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THE UNIVERSITY
OF QUEENSLAND
AUSTRALIA

CREATE CHANGE

Evaluation of the Pharmaceutical Benefits Scheme Subsidised Take Home Naloxone Pilot

Final Report



PBS Subsidised TAKE HOME NALOXONE Pilot

“ Well it felt good for me ... saving somebody's life. ...Overdoses shouldn't happen because it's preventable.

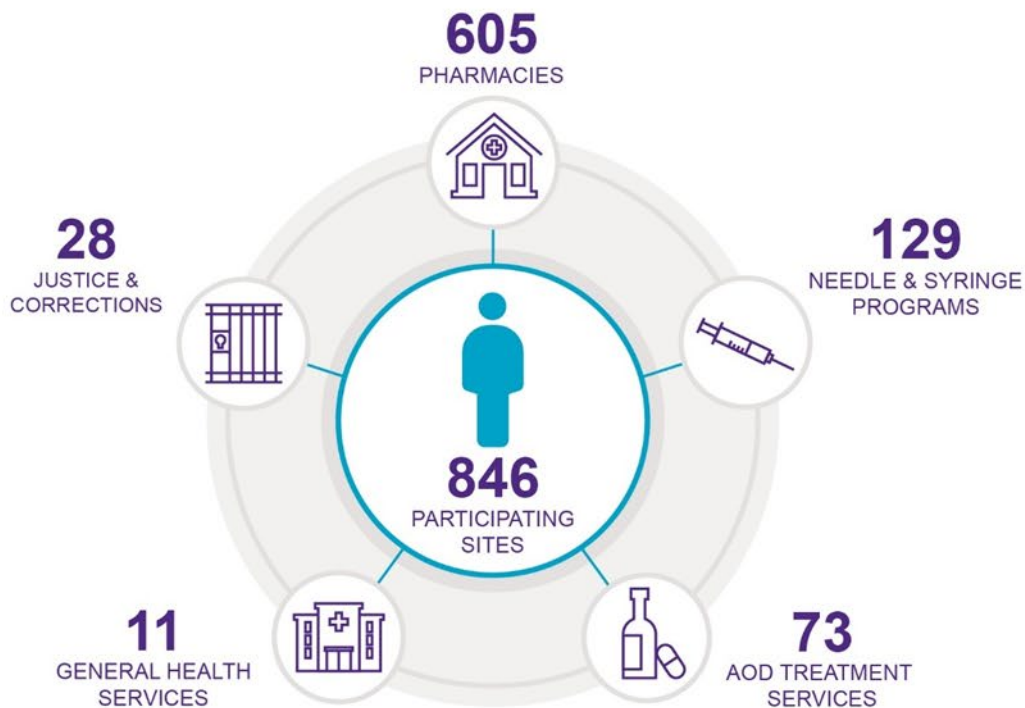
From December 2019, the Australian Government funded a Take Home Naloxone (THN) Pilot subsidised through the Pharmaceutical Benefits Scheme (PBS).

This allowed people at risk of experiencing or witnessing an opioid overdose or adverse reaction to access naloxone without cost, without a prescription and from a variety of settings in NSW, SA, and WA.

DURING THE PILOT...



THN WAS ACCESSED FROM



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Core Evaluation Team

This evaluation was undertaken and this report prepared by Dr Caroline Salom, Dr Joemer Maravilla*, Dr Natalie Thomas*, Dr Jennifer Juckel, and Ms Catherine Daly from the Institute for Social Science Research (ISSR) at The University of Queensland with support from Dr Natasa Gisev and Dr Amy Peacock from the National Drug and Alcohol Research Centre (NDARC) at UNSW Sydney. *We note joint second-authorship for Dr Thomas and Dr Maravilla in recognition of their leading contributions. Professors Lisa McDaid (ISSR), Michael Farrell (NDARC) and Raimondo Bruno (University of Tasmania) provided expert advice and Mr Tom Murphy (NDARC) provided expert statistical support.

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Acronyms

Acronym	Full name
AAS	Authorised Alternative Suppliers
ABS	Australian Bureau of Statistics
AHA	Australian Healthcare Associates (the Pilot administrator)
AIVL	Australian Injecting and Illicit Drug Users League
AIHW	Australian Institute for Health and Welfare
AMA	Australian Medical Association
AOD	Alcohol and other drugs
ASS	Access site staff
CAHMA	Canberra Alliance for Harm Minimisation and Advocacy
CNP	Clean Needle Program (South Australia); referred to as NSP in NSW and WA
CPD	Continuing Professional Development
CPR	Cardiopulmonary resuscitation
DASSA	Drug and Alcohol Services South Australia
ED	Emergency Department
ETHOS	Enhancing Treatment of Hepatitis C in Opioid Substitution Settings Study
GP	General Practitioner
HREC	Human Research Ethics Committee
HSP	Health Service Providers (WA)
IDRS	Illicit Drugs Reporting System
ISSR	Institute for Social Science Research
LHD	Local Health District (NSW)
LHN	Local Health Network (SA)
MH	Mental Health
MME	Morphine milligram equivalents
MSIC	Medically Supervised Injection Centre
NADA	NSW Network of Alcohol and other Drugs Agencies
NDARC	National Drug & Alcohol Research Centre
NDRI	National Drug Research Institute
NDSC	National Drug Strategy Committee
NGO	Non-government organisation
NNRG	National Naloxone Reference Group
NOPSAD	National Opioid Pharmacotherapy Statistics
NSP	Needle and Syringe Program; referred to as CNP in SA

Acronym	Full name
NSW Health	New South Wales Ministry of Health
NUAA	NSW Users and AIDS Association
OAT	Opioid Agonist Treatment (sometimes called opioid substitution therapy OST)
OD	Overdose
ORTHN	Overdose Response with Take Home Naloxone
OTC	Over the Counter
OWG	Opioid Working Group
PIS	Participant Information Sheet
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PHN	Primary Health Network
PPA	Pharmacy Programs Administrator – trading name for Australian Healthcare Associates
PSA	Pharmaceutical Society of Australia
PUPO	People who use prescribed opioids
PUIO	People who use illicit/non-prescribed opioids
PWID	People who inject drugs
RACGP	Royal Australian College of General Practitioners
s90	Refers to community-based pharmacists approved to supply PBS medicines from specific pharmacy premises (approved premises). Approval is provided under section 90 of the <i>National Health Act 1953</i>
s92	Refers to a medical practitioner approved to supply PBS medicines in a particular rural/remote area, where the community does not have convenient and efficient access to these medicines from a PBS approved pharmacy. This approval is provided under section 92 of the <i>National Health Act 1953</i>
s94	Refers to hospital authorities approved to supply PBS medicines under section 94 of the <i>National Health Act 1953</i>
s100	Refers to section 100 of the <i>National Health Act 1953</i> which provides for alternative supply arrangements for specified PBS medicines
SA Health	South Australia Health
SANDAS	South Australian Network of Drug & Alcohol Services
SHPA	Society of Hospital Pharmacists of Australia
SSA	Site-specific authorisation (or governance approval)
TGA	Therapeutic Goods Administration
THN	Take Home Naloxone

Acronym	Full name
UNSW	The University of New South Wales
UQ	The University of Queensland
WAMHC	Western Australia Mental Health Commission
WANADA	Western Australia Network of Alcohol & Other Drug Agencies
WHO	World Health Organization

Glossary

Term	Definition
Access Site	A site (pharmacy or Authorised Alternative Supplier) at which consumers/witnesses can obtain THN under the Pilot
Participating access site	An access site which has provided THN to a consumer or witness on at least one occasion as part of the Pilot
Authorised Alternative Supplier	A site which is not a community or hospital pharmacy, but which has been credentialed to provide THN under the Pilot e.g., a NSP or health service
Community pharmacy	A non-hospital (s90) pharmacy
Consumer	A person who uses opioids, whether prescribed or illicit, and is thus at risk of experiencing an opioid overdose
External initiatives	Initiatives which may be aligned with, but are not part of, the THN Pilot (e.g., initiatives in non-participating jurisdictions)
Goal	The higher order program or sector objective/s that the Pilot is intended to achieve
Illicit opioids	Opioid drugs (e.g., heroin, opium) that are prohibited by law
Impact	Change in broader context as a result of interventions, events or trends; often much longer term
Initiatives	Defined activities undertaken as part of the THN Pilot
Non-prescribed	Describes use of a drug or medication that is not in accordance with the prescription, whether in method or amount of use, or by a person not named in the prescription
Opioid	A class of drugs which act on opioid receptors in the brain; includes illicit drugs such as heroin, pharmaceutical drugs such as oxycodone and morphine) and synthetic drugs such as fentanyl.
Outcomes	Changes expected to occur after the delivery of an output or several outputs; broken down into immediate, intermediate, or long term, with timeframes defined for the Pilot
Output	A defined quantity of events or services provided by the Pilot
Opioid overdose	An occasion on which a person ingests a quantity of opioid that causes an adverse reaction, including respiratory depression, loss of consciousness, vomiting and/or death

