenic dependence) when deciding its scheduling classification.

The most relevant scheduling classifications for naloxone in Australia are Schedules 2 to 4. Schedule 1 is not currently in use in Australia; if a medicine is available from supermarkets or convenience stores it is very low risk and classified as 'unscheduled'. Schedule 2 medicines are only available from pharmacies but do not require a medical diagnosis or pharmacist advice to access. Schedule 3 medications are 'pharmacist-only' and require professional advice from a pharmacist to access — Schedule 3 is also known as 'over-the-counter' or OTC. Schedule 4 is prescription-only; these medicines are only accessible from a pharmacist via prescription.

Naloxone is a Schedule 3 medicine in Australia, though it can also be prescribed under the Pharmaceutical Benefits Scheme (PBS) to enable supply. Purchasing naloxone 'over-the-counter' from a pharmacy incurs a considerable cost (this varies but is generally estimated between \$50-\$80). With a prescription, this cost is reduced to a flat rate of \$39.50, and for those with a health concession, further to \$6.40. While \$6.40 may not seem like much, for many people who misuse substances it is a substantial enough barrier to make the difference between accessing and not accessing. In addition, accessing naloxone at this reduced cost involves having a health concession, attending a doctor, getting a prescription (which the GP may refuse to issue), and then attending a pharmacy and spending limited resources: an onerous process that constitutes a significant barrier for many people who would benefit from having naloxone.

A Schedule 3 classification also comes with a range of regulatory requirements beyond where it can be sold from, such as labelling and storage requirements. Each state and territory has its own set of

⁷⁹ See also Kerr et al (2008) 'Attitudes of Australian heroin users to peer distribution of naloxone for heroin overdose: Perspectives on intranasal administration', *Journal of Urban Health*, vol. 85(3): 352-60.

regulations for Schedule 3 medications. While these regulations are unlikely to pose a challenge for pharmacies or emergency departments, other distribution points such as secondary NSPs and community health centres will not meet current Schedule 3 requirements, and so will require state governments to issue exemptions in the form of clinical protocols as has been done in NSW for the ORTHN project (see below).

Naloxone distribution programs in Australia

There are several naloxone access programs currently operating in Australia, all of which target people who have a history of using or injecting drugs. These are relatively small in scale, though several have undergone significant expansion. There are also highly motivated practitioners who have established coordinated arrangements in their organisations and local communities, however, these arrangements are small and highly bespoke. The following is a summary of the main programs and efforts relating to naloxone provision in Australia.

Australian Capital Territory

The Implementing Expanded Naloxone Access in the ACT (I-ENAACT) program in the Australian Capital Territory (ACT) is Australia's first THN program.⁸⁰ I-ENAACT was initiated in 2012 by the Canberra Alliance for Harm Minimisation and Advocacy (CAHMA) and the Alcohol and Tobacco and Other Drug Association ACT (ATODA). The program offered one-hour training sessions for small groups delivered by peers to participants who had a history of opioids use. The initial program operated for two and a half years from 2012 to 2014 and trained over 200 participants in comprehensive overdose management. Participants accessed naloxone via prescriptions supplied by local GPs and a local pharmacy supplied the naloxone. Participants included 18 inmates of Canberra's prison.

57 overdose reversals were recorded using naloxone issued by the program. All reversals were successful and no adverse events were recorded.⁸¹ In 2016, the ACT government announced recurrent funding to continue the program. This included an expansion of the program to include opportunistic brief interventions (BIs) with naloxone prescribed over-the-counter without the need for a prescription. From implementation until June 2017, the CAHMA program delivered training to 500 individuals.

New South Wales

The Overdose Prevention and Emergency Naloxone (OPEN) project was initiated in New South Wales (NSW) in 2012 by the Kirketon Road Centre and the Langton Centre, two health facilities within the South Eastern Sydney Local Health District. The OPEN project was the first naloxone distribution program in Australia to be hosted by clinical services, delivering overdose education and naloxone training in small workshops. The program had poor uptake and ended in 2014, having only distributed 86 THN kits. The training model was reworked to focus on one-on-one brief interventions (BI) and the project relaunched under the name Overdose Response & Take Home Naloxone

⁸⁰ Dwyer et al (2018) 'An overview of take-home naloxone programs in Australia', *Drug and Alcohol review*, vol. 37: 440-9.

⁸¹ Ibid.

(ORTHN) project. In total, over 1000 people have been trained and received Take-Home Naloxone in NSW and 185 overdoses have been reversed as part of the OPEN/ORTHN projects.⁸²

In 2015 the Medically Supervised Injecting Centre MSIC in Sydney, nursing staff began dispensing THN to clients free of charge under a special protocol issued by the Pharmaceutical Services Branch of the NSW Ministry for Health, which was, at the time, the only such authority in Australia. The MSIC's naloxone program has since been incorporated into the ORTHN project, and now operates under its clinical protocol.

In 2016 the program was awarded a grant to fund the expansion of the program to AOD services, primary NSPs and peer outreach services across NSW.⁸³

Western Australia

Since 2013, the Western Australian Substance User Association has collaborated with the WA Mental Health Commission to deliver a naloxone distribution program to substance users, their friends and family and frontline AOD workers. The program involves training in overdose recognition and response including naloxone administration, and provides participants with two single-dose ampoules of naloxone upon completion.⁸⁴ The project has been extended to include targeted regional areas and one prison (where inmates at-risk of overdose receive naloxone upon release). In addition, a state-run drug and alcohol service has begun prescribing and dispensing naloxone to OMT clients.

At June 2017, the WA program has trained 546 people and dispensed 283 naloxone kits with 32 successful reversals reported. An 18-month evaluation recommended the program continue and be expanded. In addition, WA's Mental Health Commission's Workforce Development Branch has developed a Brief Education Tool along with other resources.

Victoria

A program training PWID and people on OMT in overdose response and naloxone administration has operated in Victoria since 2013. This is delivered by Harm Reduction Victoria (HRV) in collaboration with some specialist drug services and primary NSPs. Training is delivered in both workshops and as individual brief interventions by peer educators after which prescriptions for participants are issued by a GP and filled by service staff at a local pharmacy. While an important program, it does not involve the direct provision of THN to clients due to the somewhat onerous process of staff having to get a prescription issued and filled to supply THN to the client.

The Community Overdose Prevention and Education (COPE) program run by Penington Institute supports agencies to set-up and integrate THN programs into their existing services. This includes training for frontline workers in THN. These workers can then provide brief interventions around overdose prevention and THN to service clients. The COPE program does not provide naloxone directly to clients, though many of the services that participate in the training are able to provide naloxone or a prescription for it to their clients. COPE also facilitates a network of THN training providers which meets three times per year.

⁸² Lenton and Dietz (2018) 'Take home naloxone in Australia: Past, present and future' *National Drug Research Institute*.