Term	Definition
Pilot Administrator	Australian Healthcare Associates, contracted by the Department to administer the THN Pilot
Portal	The electronic portal established by the Pilot Administrator; through which suppliers report supply of naloxone for data collection and receive reimbursement
PBS Prescriber Bag	Medicines subsidised on the Pharmaceutical Benefits Scheme that are available without charge to prescribers for supply to patients for emergency use
Prescribed opioid	An opioid medicine which is prescribed by an approved practitioner
Problem statement	Describes the nature and extent of the problem that needs to be addressed by the Pilot
Program services	Any services provided as part of the THN Pilot
Provision events	Occasions where take home-naloxone is provided to a consumer or witness at an access site as part of the Pilot
The Pilot	The Pharmaceutical Benefits Scheme Subsidised Take Home Naloxone Pilot (the Pilot)
The Department	Australian Government Department of Health
Witness	A person who is likely to observe or witness an opioid overdose, whether they consume opioids or not

Naloxone formulations available through the Pilot (supplier)

Junalox® (Juno)	Ampoules; 400 micrograms in 1ml for intramuscular injection; unit = pack of 5 ampoules
DBL® Naloxone hydrochloride (DBL)	Ampoules; 400 micrograms in 1mL for intravenous injection; unit = pack of 5 ampoules; early formulation
Naloxone Juno® (Juno)	Ampoules; 400 micrograms in 1mL for intramuscular/subcutaneous/intravenous injection; unit = pack of 5 ampoules
Nyxoid® (Mundipharma)	Intranasal spray; 1.8mg in 0.1ml, unit - pack of 2 spray actuations
Prenoxad® (Phebra)	Pre-filled syringes; 1mg/mL in 2mL for intramuscular injection; unit = pack of 1 syringe

Executive Summary

Background

The Australian Government funded a Take Home Naloxone (THN) Pilot as part of the Pharmaceutical Benefits Scheme (PBS), allowing people at risk of experiencing or likely to witness an opioid overdose to access naloxone without a prescription, at no cost to themselves, and from a range of pharmacies and other approved sites in New South Wales, South Australia and Western Australia.

In September 2019, the Institute for Social Science Research (ISSR) at The University of Queensland (UQ), was engaged by the Australian Government Department of Health (the Department) to conduct an evaluation of the PBS-Subsidised THN Pilot (the Pilot) to inform policy and practice in preparation for a potential national roll-out of THN.

This report presents the final Evaluation findings, covering the implementation of the Pilot from commencement on 1 December 2019 up until 30 June 2021, noting that the Pilot is intended to continue until 30 June 2022.

Scope

This evaluation aimed to:

- assess the effectiveness of the Pilot as a mechanism for improving uptake and use of THN
- assess the appropriateness of the Pilot in reducing unintentional opioid overdose deaths, and
- identify opportunities to strengthen the Pilot for future national roll-out.

Evaluation Approach

The Evaluation used a mix of primary data collection activities to address the key evaluation questions. Both quantitative and qualitative data were collected from people who participated in the Pilot as consumers (recipients of THN) and front-line staff of sites where naloxone was provided (access site staff). Structured consultations with sector representatives and systematic analyses of Pilot documentation were also undertaken. Analyses of administrative and research data relating to the supply and use of opioids and naloxone were also conducted.

Key findings

The key findings of the evaluation are described below under each of the overarching evaluation questions. These findings were used to inform recommendations as to core elements for a future national roll-out and strategies to support these.

Was the THN pilot implemented as planned?

- Most key Pilot activities were implemented as planned, including the establishment of policy and systems infrastructures, legislation and supply/distribution mechanisms, and the recruitment, credentialling and training of access sites and staff.
- Implementation varied considerably between participating states; it was constrained by jurisdictional policy structures governing supply arrangements but supported by the maturity of existing naloxone programs.
- Key organisations were advised about the Pilot early in its implementation, but no public launch or awareness campaign took place to promote THN to the wider public.
- The primary focus of the Pilot remained on people who use illicit opioids.
- The number of site registrations increased steadily to a total of 1,480 by 30 June 2021; 57% of these sites (n=846) provided THN on at least one occasion during this period.

- Coordination between state implementing agencies and the Department was evident but demonstrated the importance of state-level support mechanisms for implementation.
- Point of supply promotional materials were provided but supplementary activities were needed to raise awareness of the Pilot across agencies and in the community.
- Key assumptions on which the Program Logic and Theory of Change were based held for the Pilot's implementation, apart from a limited focus on providing THN beyond the AOD sector.
- Unexpected external factors such as COVID-19 restrictions on product imports reducing naloxone stocks in March 2020 and a challenge to the THN legislation in May 2020 caused significant but temporary interruptions to Pilot activities and supply chains.

Did the THN Pilot achieve improved access?

- More occasions of naloxone supply were recorded: 27,955 supplies over 18 months of the Pilot compared to 3,579 supplies through the PBS in the previous 2 years.
- 1480 sites registered for the Pilot but only 846 (57%) provided THN during the evaluation period; the active participation rate for AAS was higher (82.5%) than that of community pharmacies (52%).
- More settings provided THN; pharmacies, specialist alcohol and other drug (AOD) services, justice and correction settings, and general health services such as hospitals.
- The majority of non-pharmacy THN sites were providers of AOD services; specialist pain clinics did not engage with the Pilot.
- More people received naloxone during the Pilot, both at risk of experiencing opioid overdose and people who may witness an overdose. Most identified as using prescribed opioids.
- The proportion of people at risk from pharmaceutical opioids who received naloxone increased from 0.15% to 1.63%.
- Consumers accessed naloxone close to home, 55% within their home postcode, and THN was available in city, regional and very remote areas.

What impact did increasing access have on the uptake and use of THN?

- More naloxone was provided to individuals: 43,212 units of THN were supplied in NSW, SA and WA during the Pilot, compared to 4,495 across Australia over the preceding 4 years
- Nasal spray comprised 84% of THN supplied and was the preferred formulation, but pre-filled syringes remained in demand, particularly for refills.
- Having naloxone accessible at services outside the AOD sector (e.g., community pharmacies) provided opportunities to raise awareness of overdose risk among people who did not use illicit opioids but were themselves at risk or likely to witness another person's overdose.
- One in five people who received THN refilled their supply at least twice in a year; 65% of refills were due to use to reverse an overdose.
- The Pilot has enabled at least 1,649 overdose reversals, the equivalent of 3 reversals per day.

What was the impact on access sites participating in the pilot?

- Most staff interviewed were very positive about the THN Pilot, noting the positive effects it had on their organisation's ability to provide THN.
- Most pharmacy staff found the THN Pilot's impact on their workload was minimal, and successfully incorporated it into existing workflows and processes.

- Most staff believed the training and credentialing systems equipped them with knowledge and skills to distribute naloxone to clients. Many expressed a preference for online training, or a choice of online or face-to-face where possible.
- Staff in AOD services and community pharmacies considered providing THN to be part of their core role, but organisations new to THN commented on the lack of funding to assist implementation.
- The impact on access sites differed by state, and by the different types of access sites that were engaged and credentialed as part of the Pilot.
- There was limited engagement by hospital pharmacies in some jurisdictions, due to barriers to implementation in these settings. There was also limited engagement by pain clinics, primary care, and mental health settings.

Were there any barriers to increasing access and/or uptake of THN? How could these barriers be overcome?

- The Pilot addressed or partially addressed a number of barriers to access and/or uptake of THN, including: cost, availability in a range of settings, access to naloxone through a range of sites, consumer knowledge of how to use naloxone, and staff knowledge of THN.
- Barriers that still need work to address include: stigma about people who use opioids, consumer and community awareness of THN, awareness of overdose risk, availability of THN at desired locations for access, and other barriers to carriage of naloxone such as fear of police response to naloxone, and negative perceptions about naloxone.
- Recommendations from consumers and access site staff to overcome barriers included public awareness campaigns and advertisement, maintaining and expanding access sites and modes of access of THN, and use of peer networks.
- Key facilitators of success of the Pilot included: the removal of cost as a barrier to naloxone; the broad appeal of Nyxoid® nasal spray formulation enhancing uptake; the activities of local and state level champions for the Pilot and local health promotion networks in promoting the Pilot; cross-sectoral collaboration to engage with potential THN consumers; increased staff knowledge and ability to provide THN; and the increased range of settings for access of THN introduced through the Pilot. Additionally, effective engagement of the AOD sector and acceptance of naloxone within the sector; and the effective work of peer organisations, networks and word of mouth helped engagement with the Pilot.

Were there any unintended consequences of increasing access to naloxone?

These risks were considered in the evaluation of the PBS-Subsidised THN Pilot. We found:

- No evidence of supply when not necessary. There were instances, particularly early in some pharmacies' involvement in the Pilot, where staff recommended naloxone to all clients who received prescribed opioid medicines, resulting in dispensing of large amounts of naloxone. This would not be considered 'unnecessary supply', because these were individuals at potential risk of overdose, albeit some may not have been deemed at 'high risk'.
- No evidence that people used opioids in a riskier manner knowing that naloxone was available. Our interviews, those of the IDRS, and of previous evaluations (e.g., the ORTHN trial) did not find any increase in use related to naloxone availability.
- No evidence that bystanders were less likely to call an ambulance. Our interview data indicates that 65% of participants who witnessed an overdose called an ambulance as part of overdose responses. Findings of the ORTHN trial evaluation were noted no change to calling of ambulance.
- No evidence of unsafe administration. Our interview data did not note any adverse situations. The inclusion of the nasal spray formulation in the Pilot and its widespread

uptake is likely to have reduced any potential risk associated with administration by injection.

What needs to be considered in relation to a national roll-out?

A future national roll out of Take Home Naloxone should include the following core elements:

1. **Ensure continuity:** Commit to implementing the national roll-out of THN on a permanent basis rather than as a Pilot and ensure continuity between the Pilot and national roll-out of THN.
2. **Ensure free access to THN:** Retain the ability for naloxone to be fully subsidised on the PBS.
3. **Ensure access without a prescription:** Retain the ability for naloxone to be provided without a prescription and without a PBS co-payment.
4. **Ensure broad availability:** Retain and further expand the ability to access THN from a range of sites, including community pharmacies, NSPs and other AOD services, on exit from correctional settings, and further settings.
5. **Ensure coordination:** Joint working between the Australian Government and state and territory governments.

Supporting elements that are important to facilitate a national roll-out include:

1. **Awareness and perceptions of THN**
 - Build awareness and reduce stigma through public awareness campaigns and targeted promotion
 - Build awareness amongst professionals within and beyond AOD sector
2. **Engagement and communication**
 - Identify and engage with professional groups to encourage participation within and beyond the AOD sector
 - Consult across a wide range of sectors and encourage partnerships
 - Identify and support local champions for THN
 - Build further capacity for peer organisations and networks
3. **Funding and resources**
 - Funding for a national coordinator position
 - Resource implementation at state/territory level
 - Establish formal communication mechanism and/or national working group
 - Develop national resources to guide implementation
4. **Training and education**
 - Standardise training for THN providers, and offer online/on-demand
 - Include naloxone in professional competencies/CPD
 - Standardise brief education materials for consumers and include information to address consumer concerns around ambulance and police attendance
5. **Program monitoring and data collection**
 - Decide on minimum data for reporting on THN supply

- Leverage existing data collection and funding arrangements to facilitate data collection

Conclusions

In summary, most of the key THN Pilot activities were implemented as planned. The Pilot improved access to take home naloxone among a large number of people, who represented each of the intended target populations. The evaluation recorded 27,955 occasions of naloxone supply over 18 months of the Pilot, compared to 3,579 supplies through the PBS in the previous 2 years. Removal of cost and prescription barriers, availability through a broad range of access site types of different naloxone formulations were key to the Pilot's success. Naloxone was successfully used to resuscitate people in opioid overdose situations. The pilot enabled at least 1,649 overdose reversals, saving an estimated three lives each day over the duration of the Pilot to date.

In some areas, the Pilot did not fully achieve all its original intentions, due in part to the challenges of rapidly scaling up existing operations with limited resources, and an initial focus solely on the alcohol and other drug sector. There were also significant challenges in attempting to implement a major new health initiative in the competing environment of the COVID-19 pandemic.

It is very strongly recommended that Take Home Naloxone be expanded and extended into an ongoing national program that forms an integral part of opioid safety stewardship. There is an established need to address the significant and ongoing risks of opioid overdose, opportunity to include an evidence based effective intervention, and strong impetus among the health sector to implement such a program.

The significant learnings from this Pilot should be taken forward, and the opportunity to continue learning from program operations ensured.

1. Introduction

1.1 Background

In response to rising concern over the rate of opioid overdose deaths in Australia, the Australian Government funded a Pilot program to provide Take Home Naloxone (THN) subsidised through the Pharmaceutical Benefits Scheme (PBS). This Pilot allowed people at risk of experiencing or likely to witness an opioid overdose or adverse reaction to access naloxone without cost, and without a prescription, from a variety of settings, including pharmacies and other authorised alternative sites in New South Wales (NSW), South Australia (SA) and Western Australia (WA).

The Institute for Social Science Research (ISSR) at The University of Queensland (UQ) was contracted by the Australian Government Department of Health (the Department) to conduct an evaluation of this Pharmaceutical Benefits Scheme Subsidised Take Home Naloxone Pilot (the Pilot). This work included developing an Evaluation Framework and analysing the extent to which the activities of the Pilot contributed to achieving its aim and objectives. The forward purpose of the Evaluation is to inform policy and practice in preparation for a national roll-out of THN.

This report presents the Evaluation findings, covering the period from the Pilot's commencement on 1 December 2019 until 30 June 2021, noting that the Pilot will continue until 30 June 2022.

It provides the background of the Evaluation (Chapter 1) and an overview of the evaluation approach, including the Program Logic and Theory of Change, key evaluation activities and the impact of COVID-19 on evaluation activities (Chapter 2). Chapters 3-8 present the findings of the key evaluation questions. Finally, the overall considerations for development of a national take home naloxone program (THN) are provided in Chapter 9, which also notes the limitations of the Evaluation. Chapter 10 provides concluding remarks.

The following supplementary information is provided as appendices, including:

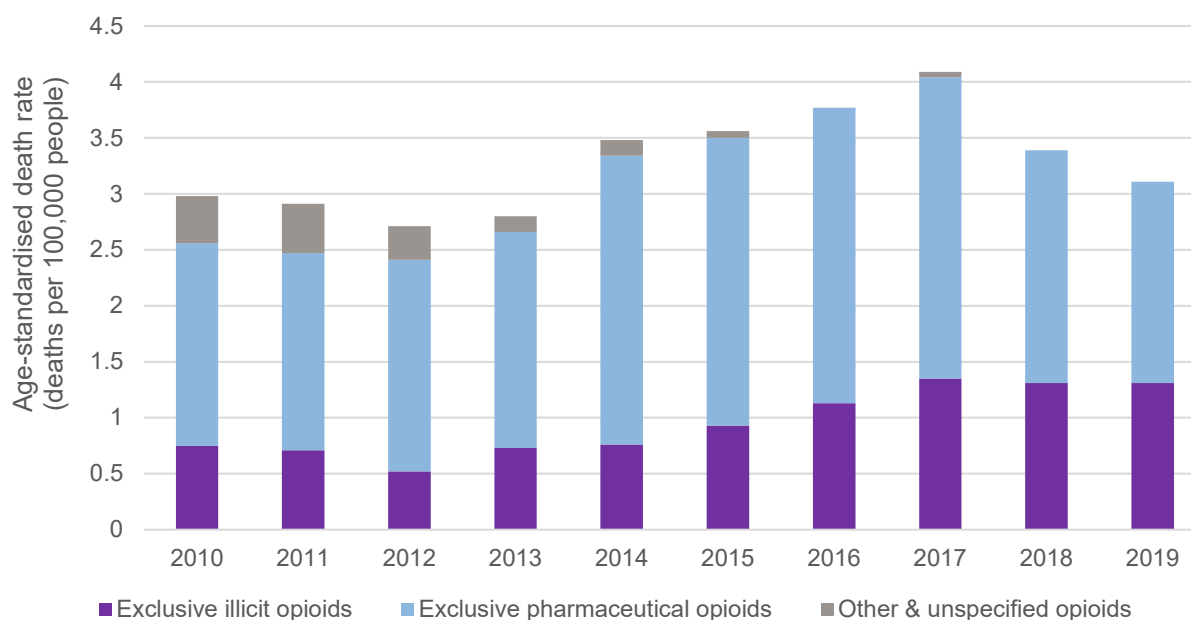
- A. Summary of current Australian THN programs (apart from the Pilot)
- B. Summary of international publicly funded THN programs
- C. Indicator matrix developed for the Evaluation
- D. Comparative prescribing of medications prior to and during the Pilot
- E. Stories from consumers about the use of THN for overdose reversals

1.1.1 Ongoing risks and costs of opioid overdose in Australia

Preliminary estimates indicate there were 1,865 drug-induced deaths of any intent among Australians in 2019^a, with opioids listed as the underlying cause in 1,129 (60%) of these, equivalent to approximately three opioid-involved deaths per day (1). In 2019, 56% of opioid-induced deaths were attributed to pharmaceutical opioids only (e.g., oxycodone, morphine), 32% to illicit opioids (i.e., heroin) only, and 11% to both. The majority (78%) of opioid-induced deaths were considered unintentional.