⁸³ Dwyer et al (2018).

⁸⁴ Ibid.

From 2014 to June 2017, COPE trained approximately 700 health and community workers in Victoria, who have then provided overdose recognition and response training to an estimated 610 people at-risk of opioid overdose, most of whom also received naloxone or a prescription for it.⁸⁵ Since July 2017, COPE has trained an additional 600 workers, taking the total to more than 1300.

Recently, the Victorian government has provided funding for select services to subsidise the cost of naloxone for distribution to service clients. This means services can cover the cost of naloxone and distribute it free to clients/ However, funding provided through the initiative is limited, meaning the availability of this subsidised supply is time-limited.

Queensland

In 2014, the Queensland Department of Health launched a pilot naloxone distribution program at Brisbane's Biala Community Health Centre (housing an opioid treatment clinic, a withdrawal clinic and a primary NSP). Initially, a weekly one-hour training session was conducted with clients after which a prescription for naloxone was issued, with two local pharmacies supplying the medicine. Participants would receive five pre-filled naloxone syringes. 12 people received naloxone in the first three months of the program. Following an evaluation of the program, the workshop format was deemed too onerous and was abandoned in favour of a brief (10-minute) one-on-one intervention that could be delivered opportunistically. Anecdotal data suggests several overdose reversals using kits from the program have taken place, and several participants have returned for replacement kits.

In addition, the Queensland Injectors Health Network (QIHN) also offers opportunistic naloxone trainings and prescription through a Brisbane-based NSP.

Tasmania, South Australia and the Northern Territory

Australia's remaining states and territories either do not have significant programs operating or are still at the early stages of development and implementation.

Policy settings and strategies

Australia's National Drug Strategy 2017–2026⁸⁶

The *National Drug Strategy 2017–2026* outlines Australia's national priorities relating to alcohol, tobacco and other drugs. The strategy identifies a commitment to the principles of harm minimisation and lists opioids as a 'priority substance', emphasising overdose as one of the main negative health consequences arising from opioid use.

The following priorities identified in the strategy support the implementation of large-scale naloxone distribution program in Australia:

- 'Enhance access to evidence informed, effective and affordable treatment' including 'reduc[ing] adverse consequences of drug use' (p.2);
- 'Providing opportunities for intervention amongst high prevalence or high-risk groups and locations, including the implementation of settings based approaches to modify risk behaviours' (p.23);

⁸⁵ Penington Institute (2018) *Annual Review 2017*; Penington Institute (2017) *Annual Review 2016*.

⁸⁶ Department of Health (2017) 'National Drug Strategy 2017-2026', Government of Australia: [http://www.health.gov.au/internet/main/publishing.nsf/Content/55E4796388E9EDE5CA25808F00035035/\\$File/National-Drug-Strategy-2017-2026.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/55E4796388E9EDE5CA25808F00035035/$File/National-Drug-Strategy-2017-2026.pdf).

- Prioritising ‘strategies that encourage safer behaviours [and] reduce harm to individuals, families and communities’ 9p. 13);
- Enhanc[ing] access to evidence-informed, effective and affordable treatment services and support services for *the* whole population...’ (p.19);
- A focus on evidence-based strategies shown to reduce alcohol and other drug hospital presentations and decrease overdose risk (p.23);
- Development of national guidelines, quality framework, public information resources and communications approaches (p.25);

The strategy identifies an increase in the prescription and use of licit opioids as a domestic and international trend for which innovative responses are required. In addition, a key criterion for evaluating the strategy is whether it reduces ‘drug-related burden of disease (including mortality)’. Given that approximately 70% of overdose deaths in Australia are associated with use of pharmaceutical opioids, naloxone distribution programs fall within the strategy’s parameters and are clearly in Australia’s interests.

National direction, jurisdictional implementation

Health policy in Australia is a highly complex area that reaches across state and federal tiers of government. A key principle underpinning Australia’s national drug strategy is ‘national direction, jurisdictional implementation’. Health interventions at the federal level include overarching frameworks or strategies (like the National Drug Strategy), or universal programs where national consistency are essential such as the Pharmaceutical Benefits Scheme (PBS) and the Medicare Benefits Schedule (MBS).

While federal leadership and support on the issue of naloxone distribution are critical, much of the work relating to coordination and implementation will occur at state level. Although the national drug strategy does identify improving national coordination of ‘innovative approaches, and developing effective responses’ (p.25) as a priority. Key areas of federal responsibility include:

- *Identifying and advancing national priorities*
- *Funding*
- *Leadership and strategic planning*
- *Supporting service quality through a nationally consistent quality framework*
- *Supporting state and territory capacity development and coordination*

Australia’s National Heroin Overdose Strategy 2001

In 2001, the federal government released the *National Heroin Overdose Strategy* which identified ‘nationally agreed upon priorities for reducing the incidence of heroin related overdose in Australia and for reducing morbidity and mortality where overdose does occur’.⁸⁷ While pharmaceutical opioids have eclipsed heroin as the leading cause of overdose death, the strategy acknowledges that a risk of overdose attends all opioids. Although the strategy is over fifteen years old, it’s goals and priorities remain important and are worth pursuing.

⁸⁷ Ministerial Council on Drug Strategy (2001) ‘National Heroin Overdose Strategy’, Government of Australia: [http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/3BBC336160FE6CD4CA2575B4001353B7/\\$File/heroin_strategy.pdf](http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/3BBC336160FE6CD4CA2575B4001353B7/$File/heroin_strategy.pdf).

Australia's National Mental Health Strategy

Mental health conditions are one of the most commonly reported chronic diseases in Australia,⁸⁸ and the co-occurrence of substance misuse and mental health disorders is common.⁸⁹ Australia's national mental health strategy outlines the National Mental Health Plan and the National Mental Health Policy and the Mental Health statement of Rights and Responsibilities.

Among its key priorities, the plan emphasises recovery, early intervention, service access and coordination, quality improvement and innovation, and a partnership approach. This last priority identifies the incorporation of mental health concerns and priorities into other policy frameworks and areas of governance, particularly in the broader areas of health as well as in criminal justice. The plan also acknowledges the gap in health outcomes for those with a mental illness compared to the general population. Unsurprisingly, this gap in health outcomes is mirrored for people who misuse substances.

Given the correlative relationship that exists between substance use and mental health, the principles informing Australia's mental health strategy support increased access to THN in Australia.

⁸⁸ AIHW (2016) *Australia's health 2016*, Canberra: Australian Institute of Health and Welfare.

⁸⁹ Whittaker et al (2015) 'Multiply disadvantaged: Health and service utilization factors faced by homeless injecting drug consumers in Australia', *Drug and Alcohol Review*, vol. 24: 379-87.