Concerningly, the rate of unintentional opioid-induced deaths has been trending upwards since 2006, from an age-standardised rate of 1.6 deaths per 100,000 people in 2006 to 4.3 deaths per 100,000 people in 2016 (the most recent year with finalised data; preliminary estimate of 3.6 deaths per 100,000 in 2019). Pharmaceutical opioids are involved in the majority of these deaths (refer to Figure 1 below).

Figure 1. Opioid-induced deaths in Australia, 2010 – 2019

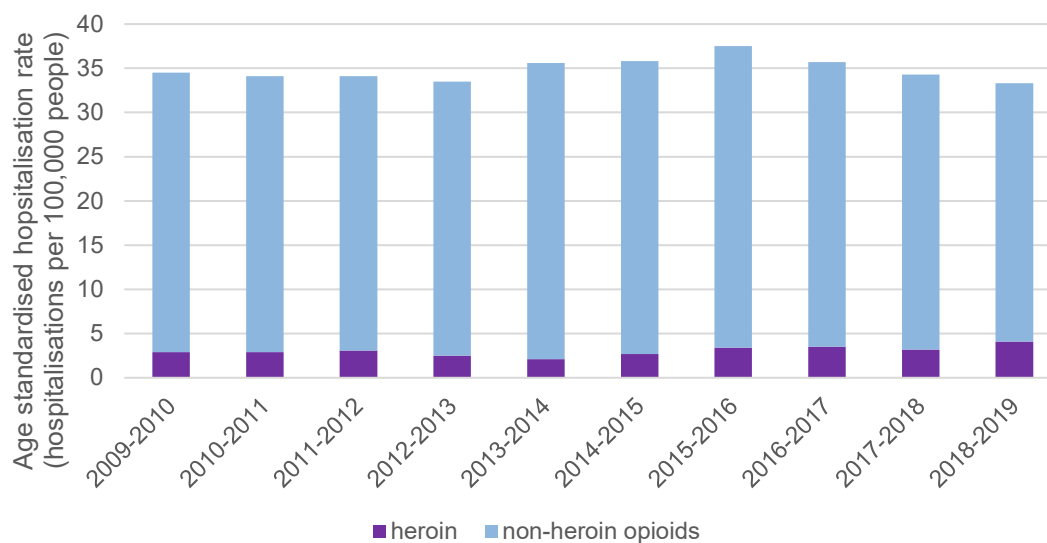


Source: NDARC Bulletin: Trends in drug-induced deaths 1997-2019 (1)

Hospitalisations in Australia due to opioid poisoning also show a steady increase, peaking at an age-standardised rate of 17.6 hospitalisations per 100,000 people in 2017 (see Figure 2), before decreasing slightly to 15.7 hospitalisations per 100,000 people in 2019 (2).

^a Causes of death data undergo a revision process. Data for 2018 and 2019 are preliminary and subject to another two rounds of revision. Data for 2017 are revised and subject to another round of revision. Data for 2016 and earlier years are final.

Figure 2. Opioid-related hospitalisations in Australia, 2009/10 – 2018/19



Source: NDARC Bulletin: Trends in drug-related hospitalisations in Australia 1999-2019 (2)

In addition to the health burden, opioid-related hospitalisations and deaths in Australia incur significant costs each year. Estimation of the social costs placed the net tangible cost of the 2,203 opioid-related deaths for 2015-2016 at \$2.49 billion dollars, and a cost of \$249.3 million for nearly 32,000 hospital separations (3). Reduction of such presentations will incur a major cost saving to the health system as well as reducing the human cost, and there is an obvious imperative to seek prevention of these deaths.

Prescribed use of opioid medicines continues to be widespread. Since 2013, approximately three million Australians have been dispensed prescription opioids each year (4). A recent review estimated that opioid doses of over 50 morphine milligram equivalents (MME) per day increase the risk of unintentional opioid overdose by a factor of 3.87, and doses over 100 MME/day by 4.27 (5). The Centers for Disease Control and Prevention (CDC) recommends that the risks of doses ≥ 50 MME/day be considered and doses ≥ 90 MME/day be avoided where possible (6). This 50MME/day threshold places an estimated 22% of all Australians receiving prescription opioids at risk of potential overdose (4).

People who regularly use illicit opioids are also at risk of overdose. It is difficult to estimate the size of this population. The 2019 National Drug Strategy Household Survey records 2.8% of the Australian population reporting recent illicit use of opioids (including extra-medical use of pharmaceutical opioids), and 0.1%, recent use of heroin (7). This is however widely acknowledged as a significant underestimate, due to under-reporting by participants, and under-representation in survey participants of people who use illicit drugs. (8, 9). A recent study estimated that people who injected opioids daily were at two-fold higher risk of overdose than those who did not inject (10). People on longer-term opioid agonist treatment (OAT), however, were found to be significantly at lower risk, although diversion of OAT creates a separate overdose risk.

Importantly, these risks, which may relate to either prescribed or illicit consumption, extend beyond major cities into Australia’s regional areas. Analyses of drug metabolites in wastewater between December 2020 and February 2021 confirm that heroin use is higher in cities (approximately 7 doses/1000 people/day were detected, compared to 2.75 doses/1000/day in regional areas)(11). However, similar analyses of oxycodone and fentanyl metabolites (which do not distinguish between prescribed and non-prescribed use) show higher use in regional areas of NSW, SA and WA (approximately 8.25 doses/1000 people/day compared to 4.5 doses/1000

per day in capital cities for each). Coupled with the lower availability of tertiary health services in regional and remote areas, the risk of opioid overdose in these areas thus requires significant attention.

1.1.2 Naloxone programs to address opioid overdose in community settings

Naloxone is a competitive opioid receptor antagonist that has been successfully used to counter the effects of opioid overdoses for decades, typically in emergency and first-response settings. Programs making naloxone more broadly available, such as THN programs, have shown promise in increasing access and use of this life-saving medicine. The following section provides a brief overview of learnings from evaluations of international and Australian THN programs that may be relevant for consideration.

1.1.2.1 International programs

The World Health Organization (WHO) recommends that “people likely to witness an opioid overdose should have access to naloxone and be instructed in its administration to enable them to use it for the emergency management of suspected opioid overdose” (12). Internationally, naloxone is available in many countries: peer distribution of naloxone is available in 15 countries, with variable funding sources including local non-government organisations and international donors (13). The WHO is currently funding, implementing and evaluating take home naloxone initiatives in Kazakhstan, Kyrgyzstan, Tajikistan, and Ukraine. In the US, naloxone is available through a range of prescription and community-based programs, but there is currently no national publicly funded system for THN (14, 15). The World Health Organization (WHO) recommends that “People likely to witness an opioid overdose should have access to naloxone and be instructed in its administration to enable them to use it for the emergency management of suspected opioid overdose” (12). Internationally, naloxone is available in many countries: peer distribution of naloxone is available in 15 countries, with variable funding sources including local non-government organisations and international donors (13). The WHO is currently funding, implementing and evaluating take home naloxone initiatives in Kazakhstan, Kyrgyzstan, Tajikistan, and Ukraine. In the US, naloxone is available through a range of prescription and community-based programs, but there is currently no national publicly funded system for THN (14, 15).

Despite the increasing availability of naloxone programs, there are fewer examples of large-scale publicly funded provision of naloxone that have been evaluated. Those examples that do exist can provide important lessons for the Australian public provision of THN. National THN programs are publicly funded in Canada, Italy, Northern Ireland, Scotland and Wales (16-19) All these jurisdictions provide THN for free from community organisations, harm reduction and addiction services, outreach, and other relevant services, within health systems that are broadly comparable to Australia. A very recent report on the WHO naloxone program demonstrates successful implementation, in line with WHO recommendations, of community-managed naloxone in low- and middle-income countries (12). See Appendix A for a summary of international THN programs. Evaluations of these programs have highlighted a number of key features for success in these programs, discussed below.

1.1.2.1.1 Need for strong guidance from government or guiding agency

International THN programs identify a need for strong guidance from governments and/or guiding agencies, as well as clear and thorough procedures which enable program success. An evaluation of Italy’s THN model recommends that governments give clear operative guidelines to agencies that include THN, in order to stabilise criteria, guarantee availability nationally and enforce the importance of counselling and education (19). A Scottish evaluation identified that having a steering group guiding the program was helpful at the strategic local level (20). In Wales, it was recommended that strong guidance be given at implementation through official

detailed documentation, with procedures established to enable program success independent of specific individuals involved (21). Research from Canada also identified a lack of guidelines for Canadian pharmacists to assist with identifying appropriate clients for THN distribution and education (22).

1.1.2.1.2 Opt out and follow up systems

Research from Canada, where numbers of prescription opioid-related deaths are high, recommends that all patients taking opioid medications should be provided with THN and counselled by a pharmacist through an opt out system (22). Under such a system, all opioid prescriptions above a defined threshold trigger automatic provision of naloxone; the pharmacist must opt out to not supply. This automatic dispensing imperative removes the need for pharmacists to undertake a risk assessment in order to dispense THN (22). An opt out system was also recommended by Public Health Wales (2020) for THN provided through community pharmacy NSP services (23).

Research from Northern Ireland and Canada also recommended that THN providers develop a follow up system so that patients are contacted about resupply and kit expiry and have education reinforced (22, 24). Canadian recommendations suggest that pharmacies dispensing naloxone follow-up patients at 3 months and 1 year after THN dispensing through an alert system (22).

1.1.2.1.3 Training and education

THN provision generally occurs alongside training and education on its use. A Scottish evaluation recommended that a brief 1:1 intervention approach be expanded in scope to reach more of the target population, shortening the length of training from 1.5 hours to 15 – 20 minutes (20). Likewise, the evaluation in Wales also recommended that 1:1 and ad hoc training be used more widely, and that training should be kept short, as lengthy training sessions may act as a deterrent (21). Both of these studies involved use of injectable naloxone, which has been found to require more training time than intranasal naloxone (25). Evaluation of the WHO naloxone programs demonstrated the utility of a cascading train-the-trainer model to enable greater reach into the target populations (12).

Training and promotion of THN which addresses the myths of legal consequences was recommended in Northern Ireland, where fear of reprisals, searches and social services involvement for THN consumers with children was identified as a barrier to uptake and use of THN (24).

1.1.2.1.4 Promotion of THN through media, social media and advertising

In Italy, lack of public awareness was reported as an impediment to widespread uptake of THN, despite it being broadly available at no cost to recipients. Media and social media campaigns were identified as an opportunity for public education on naloxone, with the aim of making it an everyday word and reducing associated stigma (19). In Northern Ireland, advertising through GP surgeries, pharmacies, hostels and prisons was recommended to improve public education and awareness (19, 24). In Northern Ireland, advertising through GP surgeries, pharmacies, hostels and prisons was recommended to improve public education and awareness (24).

1.1.2.2 Australian THN programs prior to the PBS-Subsidised THN Pilot

The first Australian THN program was introduced in the ACT in 2011. Since then, programs varying in scope, duration and focus have been established in each State and Territory. A summary of THN programs in Australia, outside of the THN Pilot, can be found in Appendix B.

A review of evaluations of Australian THN programs prior to the 2019 PBS-subsidised THN Pilot shows that THN programs were effective in increasing appropriate responses to opioid overdoses (26). We identified a number of themes across evaluations of those programs that may be considered for this evaluation, discussed below.

1.1.2.2.1 Multiple settings are viable

Evaluations of THN programs in the ACT, NSW, Victoria and WA have found that naloxone can be safely and appropriately distributed in both medical and non-medical (including justice) settings within an Australian context (26-31).

THN programs across Australia have also looked to innovative methods of distributing naloxone, with the WA Peer Naloxone Education Project (2013-2015) offering brief intervention/education and postal THN supply, and the long-standing program run in the ACT by the Canberra Alliance for Harm Minimisation and Advocacy (CAHMA) now (2021) offering THN delivery and brief intervention at the client's home or another location (32, 33).

1.1.2.2.2 Funding challenges

While some state programs have since secured ongoing funding from their respective governments (e.g., ACT and Victoria), many THN access sites received no additional funding for supplying THN, instead using existing resources and redirecting resources from existing budgets. The evaluation of the ACT program noted that purchase of naloxone accounted for less than one-fifth of the program delivery costs, with personnel costs playing a significant role (28, 34).

1.1.2.2.3 Training and education for naloxone recipients

Across the ACT, NSW (prior to the Pilot), Victoria and QLD, training which lasted between 30 minutes and 2 hours depending on jurisdiction was deemed too lengthy, with a brief intervention model of between 10 and 20 minutes recommended and implemented in many jurisdictions (28, 34). This applied for both the injectable and intranasal formulations, with research on the latter showing that less than 10 minutes training could be sufficient for successful overdose reversal (25, 34). Evaluations from these jurisdictions also recommended that naloxone training and provision should occur across a wide range of formal, informal and opportunistic settings (28, 34). Refresher or follow-up training was recommended to reinforce the education provided, as some knowledge was not retained by participants in the months following (27, 28, 33).

1.1.2.2.4 Reinforcement of emergency care as part of overdose responses

Reluctance to call an ambulance during an overdose event was recorded in evaluations across the ACT, NSW and WA, with concerns including police involvement, drawing attention to (illicit) drug use or involvement in overdose situation, cost of the ambulance and the witness judging that the individual who had overdosed had recovered (27, 28, 33). Training which reinforces the importance of calling an ambulance was identified as a manner to address these barriers, with further education explicitly addressing these concerns also recommended (27, 28).

1.2 Establishment of the PBS-Subsidised Take Home Naloxone Pilot

Prior to the commencement of the THN Pilot on 1 December 2019, naloxone was (and continues to be) available from community pharmacies in all states and territories subsidised under the Pharmaceutical Benefits Scheme (PBS). Naloxone ampoules (sponsored by Juno Pharmaceuticals and Pfizer Australia), pre-filled syringes (sponsored by Phebra) and nasal sprays (sponsored by Mundipharma) are available on the PBS as an unrestricted benefit when prescribed by a medical practitioner or a nurse practitioner. This listing means that in 2021, patients with a PBS prescription for naloxone pay a maximum co-payment of \$41.30 per script (providing five ampoules, or one pre-filled syringe or two nasal sprays), with concessional patients paying \$6.60. As naloxone is a Schedule 3 'Pharmacist Only' medicine, it has also been available since 2016 in all states and territories *without a prescription* over the counter (OTC) from pharmacies, but at varying cost, and uptake of OTC naloxone under these conditions was low (35). Naloxone is also PBS listed through the 'prescriber bag'. This means that the medicine can be provided without charge to eligible prescribers for immediate administration or emergency use. Requirements for a prescription, or the cost without a prescription, have been identified in earlier evaluations as significant barriers to widespread uptake of naloxone (36).

In February 2019, the Australian Government announced funding of \$10 million for a pilot to increase the access to and availability of naloxone for people at risk of experiencing or witnessing an opioid overdose. In this Pilot, which commenced on 1 December 2019, the Australian Government made naloxone available for free, without a prescription, from pharmacies and other approved sites in NSW, SA and WA.

The legislation that supports the THN Pilot, the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (the Special Arrangement) allows for naloxone to be supplied outside of the usual PBS supply arrangements described above in NSW, SA and WA. Under the THN Pilot arrangements, individuals are not charged a co-payment for naloxone (i.e., it is supplied free of charge), and they do not need to visit a medical or nurse practitioner to get a prescription. A patient cannot be charged any additional private fees for naloxone supplied under the Pilot. Also specific to the Pilot is that in addition to availability through pharmacies, the PBS listed naloxone can be accessed from a broader range of settings (Authorised Alternative Suppliers, or AAS) such as hospitals and other authorised persons or organisations such as needle and syringe programs, alcohol and other drug treatment centres or correctional release programs.

The Pilot targets a broad range of potential THN consumers. In addition to people who use illicit opioids such as heroin, priority beneficiaries of the Pilot include individuals who are taking prescription opioids to manage chronic pain. People who may witness an opioid overdose are another priority population who can access naloxone for free and without a prescription as part of the Pilot. This group may include peers, family and community members, as well as in-home healthcare and support staff, treatment providers, custodial release program officers and first responders.

This Pilot was implemented in NSW, SA and WA, complementing existing state-based programs and infrastructures and in partnership with the NSW Ministry of Health (NSW Health), Drug and Alcohol Services South Australia (DASSA) and the Western Australia Mental Health Commission (WAMHC), respectively. Australian Healthcare Associates (AHA) was contracted as the administrator for the Pilot to manage a range of administrative functions including registration of participating sites, claiming and reimbursement arrangements.