Part Three – The model

So far, this report has examined various considerations regarding naloxone as well as several innovative ways of ensuring naloxone is on-hand when it is needed. However, the model proposed in this report is limited to the distribution of *Take-Home Naloxone* only. Analogous interventions not involving the provision of THN (such as having police and fire personnel carry naloxone) are features of international responses and are worth due consideration for the Australian context. However, such interventions are beyond the scope of the model proposed in this report. The report will, however, list interventions that should be considered as a means of supplementing the proposed THN model as part of a wider response to overdose.

In addition, reforms in prescribing practices of doctors, both the over-prescription of opioids and the under-prescription of naloxone, must be addressed. No model for the distribution of THN will ever engage everyone who is at-risk of opioid overdose, so a multi-pronged response is crucial. Given that naloxone is available through prescription at a price that is affordable for most, this should be the primary mechanisms of access, with a THN program providing to those not well serviced by other means of access.

The following section provides a brief description of the model proposed by Penington institute before listing the key features in more detail. The model is also represented in a table (see below). Following this, the benefits and risks of the model we propose are discussed, the recommendation are contextualised in relation to other programs and justified.

A model for Take-Home Naloxone in Australia

In the model that Penington Institute proposes in this report, THN is provided to people likely to experience or witness an opioid overdose at no cost. THN will be accessible from a range of outlets (pharmacies, NSPs, emergency departments, custodial settings, etc.) to capture the diverse population of those at-risk of opioid overdose. Overdose prevention education and training in naloxone administration are available from all THN distribution points. THN kits containing injectable and intra-nasal formulations of naloxone will be available through the program. Accompanying the program's roll-out will be a national public awareness campaign to increase the salience of overdose as a significant issue of public health, along with tailored information provision targeting specific at-risk populations (PWID, people misusing prescription opioids).

The following is a description of the model proposed for subsidised community naloxone distribution in Australia.

Public awareness

As stated previously in this report, the issue of overdose does not have the public salience in Australia as it has in other countries experiencing heightened overdose mortality rates. Essential for the success of the proposed model is a concerted, multifaceted effort to raise the profile of overdose as a significant public health issue. This must be done in a clear and non-stigmatising manner, both to the public broader and targeting specific at-risk populations, and utilising a range of media.

Without awareness and knowledge, demand cannot be effectively generated. And as we know, knowledge of naloxone is lacking in the public domain and mixed within at-risk populations. Raising

awareness about overdose and naloxone (particularly THN) as an appropriate response is a critical first-step in THN distribution.

Scope

The program is national in scope: it ensures distribution and consistent service quality and delivery across the country. If a national program is not possible, a coordinated network of state and territory programs operating under a national standard or set of guidelines should be implemented.

Access

As a Schedule 3 medicine, naloxone is available over-the-counter at pharmacies though it also has a Pharmaceutical Benefits Advisory Committee (PBAC) listing making it available via prescription at a subsidised cost. The cost of naloxone ‘over-the-counter’ is considerable, while naloxone via prescription costs \$39.50 or \$6.40 for those with a concession or healthcare card.

Many of those at-risk of opioid overdose are unable to access naloxone through the mechanisms currently in place. This is due either to the cost of accessing naloxone, the onerous process of getting a prescription for it, or a combination of both.

To address this, Penington Institute proposes a program that provides Take-Home Naloxone (THN) free of charge to those at risk of opioid overdose.

Targeted populations

The following are key cohorts to be targeted by this program. However, the delineation made in this report between these cohorts is artificial. Substance use is complex, involving a diverse spectrum of behaviours, people and experiences. Evidence shows that poly-drug use is the norm, estimated at approximately 60% of accidental drug-induced deaths.⁹⁰ People who inject drugs may also use pharmaceuticals (prescribed or diverted), and those only using prescribed medications may also use these in combination with alcohol, or other pharmaceuticals such as benzodiazepines.

Further, while this report differentiates people who inject drugs from those misusing prescription medicines, evidence suggests a significant degree of overlap between these populations. A small study reviewing Victorian coroners’ reports of drug-induced deaths found that in more than two thirds of deaths involving pharmaceutical opioids, the opioids involved were prescribed to the decedent. Further, of 110 deaths involving pharmaceutical opioids used in conjunction with other drugs, 39% involved illicit drugs. While the data set is limited, it does suggest a degree of crossover between these important populations.⁹¹

People who inject drugs

Injecting drug use is associated with numerous social harms (such as disadvantage, poverty and social marginalisation) and poor health outcomes (hepatitis C infection, chronic ill-health, overdose). Some people who inject drugs find it difficult to access mainstream health and other services and so need to access specialised services that cater to their needs (such as Needle and Syringe Programs).

⁹⁰ ABS (2017).

⁹¹ Ogeil et al (2018) ‘Pharmaceutical opioid overdose deaths and the presence of witnesses’, *International Journal of Drug Policy*, vol. 55: 8-13.

As such, this cohort are unlikely to purchase naloxone or go through the process of getting a prescription for it. Providing naloxone free-of-charge to this population at services that they already attend is essential.

Further, PWID are highly likely to witness overdose, making them prime candidates for THN provision. Empowering PWID to respond effectively to overdose by providing THN not only reduces their risk of fatal overdose but may also reduce the risk for others around them.

People prescribed strong opioids

At high doses (90 MME or greater), opioids can depress the respiratory system to the point that a person becomes unable to breathe properly. This is an opioid overdose and puts a person at significant risk of injury or death. Strong opioids (those classified as Schedule 8 on the Poisons Standard) carry a significant risk of overdose.

However, people who are prescribed opioids often do not see themselves as being at-risk of overdose. This occurs for several reasons: they associate overdose with illicit opioids such as heroin; the opioids were prescribed by their doctor; and they are unable to recognise the signs and symptoms of overdose. This makes this cohort difficult to engage in discussions about overdose and naloxone prescription.

Ideally, members of this cohort that are at-risk of opioid overdose would receive information and a naloxone prescription from the doctor prescribing them strong opioids. It is less likely that this cohort will engage with service providers such as NSPs, so the initial interaction with their doctor should be capitalised on. This discussion with a doctor about overdose and naloxone does not always occur and so it is important that accessible and affordable (free) naloxone be available to them.

People misusing pharmaceutical opioids

The misuse of pharmaceutical opioids may involve either prescribed and diverted opioids (or both). Misuse of prescribed opioids occurs when a person is prescribed opioids as medication though uses them in a manner not recommended by a doctor. The misuse of diverted pharmaceutical opioids occurs when someone obtains opioids not prescribed to them. Pharmaceutical opioids can be very potent which can make dosing difficult for this cohort.

Soon-to-be-released inmates of custodial facilities

Inmates with a history of opioid or drug use are at high-risk of overdose in the period following their release from incarceration.

Friends and family

The friends and family of PWUD are often witnesses to overdose, meaning they are the first to respond to an overdose. In some tragic cases, friends and family members are not aware they are witnessing an overdose and so fail to respond. It is therefore essential that training in how to recognise and respond to an overdose is available for friends and family of PWUD, and that THN is accessible to them.

Distribution points

Free naloxone needs to be accessible through services utilised by those at risk of overdose. The following are the key distribution points for THN in the proposed model (see Table 4 below for an overview):

- Needle and Syringe Programs (primary and secondary);
- Homeless and mental health services;
- OMT providers and other drug treatment programs;
- peer outreach;
- pharmacies;
- emergency departments;
- pain management clinics;
- supervised injecting facilities;
- community health agencies (including specialist services for Aboriginal and Torres Strait Islanders);
- custodial facilities.

Cost to consumer

Naloxone kits are available free-of-charge from the sites identified above.

Naloxone will remain available from pharmacies over-the-counter and via prescription.

Cost to Distributor

Distributing naloxone will involve costs to participating agencies in terms of time and labour. While providing training in naloxone administration to clients is the most obvious cost, additional costs include ordering, delivery, stock-take and record keeping. Program funding will compensate agencies for these costs.

Products

Distribution points provide both injectable and intra-nasal naloxone.

Injectable

A kit of injectable naloxone should contain three single dose ampoules, three 3ml syringes and three 23-gauge needles OR a single five-dose preloaded syringe (this comes with needles). In addition, injectable kits should contain alcohol wipes and instructions.

Intra-nasal

An intra-nasal kit should contain two units of intra-nasal naloxone and instructions.

Education and training

Education and training are components of this model for an Australian THN program. A standardised national education and training resource will be developed, based on the ORTHN model from NSW to ensure consistency across jurisdictions. Education and training programs must be flexible and adaptable to suit different audiences and contexts (i.e. group workshops run at homelessness services and opportunistic one-on-one training conducted by an NSP or outreach worker).

Education and training should be delivered by staff in settings that clients are already attending. Overdose and naloxone training program will cover the following areas:

- preventing an overdose;
- recognising an overdose;
- effective responses to overdose including the administration of naloxone;
- the importance of contacting emergency services;
- the use of recovery position and rescue breathing.

Training models will be developed for three kinds of training: group workshops, one-on-one training and opportunistic Brief Interventions (BI). Group and one-on-one training can cover a range of topics related to overdose and allow for questions and discussions whereas BI training will focus only on the essential elements of responding to an overdose.

Training modules (based on the COPE program's training resources) will be developed for both injectable and intra-nasal naloxone.

Professions

Professions authorised to supply naloxone differ between Australia's states and territories. This should be clarified under national guidelines authorising the following professions to supply THN without a prescription:

- registered nurses
- AOD and NSP workers
- pharmacy staff
- staff at community services
- outreach workers and peers
- emergency department staff
- medical staff

State and territory health authorities will need to issue executive protocols authorising naloxone to be dispensed by specified professionals (or in relevant settings such as drug treatment centres and NSPs) directly to clients without the need for a prescription.

In addition, peer outreach training and distribution needs to be authorised. Peers are a crucial means of knowledge dissemination for many populations at-risk of overdose and this should be exploited to maximise training and supply opportunities.

Governance

Governance will need to be developed for agencies and staff participating in the THN for compliance purposes. These will need to cover agency eligibility, staff eligibility, and staff training and credentialing.

NSW's ORTHN project operates under a state-wide clinical protocol issued by the NSW government authorising the ORTHN project and providing capacity for a wider range of credentialed workers to supply THN to clients. This required the development of a patient care model that outlined adherence to the protocol's procedures, requirements and quality assurance processes. This supports participating agencies in providing overdose response interventions including THN.

Australia's states and territories will need to adopt their own protocols (including eligibility criteria for participating agencies and credentialing frameworks). These should be informed by national guidelines to ensure consistency.

Eligibility frameworks for agency and staff

Eligibility frameworks will need to be developed for both agencies and staff. For agencies, criteria for THN distribution will need to be developed so as to assess the capacity of agencies to comply with the program's clinical protocol, as well as restrictions relating to S3 medications such as storage requirements, procurement procedures, documentation and having an overdose response protocol implemented.

Staff eligibility frameworks will outline the requisite criteria for supplying THN to service clients. The framework should include employment in a relevant role; experience providing clinical interventions with people experiencing substance use; assessing appropriate knowledge, skills and attitudes required to supply THN, and the persons consent to participate and comply with relevant policies, quality assurance procedures and the clinical protocol under which the program operates.

Credentialing framework

A credentialing framework will need to be developed to ensure workers supplying THN to clients are appropriately trained and have the requisite competencies to do so. The framework should address:

- Overview of opioid overdose including risk factors and appropriate interventions;
- Overview of naloxone, including administration of different formulations and contraindications;
- Medication handling, storage and documentation requirements;
- Delivery of training in overdose prevention including THN provision;

Overdose response protocol

Participating organisations will need to implement a protocol for overdose response. Some agencies, such as emergency departments and primary NSPs, will likely already have such protocols in place, though other agencies will need to develop these. Agencies should be provided with a template for an overdose response protocol based on the clinical protocol of the ORTHN project operating in Sydney.

Data collection and monitoring

Agencies will be required to keep accurate records for each dispensation to allow total number of kits dispensed from each site and dispensing patterns (i.e. periods of high demand) to be tracked.

The following personal data will be collected from clients: age range, initials, gender, whether the kit is for them or someone they know, whether it is a first or replacement kit and the reason for replacement (lost, used or out of date).

Effective monitoring and data collection are crucial for program evaluations to be conducted effectively.

The development of a documentation checklist or protocol can assist agencies in adhering to documentation and data collection standards.

Implementation

Given overdose constitutes a significant public health emergency on par with (indeed, exceeding) the national road-toll, implementation of the proposed model should be prioritised, seeking to achieve full implementation as quickly as possible. Lessons learnt from smaller-scale THN programs and pilots in Australia will allow for the process of implementation to be expedited. However, lessons from international programs indicate that some aspects of a THN program will take longer to implement than others, so time delays and implementation delays with certain agencies (such as custodial settings) should be anticipated.

Many eligible agencies will already have some experience with overdose prevention training and naloxone while others, such as secondary NSPs will require more capacity-building, have higher training requirements and may require tailored support.

Implementation in custodial settings will likely face time-delays as the safety protocols and policies attending these facilities are more complex.