1.3 Key evaluation questions and report structure

The Evaluation of the Pilot was designed by ISSR in collaboration with the Department, and is structured around the following agreed key evaluation questions:

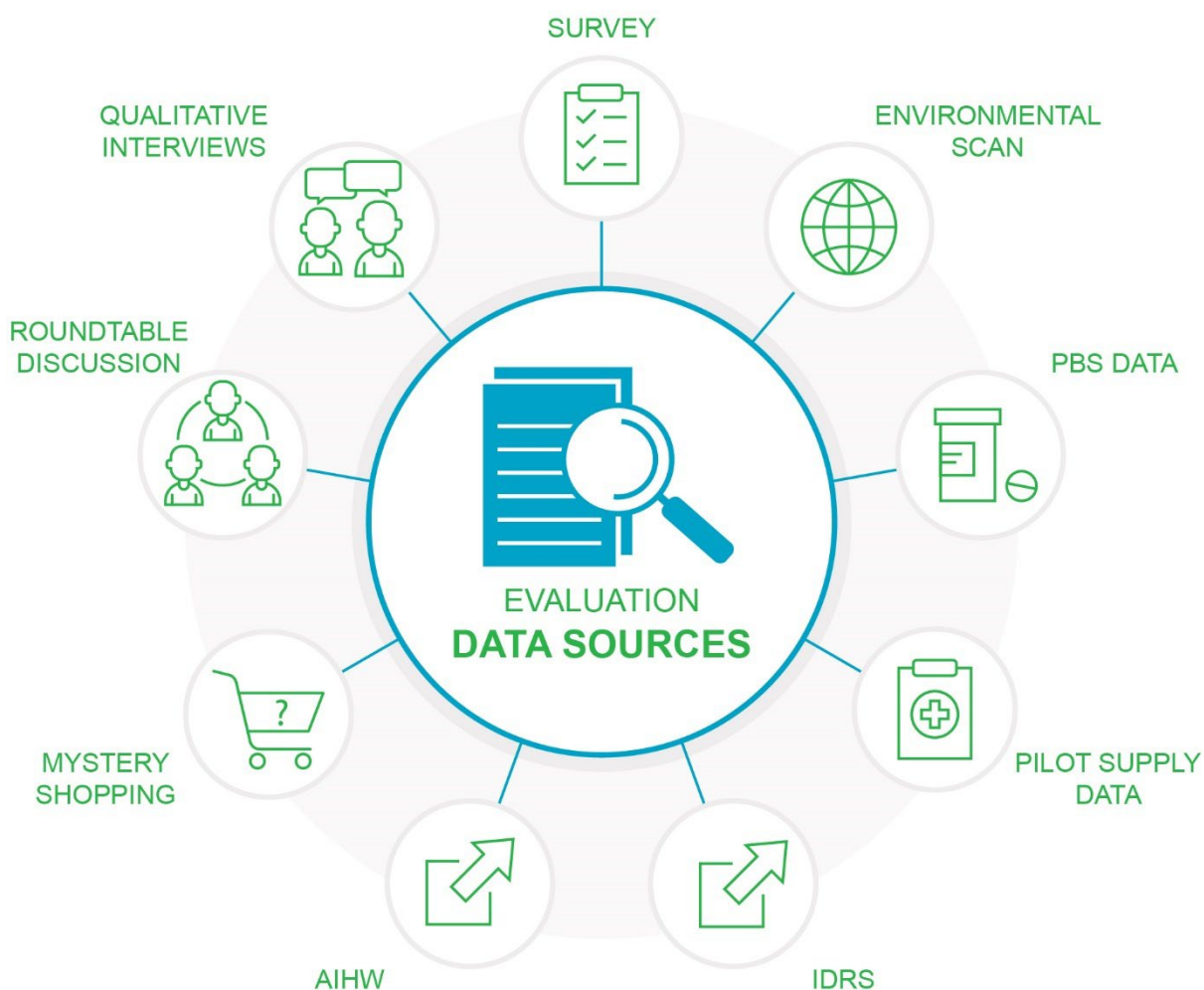
1. Was the THN Pilot implemented as planned?
2. Did the THN Pilot achieve improved access?
3. What impact did increasing access have on the uptake and use of THN?
4. What was the impact on access sites participating in the Pilot?
5. Were there barriers to increasing access and/or uptake of THN? How could these be overcome?
6. Were there any unintended consequences of increasing access to naloxone?
7. What needs to be considered in relation to a potential national roll out?

These questions were used to inform the evaluation approach, as described in Chapter 2. In the following Chapters (3-8), we report on the evaluation findings against these key questions. These findings are then synthesised to inform our recommendations for considerations for a potential national roll out, which is discussed in Chapter 9.

2. Overarching Evaluation Approach

Key points

- This Evaluation used a multi-disciplinary approach to address the key evaluation questions, and was designed to build on, rather than duplicate, previous evaluations.
- The Program Logic and Theory of Change informed the design of the Evaluation.
- Multiple primary data sources inform the findings presented throughout this report: 320 consumer interviews, 66 frontline staff interviews, 24 mystery shopping events and 25 roundtable consultations of senior sector representatives, in addition to point-of-supply data. Research and administrative data were also examined.



2.1 Evaluation approach

The Pilot was designed to address the needs of multiple stakeholders: people who use illicit drugs and/or prescribed opioid medicines; their families, friends and carers; organisations that support them; emergency and other healthcare organisations and governments. The Pilot's evaluation, therefore, required a balanced multidisciplinary approach to incorporate findings relevant to all these stakeholders. The evaluation team worked with stakeholders while conducting monitoring activities to incorporate implementation variabilities between the states and changes across the duration of the Pilot. We undertook the following as part of the evaluation:

- Analysis of the effectiveness of the Pilot
- Analysis and consolidation of findings from the individual state operations during the Pilot (the evaluation was designed to build on, but not duplicate, the results of previous evaluations of other take home naloxone programs)
- Consideration of other relevant programs or services as they relate to the Pilot (e.g., referral pathways, shared care approaches etc.)
- Consultation with key stakeholders regarding the optimal components of a national roll-out of THN, and how this could be monitored.

To address the key evaluation questions agreed upon during the design phase of the evaluation, we triangulated data from a number of sources and perspectives.

The evaluation scope was limited (as agreed with the Department) to exclude exploration of:

- The clinical effectiveness of naloxone in reversing opioid overdoses (or relative efficacy of various formulations of naloxone), as this was well established in the literature
- The content of training provided to access sites and the content of the Brief Intervention/Education/training provided at access sites to participants, as this had been examined in previous evaluations in Australia and continued to be a state-based responsibility
- Analysis of the cost-benefits or value-for-money of the Pilot
- Analysis of change in the rates of drug-related deaths that could be attributed to the Pilot, as the required data (drug-related deaths) were not available prior to the end of the evaluation period
- Examination of naloxone-related activities that were not part of this Pilot
- Analysis of the legislative environments and requirements that enabled the Pilot in each state, these having been covered in a report commissioned by the Department from the Burnet Institute in mid-2019 (37).

2.1.1 Program Logic and Theory of Change

The evaluation is based on a formal Program Logic and Theory of Change, which were developed for the Pilot by the Evaluation Team in conjunction with the Department and core stakeholder group and agreed as the basis for the Evaluation Plan. The principal elements are outlined below.

The agreed **Goal** of the Pilot is to improve the access to and uptake of naloxone by a range of end-users by addressing these barriers. The **Theory of Change** for the Pilot suggests that:

- Promoting the importance of naloxone to people who use prescription and/or illicit opioids will increase community awareness of naloxone as a medication to counteract opioid overdose and increase the number of people who wish to access naloxone
- Removing the cost of naloxone and increasing the number and type of access sites will increase the number of people who are able to access naloxone
- Increasing the number of people (both consumers and witnesses) who access naloxone and are comfortable using it to counteract opioid overdoses will contribute to the lowering of unintentional opioid overdose deaths.

The **Program Logic** (Figure 3) represents the expected activities (outputs), the anticipated outcomes of these, and desired impact of the THN Pilot. It specifies assumptions on which this Logic is based, and accepts that a range of external factors beyond the control of the Pilot may also influence events, processes and outcomes described.

The following terms are used to describe the components of the Program Logic:

- **Problem statement:** describes the nature and extent of the problem that needs to be addressed by the Pilot
- **Inputs:** Financial, human and other resources used to undertake activities which are expected to produce outputs
- **Output:** A defined quantity of items, events and services provided by the Pilot
- **Outcomes:** Changes that are expected to occur after the delivery of an output or several outputs; outcomes are broken down into early, intermediate, and long term, with timeframes defined for the Pilot
- **Impact:** Change in context as a result of interventions, events or trends; often much longer term (3-5 years post-intervention), and may not be expected to be observed within the timeframe of the Pilot

Our evaluation examined whether the expected activities took place and the expected outcomes occurred. We assessed whether the assumptions articulated for the Program Logic held over the course of the Pilot, and whether the specified external factors did affect its implementation (see Section 3.2).