Table 3 – Key access points of the proposed model

Access point	Populations	Justification	Workforce	Appropriate training	Cost to Consumer	Formulation
Primary NSP	PWID/PWUD	At-risk of overdose; likely to witness overdose	GP, nurse, NSP staff, peers, allied health worker, AOD worker	Workshops, brief intervention (BI)	Free	Injectable, intra-nasal
Secondary NSP	PWID/PWUD	At-risk of overdose; likely to witness overdose	Pharmacist, frontline staff	BI, one-on-one	Free	Injectable, intra-nasal
OMT providers (pharmacy)	PWID/PWUD	At-risk of overdose; may experience increased risk of OMT ceased	Pharmacist, allied health worker, AOD worker	One-on-one	Free	Injectable, intra-nasal
Pharmacies (not providing OMT)	People likely to experience an overdose, friends and family	Wide coverage and highly accessible	Pharmacist, frontline staff	One-on-one, BI	Free ¹	Injectable, intra-nasal
Supervised Injecting Facility	PWID	At-risk of overdose	Doctor, nurse, allied health worker, AOD worker	One-on-one, BI	Free	Injectable, intra-nasal
Custodial facilities	Soon-to-be-released inmates with history of drug use	High risk of overdose in weeks following release	Nurse, doctor	Workshop, one-on-one	Free	Injectable, intra-nasal
Drug treatment service	Patients receiving drug treatment	Increased risk of overdose due to abstinence; decreased tolerance	Doctor, nurse, AOD clinician, allied health worker, AOD worker	One-on-one	Free	Injectable, intra-nasal
Emergency departments	People who have recently experienced an overdose	Risk of overdose increased with recent overdose	Doctor, nurse	One-on-one, BI	Free	Injectable, intra-nasal
Community health/services	PWUD, friends and family	PWUD likely to access community health services	GP, nurse, allied health worker, AOD worker	Workshops, one-on-one	Free	Injectable, intra-nasal
Outreach (peer)	PWID/PWUD	Engaged with people at risk of opioid overdose and PWID	Peer worker, outreach worker	One-on-one, BI	Free	Injectable, intra-nasal

¹At pharmacies, naloxone may also be available via prescription or over the counter.

Key features and considerations

This section discusses the key features of the program (such as the types of agencies authorised to distribute THN) in more detail.

Distribution points

Having multiple access points for naloxone is critical to ensure the program captures the diverse population of those at risk of opioid overdose. The inclusion of each agency type in the model is discussed in detail:

Needle and Syringe Programs (NSPs)

NSPs are a critical point of access for PWID and PWUD. NSPs in Australia consist of both primary and secondary sites:

Primary NSPs:

Primary NSPs are services dedicated to the provision of a range of injecting equipment to PWID and PWUD. They also deliver information on a range of issues such as health and drug use, can refer clients to health and social services (including drug treatment services). Some primary NSPs provide additional services such as primary healthcare or counselling.

Secondary NSPs:

Secondary NSPs are services that operate within existing services such as hospitals and other health or community organisations, or a pharmacy. NSP services are provided in addition to their primary functions. The staff engagement and range of equipment at a secondary NSP be limited compared to that of a primary site.

Opioid Maintenance Therapy and other drug treatment providers

Opioid Maintenance Therapy (also known as OST or ORT) is a form of treatment for people who use opioids. Patients are prescribed therapeutic doses of methadone or buprenorphine by a doctor and access this through OMT providers (usually pharmacies). OMT is used to stabilise a person's substance use, reduce high-risk behaviours associated with it and ultimately reduce the morbidity and mortality associated with use of illicit opioids.⁹² OMT also helps people avoid the uncomfortable withdrawal symptoms that result from abstinence. Because patients must attend for treatment regularly, OMT providers are an effective means of engagement for PWID and PWUD in naloxone training.

Other forms of drug treatment include counselling, withdrawal or detoxification centres and residential rehabilitation. Given that risk of overdose is heightened following a period of abstinence (including abstinence from OMT), all treatment types should be included as naloxone distribution points.

Supervised Injecting Facilities (SIFs)

Australia currently has one SIF operating in King's Cross in Sydney, while another opened in Melbourne in 2018. Take-Home Naloxone is already available at the Sydney site.

⁹² WHO (2009) 'Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence', World Health Organisation:
http://apps.who.int/iris/bitstream/handle/10665/43948/9789241547543_eng.pdf;jsessionid=A1B594BE6AC0A6EECFBD7FD79A30B4AC?sequence=1.

Pharmacies

Pharmacies are widespread, easily accessible and already dispense medications (with some providing OMT and NSP services). Pharmacies are the primary means of access to prescription medications such as S8 opioids, providing an important opportunity to engage individuals regarding overdose and naloxone. This makes pharmacies highly suited to dispense THN to a range of priority populations.

Emergency departments

If an ambulance attends an overdose, the person will often receive treatment in the emergency department of a local hospital. Unlike other access point, emergency departments capture all populations at risk of opioid overdose. While emergency departments are only able to engage a person after they have overdosed, a recent overdose is the most reliable predictor of future overdose. This makes emergency departments a critical point of intervention for naloxone distribution, as those leaving an ED following an overdose are at high-risk.

Custodial facilities

People newly released from custodial facilities are at significant risk of opioid overdose. Most of the international THN programs examined in this report distribute naloxone to at-risk inmates upon release (Massachusetts does not). Custodial facilities are the most effective site of engagement for this population, as training takes place prior to release and naloxone is provided to them in their release kit.

The term ‘custodial facilities’ encompasses prisons as well as remand, detention centres and police lock-up.

Peers and drug user organisations

Engagement of PWID and PWUD by peers and drug user organisations is an important means of providing non-judgemental information, resources and support in an accessible format. Peer workers will be trained to deliver overdose prevention training (including naloxone administration) and provide THN kits as part of outreach with populations at-risk of opioid overdose.

Outreach

Outreach is a means of providing services to populations that might otherwise not be able to access them. Outreach has formed a core part of the service response to populations experiencing issues relating to drug and alcohol for several decades. Outreach is done by outreach workers, volunteers and peers through a variety of programs and organisations working with marginalised or vulnerable populations.

Community health organisations

Community health organisations comprise networks of agencies that deliver a range of health and related services in localised community settings. Community health agencies provide a range of universal access services and may also provide targeted services for specific populations (for example, specialist HIV services, or indigenous health and welfare services). The services available through a community health organisation varies, though usually consist of a mix of primary healthcare, human services, and community-based support services.

Community health organisations often act as access hubs, both offering multiple services as well as being able to provide referrals (for example, for AOD counselling). They work with a range of populations and often have pre-established links with high priority populations.

General practitioners (GPs) and specialists

In this proposed model, GPs and specialists (such as pain specialists) are not included as a distribution point for THN kits. However, given that pharmaceutical opioids account for more overdose deaths than illicit opioids such as heroin, doctors have a critical role to play in getting naloxone into the hands of people who need it.

People who are at-risk of opioid overdose do have interactions with doctors; at drug treatment facilities, seeing their GP, accessing their OMT and when they get a prescription for the opioids they have begun to misuse. These are too often missed opportunities, not only for conversations about overdose to be held, but to utilise the conventional mechanism for accessing naloxone: having a doctor prescribe it.

These interactions must be further capitalised upon: THN programs do not need to engage with everyone who is at-risk, overdose and naloxone interventions at the time of opioid prescribing are also essential. The best way for someone on prescription opioids to hear about and receive naloxone is to have it prescribed at the same time as their opioid medication is prescribed. This will also serve to destigmatise overdose by reinforcing the message that overdose can affect anyone, not just those who inject drugs.

Education and training

All programs examined for this report include education and training, either as a recommended or mandatory condition of the program. Several studies and program evaluations have demonstrated, overdose education and response training is correlated with increased ability to recognise and respond effectively to an overdose, increased participation in naloxone distribution programs and an increase in the likelihood that a person will respond.^{93 94 95}

Research by Behar et al found that brief training sessions (5 - 10 minutes) are sufficient for clients to demonstrate correct naloxone administration.⁹⁶ While longer sessions may allow additional information to be covered, this research suggests that longer training sessions may act as a disincentive for clients, decreasing participation and uptake. Key topics to include in training are contacting emergency services, use of the recovery position and administering naloxone correctly.

However, while training has been shown to improve the capacity to respond to an overdose, additional research found that training is not essential for the successful administration of naloxone by laypersons to reverse an overdose.⁹⁷

⁹³ Behar et al (2015) 'Brief overdose education is sufficient for naloxone distribution to opioid users', *Drug and Alcohol Dependence*, vol. 148: 209-12.

⁹⁴ Bennet and Holloway (2012) 'The impact of take-home naloxone and training on opiate overdose knowledge and response: An evaluation of the THN Project in Wales' *Drugs: Education, prevention, policy*, vol. 19(4): 320-8.

⁹⁵ McAuley et al (2016) 'Engagement in a National Naloxone Programme among people who inject drugs', *Drug and Alcohol Dependence*, vol. 162: 236-40.

⁹⁶ Behar et al (2015) 'Brief overdose education is sufficient for naloxone distribution to opioid users', *Drug and Alcohol Dependence*, vol. 148: 209-12.

⁹⁷ Doe Simpkins et al (2014) 'Overdose rescues by trained and untrained participants and change in opioids use amongst substance-using participants in overdose education and naloxone distribution programs: a retrospective cohort study' *BMC Public Health*, vol. 14: 297-308.

The ORTHN project in NSW has developed a standardised procedure for a Brief Intervention (BI) along with additional resources. In addition, the COPE training resource developed by Penington Institute has been used to train frontline workers in Victoria since 2014. A national standardised training program can be developed out of the work already done here.

Just as demand is a critical component when considering supply, education and training are critical components when considering uptake and use. To ensure training is accessible, it should be flexible and able to be adapted depending on the audience. For example, an hour-long session will not be suited to a client attending an NSP to pick up a fit-pack. In this situation, a brief intervention (BI) will be far more suited.

To ensure consistency of training quality across the program, a standardised national training resource should be developed. This resource will require that all training address the following:

- how to avoid risk factors for overdose
- how to identify an overdose;
- the importance of calling emergency services first;
- using the recovery position;
- how to correctly administer naloxone.

These five elements can be addressed in an opportunistic Brief Intervention and are sufficient for effective administration of naloxone by laypersons. However, in longer training sessions (such as workshops and scheduled group training), additional elements of overdose response (rescue breaths and CPR) should also be included.

All staff supplying naloxone (NSP staff, allied health workers, pharmacy staff, peers, etc.) will be trained to use the standardised resource with clients and will then be credentialed as a trainer. Training will be available to all agency staff regardless of position or level of education.

While it is important that education and training programs target those at risk, others should not be excluded from accessing such resources. Advertising opportunities for training and education has the potential to capture hard-to-access populations as well as the friends and family of people at-risk.

Formulations, doses and kits

Currently, two formulations of injectable naloxone are available in Australia: glass ampoules and a pre-filled syringe. Intra-nasal naloxone, which is available in several countries, is not yet available in Australia.

Intra-nasal naloxone is included in the model proposed in this report as it is effective and presents a non-invasive and user-friendly alternative to formulations that require injection.

- Pre-filled naloxone syringes contain 2mg/2ml of naloxone (equivalent of five doses) and already contains a needle tip for administration;
- A single glass ampoule contains a single dose (0.4mg/1ml) and must be dispensed with at least one syringe and needle (ideally, additional safety paraphernalia such as alcohol wipes and non-latex gloves are also provided);
- Intra-nasal units contain 1.8mg, 2mg or 4mg depending on brand. No needles or other injecting paraphernalia are necessary.

The availability of intra-nasal naloxone has been an important development in responses to overdose, and intra-nasal units have been included in several international naloxone distribution programs. Because it does not require an injection to be administered, intra-nasal naloxone removes a significant barrier to use and uptake. Given that a significant proportion of fatal opioid overdoses are now occurring within non-injecting populations, intra-nasal naloxone should be prioritised within state-funded THN programs.

Client feedback from the program in Ontario revealed a small but significant proportion of client's preference for injectable over intra-nasal naloxone. The Ontario program, initially providing one formulation from each program tier, has moved towards making both injectable and intra-nasal formulations available from all access points.

In terms of dosage, this differs significantly between the formulations. Where 0.4mg is considered a single dose of intramuscular naloxone (administered via injection), due to the different uptake mechanism involved, a single dose of intra-nasal naloxone is 2mg. Recent research has shown that 2mg administered intra-nasally has an effect equivalent to 0.4mg administered intra-muscularly.⁹⁸ As such, 2mg of naloxone administered intra-nasally should be considered a single dose.

While there is no risk of poisoning from naloxone, administering a high dose can lead to precipitated withdrawal symptoms in the person which can be highly unpleasant, disorientating and lead to rapid re-use of opioids therefore risking further overdose or reluctance to use naloxone.

Because naloxone's half-life is shorter than most opioids, multiple doses may be needed and so should be provided as part of any naloxone distribution program.

Logistics

The logistics of naloxone distribution are complex and multi-layered, and each jurisdictional context will have its own challenges. When proposing a model, it is not possible to anticipate all logistical hurdles that will arise for each jurisdiction. However, the proposed model will need to be consistent with state and territory regulations and directives regarding procurement, storage, labelling, staffing and so on, or be granted exemptions from these regulatory limitations.

This section identifies and describes several logistical considerations that other naloxone programs have encountered, though this list is by no means exhaustive.

Kit assembly

What a naloxone kit contains and where and how a kit is assembled has significant logistical implications. There are many relevant regulatory requirements relating to medicines that will determine how kits are classified (i.e. as medical devices). These may, for example, prevent an organisation from dividing a pack of naloxone ampoules into individual doses.