Noting the above definition, we would not expect to see the impacts for this Pilot (*reduction of opioid overdose deaths and change in patterns of opioid use*; refer to Figure 3) during the timeframe of this Pilot. In addition to this expectation, there is typically a lag of 2-3 years in receiving final estimates of drug-induced deaths^b, meaning that evidence of any such changes will not be available for several years after that time.

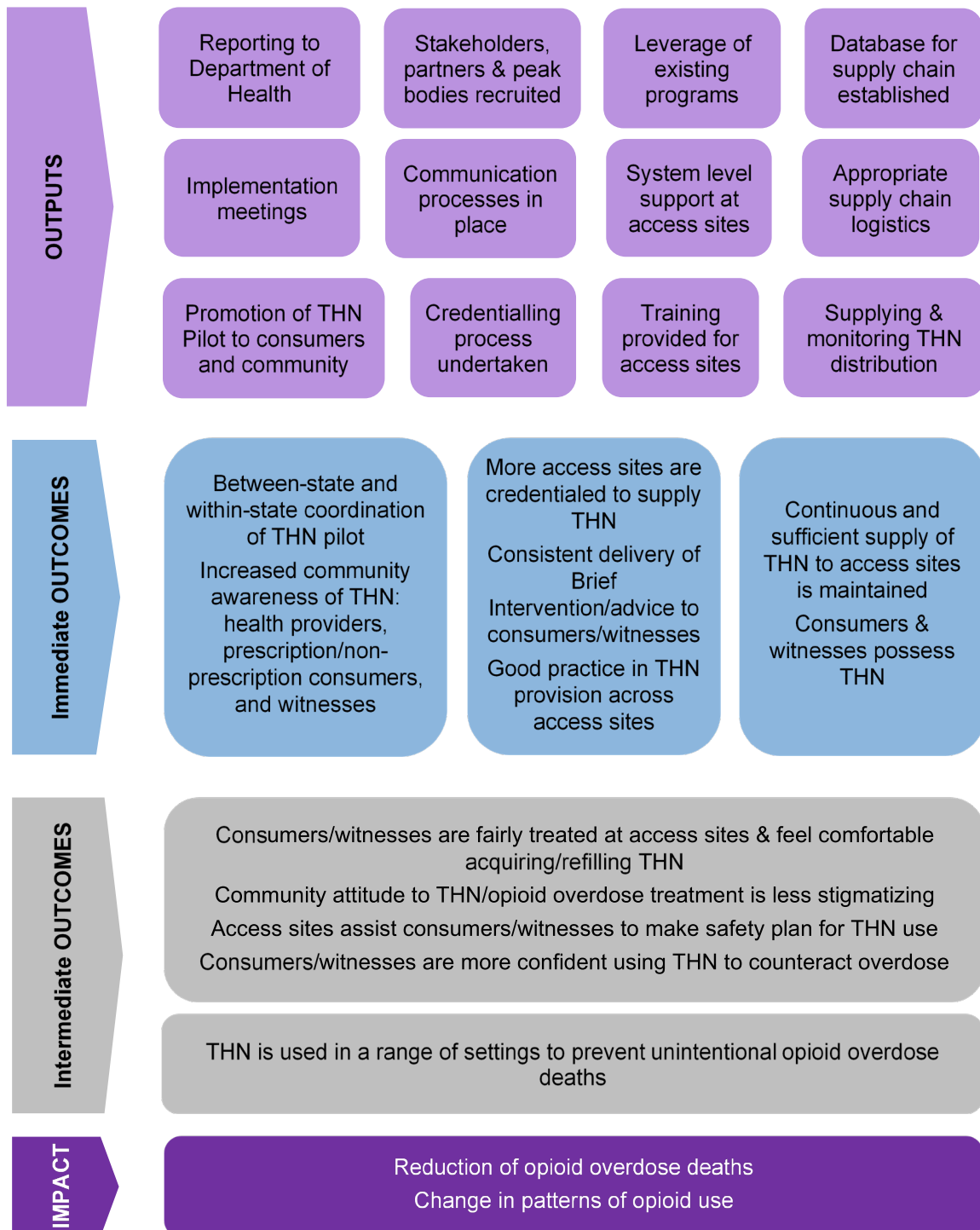
An extensive Indicator Matrix (matrix) was constructed to allow us to monitor the occurrence of the expected outputs and assess whether anticipated outcomes took place. This matrix specified assessment methods and data sources for each indicator and was agreed with the Department as part of the approved Evaluation Plan. An abbreviated version is included as Appendix C. Evaluation activities were designed to address this matrix. The activities included collection and analysis of primary data, analysis of administrative data, stakeholder consultations and analyses of program documentation. These are described briefly in the following section (Section 2.2: Key evaluation activities).

^b For example, preliminary 2020 estimates for drug-induced deaths will be released in September 2021, with final 2017 numbers being released at the same time by ABS

Figure 3. Program Logic for the PBS Subsidised THN Pilot

Problem Statement:

Limited access to naloxone is a barrier to addressing the increased rate of opioid overdose-related deaths in Australia. Factors thought to be among the key barriers to uptake and use of naloxone are: low awareness of naloxone among individuals who use illicit and/or prescription opioids (consumers); low awareness among families and community members who are likely to witness an overdose (witnesses); the cost of purchasing naloxone; and the lack of naloxone availability in community settings, especially in regional areas.



2.1.2 Ethics

Ethics approvals for all evaluation activities were obtained from The University of Queensland Human Research Ethics Committee (HREC approval # 2019002505) and from St Vincent's Hospital Sydney under the National Mutual Acceptance Scheme (approval # 2020/ETH00376), which provided reciprocal approval with public health government HRECs in NSW, SA and WA. Site-specific approvals and additional clearances were obtained through local governance arrangements where required. All participants provided informed consent prior to engagement with the evaluation.

2.2 Key evaluation activities

2.2.1 Primary data collection

We undertook a suite of primary data collection activities that gathered quantitative and qualitative data from people who participated in the Pilot as consumers (recipients of THN) and front-line staff of sites where naloxone was provided (Access Site staff). These included interviews of consumers and staff, and direct observation of practice (mystery shopping). We did not seek a representative sample, but aimed for inclusion of a range of perspectives and settings, particularly those not examined in previous evaluations. Where possible we conducted repeat interviews across the period of the Pilot to assess any potential change during maturation of the Pilot implementation.

Consumers were recruited through pharmacies and other Authorised Alternative Suppliers (AAS). We conducted 320 consumer interviews of 213 individuals; 131 were interviewed once, 60 twice and 23 on three occasions. Repeat interviews were conducted at least four months apart, depending on the time of initial recruitment. Consumer interviews were semi-structured, conducted primarily over the phone, and participants were reimbursed for their participation.

Access site staff interviews (n=66) were also semi-structured and conducted over the phone, but participants were not reimbursed. Consumer interviews covered experience of receiving THN, personal circumstances and use of THN. Staff interviews discussed experience of and confidence in providing THN, and procedural and workload changes needed to provide THN under the Pilot. Follow up interviews (n=15) were conducted over the phone to discuss changes in practice over time as the Pilot progressed.

Mystery shopping visits (n=24) were undertaken to directly observe the settings and practices of THN provision. Sites were selected using information on the recorded frequency of THN provision (high, low, or sudden changes) or to represent a key location/service type. Mystery shopping visitors observed the setting, requested naloxone, and recorded their experience according to a checklist immediately post-visit.

Table 1 below shows the distribution of these interviews across the Pilot states, types of consumers (as self-identified to the research coordinator) and access site types. Note that consumers who self-identified as using prescribed opioids may also have used illicit and/or diverted prescription opioids. "Potential witnesses" were people who declared no opioid use, and "other people" was a proxy option to include people who identified as primarily using illicit and/or diverted prescription opioids.