The Centre for Disease Control in British Columbia (BCCDC) has a pharmacy on site. When BC first started distributing THN, the pharmacy at BCCDC had to assemble each kit by hand. This involved ordering each element separately — naloxone, syringes, kit cases, rubber gloves, alcohol wipes — before assembling each kit. Given the BCCDC often distributes 10,000 individual kits a month, this was a significant undertaking in terms of time and resources. The solution was to find a company

⁹⁸ McDonald (2017) 'Pharmacokinetics of concentrated naloxone nasal spray for opioid overdose reversal: Phase 1 healthy volunteer study', *Addiction*, vol. 113: 484-493.

that could supply pre-assembled kits containing everything except the naloxone ampoules. The kits arrive, the naloxone is added by the BCCDC pharmacy and the kits are distributed.

This example highlights the challenges THN programs can face initially, as well as how they can be overcome.

Distribution points

The types of agencies that distribute naloxone will have significant logistical implications for a THN program. Including non-medical settings such as homeless shelters and drop-in centres will create challenges relating to training, storage and regulatory certification. How each agency receives a supply of naloxone is another important consideration.

Each type of agency will have its own needs and requirements and these need to be addressed in the development phase, and then re-evaluated throughout implementation.

Supply chain

How naloxone and other materials are procured will be determined by an array of factors including cost, whether materials are manufactured domestically, shipping times and regulations relating to importation, among others. Supply chain activities will also need to be consistent with state policies relating to medication handling, licensing and procurement.

Logistical implications relating to the supply chain cannot be accurately anticipated in this report, though will need to be actively managed for as long as the program operates.

Public awareness campaign

A well-funded public awareness campaign that is both factual and non-stigmatising will be developed to coincide with the program to highlight overdose as a serious public health issue. The campaign will put a human face to the issue of overdose and challenge the stigmatising stereotype of people who inject drugs (PWID) and the negative connotations this carries.

Significant work in de-stigmatisation has been conducted to address issues associated with anxiety, depression and other mental illnesses. For example, Beyondblue has developed and delivered several public awareness campaigns addressing the stigma associated with mental illness. This work has helped to improve community understanding on mental illness (and the stigma attached to it). No comparable work to destigmatise substance misuse and overdose has been undertaken in Australia.

People with substance dependence are often highly marginalised and suffer a range of morbidities (many of which are also stigmatised, including mental illness and homelessness). A public awareness campaign addressing overdose will need to focus on de-stigmatisation as well as addressing the complexity of these issues.

A public awareness campaign focusing on overdose must address:

- Inaccurate stereotypes attached to people who use substances;
- The risks of overdose including from pharmaceuticals;
- That overdose affects people from all walks of life;
- That naloxone is an essential medicine and carrying naloxone is legal.

While the purpose of a broad public awareness campaign is to increase the level of public awareness regarding substance misuse and overdose, specific information dissemination targeted at specific populations will also be required. These more focused campaigns, with appropriate targeting to ATSI and CALD communities, will target the following populations:

- People who inject drugs;
- People at risk of overdose from prescription medicines or illegal drugs;
- Families and friends of people misusing substances;

The purpose of these is to provide accurate, appropriate and tailored information for each population regarding the national naloxone program. Each campaign will be tailored to the needs of each population. For example, the campaign targeting PWID will be prominent in NSPs, treatment centres and pharmacotherapy providers. In contrast, the campaign targeting people misusing prescription medicines will appear in pharmacies, primary care and other relevant services.

Evaluation

An independent body will be commissioned prior to implementation to evaluate the program. Evaluation is an essential element in the successful development, implementation and expansion of naloxone distribution programs.

The program's eligibility framework will include documentation requirements. Distribution points will be required to collect data as part of their participation in the program. These data will be used by the commissioned body to measure the program's outputs in the following areas:

- Number of kits distributed;
- Proportion of kits distributed as first-time and replacement kits;
- Effect on overdose rates and overdose mortality rates;
- Program efficiency and cost;
- Initial and ongoing levels of access and uptake.

Table 4: the key elements of the proposed model for naloxone distribution in Australia

Feature	Description	Recommendation	Outcome
Scope	A national program or network of state- and territory-based programs	National	Ensures consistency of access across the country, as well as avoiding setting up eight separate state- and territory-based programs
Populations	Who is targeted by the program	PWID/PWUD, people prescribed strong opioids, people at-risk of experiencing or witnessing an overdose	People who are at-risk of experiencing an overdose can access free naloxone easily
Cost to consumer to receive kit	The cost to receive a naloxone kit through the program from a participating agency	Free through program	The cost barrier is removed
Reimbursement for dispensation	Level of reimbursement to services for dispensing kits.	Services are reimbursed for the cost of training, dispensation, time, labour etc. (Cost of kits covered by government)	Services are adequately compensated for for resources spent supplying kits
Distribution points	Access points for obtaining a naloxone kit	NSPs, OMT providers, emergency departments, custodial settings, community health agencies, community services, pain management clinics, pharmacies	A wide array of access points increases coverage and allows for capture of different sections of the at-risk populations
Education and training	Overdose education and training in administering naloxone	Standardised training resources available to staff at all access points	Training in overdose response and naloxone administration is available at all access points
Naloxone products	The formulations of naloxone available through the program	Injectable naloxone (ampoules and pre-loaded, five-dose syringes); Intra-nasal naloxone	Clients can access their preferred formulation of naloxone

Challenges in Australia

Federal-State coordination

According to the Australian Institute of Health and Welfare:

The Australian health system comprises a set of public and private service providers in multiple settings, supported by a variety of legislative, regulatory and funding arrangements, with responsibilities distributed across the three levels of government, nongovernment organisation and individuals. This web of public and private providers, settings, participants and supporting mechanisms is nothing short of complex.⁹⁹

This complexity represents a significant hurdle to equitable access to naloxone across the country. Differing legislative and regulatory arrangements in the states and territories make the prospect of developing a naloxone distribution program for each Australian state and territory highly complex.

A federally funded national program has several advantages over a network of state-based programs, both at the level of implementation and outcomes. By identifying national priorities and standards, and by providing strategic leadership, the Commonwealth can circumvent much of the complexity highlighted above.

Required legislative changes and exemptions

A range of legislative and regulatory exemptions will be required (primarily at the state and territory level) for a national THN program to be implemented in Australia. This is because many services (such as secondary NSPs) simply do not have medical staff or pharmacists on site to prescribe or supply naloxone.

For example, because S3 medications are classified as ‘pharmacy only’, most states and territories prohibit purchase and supply of S3s by anyone other than a pharmacist or medical practitioner. This will either need to be addressed to allow non-pharmacy agencies such as NSPs to order, store and supply naloxone

In this case, legislative or executive exemptions for agencies issued by relevant government departments are likely to be a more efficient solution than pursuing legislative reforms or the rescheduling of naloxone.

There are a range of other legislative or regulatory hurdles that will need to be addressed for the national THN program to operate effectively. The current prohibition on third-party supply disallows the issuing of prescriptions on behalf of another person. Changing this will allow the family and friends of people using opioids to access naloxone.

An example of an exemption from regulatory requirements being issued to allow THN distribution is the NSW Health Department authorising nurses at the Supervised Injecting Facility in Sydney to dispense THN directly to clients. However, the MSIC now operates under the clinical protocol of the ORTHN project.

Additionally, work is being done in Western Australia to implement a Structured Administration Supply Arrangement (SASA) — issued by the Chief Pharmacist — which will allow non-health workers to supply THN to clients of drug treatment programs and NSPs.

⁹⁹ AIHW (2012) *Australia's Health 2012*, Canberra: Australian Institute of Health and Welfare

Schedule 3 restrictions

As a Schedule 3 (S3) medication, naloxone is subject to a range of restrictions relating to the conditions under which it can be dispensed.

The main restriction for S3 medicines is that they require a pharmacist intervention to be dispensed. For naloxone, this prevents staff at services like NSPs from dispensing naloxone to clients. However, a handful of naloxone programs operate under exemptions from this rule. In addition, conditions relating to labelling are also determined by scheduling.

While scheduling is set nationally, each state and territory implements its own scheduling controls. For example, New South Wales requires that S3 medications be kept in a lockable room or enclosure to which the public does not have access. Additionally, the storage area must be separate from food intended for consumption by humans or animals, and stored in such a way that leaking, or breaking down, not pose a poison hazard. In contrast, Victoria only recommends that S3 medicines be stored in the same manner as S4 medicines.

Restrictions attending naloxone's scheduling status will need to be addressed for a national THN program to be implemented successfully. Exemptions for specific medicines can be issued if sufficient benefit is determined. Exemptions from the current regulatory requirements attending S3 medicines will need to be obtained from state governments to facilitate supply of naloxone through the THN program.

Prescription trends

Australian research by Roxburgh et al has shown that for most pharmaceutical opioids, the rate of deaths is correlated to rates of dispensation (fentanyl is the only exception, possibly indicating increases in extra-medical use of fentanyl).¹⁰⁰ These findings suggest that rates of mortality involving pharmaceutical opioids are determined by rates of dispensation. Demonstrably, while illicit opioids and the importation of pharmaceuticals certainly contribute to overdose mortality, addressing the rates at which opioids are being prescribed is critical to reduce the harms associated with opioid overdose. As an intervention, naloxone is effective at responding to overdose. However, while reducing the rate of overdose is a more effective means of reducing associated harms naloxone is an emergency response that requires rapid scaling up whilst other measures are put in place to reduce the incidence of overdose, such as inappropriate prescribing. However, these issues and the reforms necessary to address them are beyond the scope of this report.

¹⁰⁰ Roxburgh et al (2017) 'Trends in heroin and pharmaceutical opioid overdose deaths in Australia', *Drug and Alcohol Dependence*, vol. 179: 291-8.

Additional recommendations

The following are additional features that Penington Institute recommends as part of an Australian THN program.

Good Samaritan laws

Good Samaritan laws is a general term for laws designed to protect those who act to provide assistance in emergency situations for legal liability from harms arising from their actions. For example, pushing someone from the path of an oncoming car may save their life, though the push may also cause them injury. In such as case, Good Samaritan laws would protect this person from criminal or civil liability in relation to the other person's injury.

Each Australian state and territory has its own Good Samaritan laws (for example, in Victoria, it is the *Wrongs Act 1958*). State and territory governments should be encouraged to review their Good Samaritan laws in relation to overdose and naloxone.

Good Samaritan laws have been clarified nationally in Canada¹⁰¹ and in many states in the US, in response to overdose and naloxone specifically.¹⁰² These changes have responded concerns regarding criminal and civil liability for laypersons administering naloxone and laypersons calling emergency services when an overdose is witnessed.

Prescribing guidelines

The National Prescribing Service should amend their information for prescribing opioids to include a recommendation that the doctor discuss the risk of overdose with a patient when prescribing opioids and inform them about naloxone and where kits are available.

The US Centre for Disease Control has issued comprehensive prescribing guidelines for opioids.¹⁰³ These cover dose, titration, length of treatment, appropriateness of treatment, risk of the development of tolerance and/or iatrogenic dependence and a range of other considerations. While these guidelines are specifically for the treatment of chronic non-cancer pain, prescribing guidelines for the Australian context can be developed from these.

In addition, these guidelines should include indications for when it is appropriate for a prescription for naloxone to be issued along with a prescription for opioid analgesics, for example, when receiving several scrips for strong (S8) opioids.

Police

Naloxone is a legal medicine that is legal for laypersons to carry. However, anecdotal reportage suggests that many people who do or would like to access naloxone have either had it confiscated by police or fear this happening. State and territory police services will need to ensure guidance to their officers so that they understand carrying naloxone and attendant paraphernalia such as syringes and needles is legal.

¹⁰¹ Health Canada (2017) 'About the Good Samaritan Drug Overdose Act', Government of Canada: <https://www.canada.ca/en/health-canada/services/substance-abuse/prescription-drug-abuse/opioids/about-good-samaritan-drug-overdose-act.html>.

¹⁰² Davis et al (2017) 'Legal interventions to reduce overdose mortality: naloxone access and overdose Good Samaritan laws', *The Network for Public Health and Law*: <http://www.canadianharmreduction.com/sites/default/files/2012%20Network%20for%20Public%20Health%20-%20naloxone%20summary%20US.pdf>.

¹⁰³ Chou et al (2009) 'Clinical guidelines for use of chronic opioid therapy in chronic noncancer pain', *The Journal of Pain*, vol. 10(2): 113-30.

Multifaceted drug approaches

While the provision of THN has been demonstrated to be an effective means of mitigating some of the harms associated with opioid use; there remains a significant role for practitioners and policy makers to address the admittedly complex underlying causes of substance misuse and overdose, which the provision of THN is not able to address. Holistic and multifaceted approaches to substance misuse that focus on care and empowering those affected are required, and emergency responses such as THN programs, will always be insufficient to address the complex underlying causes. As researcher examining THN programs in British Columbia state, naloxone ‘while good, is not good enough’ to sufficiently address the harms associated with opioid overdose, namely, the preventable deaths of thousands per year.¹⁰⁴¹⁰⁵

¹⁰⁴ Irvine et al (2018) ‘Distribution of take-home opioid antagonist kits during a synthetic opioid epidemic in British Columbia, Canada: a modelling study’, *Lancet Public Health*: [http://dx.doi.org/10.1016/S2468-2667\(18\)30044-6](http://dx.doi.org/10.1016/S2468-2667(18)30044-6)

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