Table 1: Primary data collection completed for the Pilot evaluation

Participants/Setting	NSW	SA	WA	Total
Interviews with consumers	110	88	122	320
<i>People who use prescribed opioids</i>	25	38	17	80
<i>Potential witnesses (no declared opioid use)</i>	30	23	26	79
<i>“Other” people</i>	55	27	79	161
Interviews with access site staff	27	20	19	66
<i>Community pharmacies</i>	11	15	12	38
<i>Government AOD/health agencies</i>	9	°	1	10
<i>NGOs</i>	4	5	6	15
<i>Justice/corrections agencies</i>	3	°	°	3
Observation of practice at access sites (mystery shopping)	8	7	9	24
<i>Community pharmacies</i>	7	6	7	20
<i>Other services*</i>	1	1	2	4

NSW=New South Wales; SA=South Australia; WA=Western Australia; AOD=alcohol & other drug support service; NGO=non-government organisation; * includes non-AOD health services and outreach programs

The qualitative sections of interviews with consumers and access site staff were transcribed and subsequently analysed using framework analysis.(38)

After familiarisation, an initial coding framework was developed based on broad categories relevant to the evaluation questions and indicator matrix (Appendix C). For consumer interviews, the coding framework consisted of the following topics: healthcare, how they were introduced to naloxone, comfort during the supply event, brief intervention experience, barriers to THN, and recommendations for improvement. The coding framework for access site staff interviews consisted of the following categories: policies and procedures, administration/workload, training, comfort with supplying THN for the staff member, barriers, and recommendations for improvement.

All qualitative interviews were then coded using these frameworks in qualitative data analysis software Nvivo 12.^d Three analysts coded the interview transcripts independently, meeting regularly to discuss the coding framework and maintain consistency in coding.

Data from the quantitative component of the consumer interviews were analysed using STATA 15. Details of individual analyses are presented separately in each chapter.

° Health agencies in SA and justice/corrections agencies in SA and WA did not provide THN under the Pilot

^d Unlike quantitative data analysis software, qualitative data analysis software does not analyse the qualitative data itself but provides an efficient way of storing, organising and coding the data (in this case, interview transcripts).

The mystery shopping observations were analysed using quantitative content analysis using a pre-defined template in Excel.

2.2.2 Point of supply data

In addition to these interviews, we designed quantitative data collection systems to be used at each point of naloxone supply (pharmacies and AAS) to gather data about the naloxone distributed and the recipients.

THN distribution data were collected from December 2019 to June 2021, using a web portal established by the Program Administrator (the PPA portal) to manage reimbursement claims and manually by AAS in WA. Data on date, quantity and formulation/s provided and location were recorded for all supply and provided to the evaluation team where site-specific ethics approval had been granted. This comprised information on 94% of all supply (n=27,955 occasions). Additional information on gender, estimated age group, home postcode, self-identified consumer type, other medications used by the consumer, perceived risk of experiencing or witnessing an overdose, and repeat access to THN was recorded for consenting participants only; these data represented 48% of all supply (n=13,525 occasions).

2.2.3 Consultations

Implementation agencies

We conducted quarterly check-in meetings with the state-based implementation agencies to understand how Pilot activities were progressing, what hurdles were being experienced and what solutions were proposed and being tested. Key issues, solutions and recommendations were noted for these meetings.

Sector representatives

We conducted a series of roundtable consultations (n=25) and individual interviews (n=8) with leaders and representatives (n=75) from multiple sectors relevant to the Pilot. These included hospitals, pharmacies, non-government health organisations, professional peak bodies, non-Pilot naloxone programs, researchers, pharmaceutical companies, and Justice/Corrections officials. Some were directly involved in implementation of the Pilot, some had been consulted as part of the pre-implementation roundtables, and others represented key experts in research and practice around overdose responses and implementation settings. These data were analysed qualitatively in Nvivo 12 using the evaluation questions as a guide.

2.2.4 Analysis of research and administrative data

We analysed research and administrative data to provide information directly relating to Pilot activities, or to provide context about the environment in which the Pilot was delivered. These included:

- PBS data on all dispensings^e of opioid medicines^f and naloxone from January 2015 to April 2021 were examined to: i) assess levels of potential overdose risk associated with prescribed opioids according to established dose thresholds, ii) identify any changes in general and high-risk use over time during the Pilot, and iii) compare naloxone provided during the Pilot with that provided through the PBS prior to the Pilot, or in non-Pilot states (4). Naloxone supplied through PBS Prescriber Bag provisions was excluded for

^e “Dispensings” refers to dispensing events

^f Excluding medicines prescribed for Opioid Agonist Therapy (OAT)

these analyses. Data on trends in dispensings of statin medicines over this period were used as a comparison because changes in general use would be expected to show in the statins, whereas changes specific to the Pilot would not. This approach allowed us to account for the effect of external factors that may have impacted dispensing patterns in the Pilot and non-Pilot jurisdictions.

- Relevant data about awareness, uptake and use of naloxone from the annual illicit Drugs Reporting System (IDRS) between 2015-2021 were analysed to provide contextual information about people who regularly inject drugs.
- Australian drug-related hospitalisations data from the National Hospital Morbidity Database and drug-related deaths data from the Cause of Death Unit Record File between 2009 and 2019 were accessed through the National Drug and Alcohol Research Centre (NDARC) for analysis.
- Hospital Emergency Department and Ambulance Service data covering the period of the Pilot were not available during the time of the evaluation.

2.2.5 Environmental scanning

We examined changes in policy, practice and social landscape using program documentation and other informal data sources. We analysed a range of documents relating to the processes of the Pilot operations, including:

- Legislative documents relevant to the enabling and conduct of the Pilot
- Policies and guidelines developed and implemented during the Pilot at Australian Government and State level
- Minutes of meetings held between the implementation agencies
- Logs and content of communications activities undertaken as part of the Pilot.

We regularly scanned the media, websites established for the Pilot, professional body information outlets (e.g., Pharmaceutical Society of Australia website) and published literature for items relating to the Pilot or to similar programs in other settings, both Australian and international.

2.2.6 Review of indicator matrix

We assessed the available evidence for each key evaluation question and indicator outlined in the indicator matrix. We drew on all available data sources to address each question, rather than presenting individual results from each data source, as outlined in Table 2.

Table 2. Evidence synthesis

KEY EVALUATION QUESTIONS	Primary Data		Administrative Data	Environmental scanning
	Collection	Consultations		
1. Was the THN Pilot Implemented as planned?	Quantitative interview, Qualitative interview, Mystery shop	Round table	THN supply data	Environmental scan
2. Did the THN pilot achieve improved access?	Qualitative interview	Round table	THN supply data PBS data	Research data
3. What was the effect of increasing the range/number of access sites on THN uptake?	Quantitative interview, Qualitative interview	Round table	THN supply data PBS data	Research data

4. What was the impact on access sites?	Qualitative interview, Mystery shop	Round table		Environmental scan
5. Were there any barriers to increasing access and/or uptake of THN?	Qualitative interview, Mystery shop	Round table		Environmental scan
6. Were there any unintended consequences of increasing access to naloxone?	Qualitative interview	Round table	THN supply data	Research data
7. What needs to be considered in relation to a national roll out	Quantitative interview, Qualitative interview	Round table	THN supply data	Environmental scan

Impacts of COVID-19 on evaluation activities

The COVID-19 pandemic necessitated a number of changes to the original evaluation protocols.

Interviews with consumers and access site staff and roundtable consultations with sector representatives were migrated to remote modes (phone and/or teleconference) to ensure the health and safety of participants and researchers were protected.

This also necessitated changes in the processes for obtaining informed consent for interviews and consultations. Consumers provided verbal consent for evaluation data recording at point of supply; consumers and staff provided verbal consent prior to being interviewed. Consultation participants provided consent via email.

All such changes required further approvals by Ethics bodies, resulting in some delays to recruitment of participants and collection of data.

Mystery shopping observations were delayed until restrictions lifted sufficiently to allow in-person visits to access sites.

3. Was the THN Pilot implemented as planned?

Key points

- Most key Pilot activities were implemented as planned, including the establishment of policy and systems infrastructures, legislation and supply/distribution mechanisms, and the recruitment, credentialling and training of access sites and staff.
- Implementation varied considerably between participating states; it was constrained by jurisdictional policy structures governing supply arrangements but supported by the maturity of existing naloxone programs.
- Key organisations were advised about the Pilot early in its implementation, but no public launch or awareness campaign took place to promote THN to the wider public.
- The primary focus of the Pilot remained on people who use illicit opioids.
- The number of site registrations increased steadily to a total of 1,480 by 30 June 2021; 57% of these sites (n=846) provided THN on at least one occasion during this period.
- Coordination between state implementing agencies and the Department was evident but demonstrated the importance of state-level support mechanisms for implementation.
- Point of supply promotional materials were provided but supplementary activities were needed to raise awareness of the Pilot across agencies and in the community.
- Key assumptions on which the Program Logic and Theory of Change were based held for the Pilot's implementation, apart from a limited focus on providing THN beyond the AOD sector.
- Unexpected external factors such as COVID-19 restrictions on product imports reducing naloxone stocks in March 2020 and a challenge to the THN legislation in May 2020 caused significant but temporary interruptions to Pilot activities and supply chains.

3.1 Did the Pilot proceed as expected?

This section provides a brief overview of how the development and implementation of the Pilot aligned with the key expected activities (outputs) described in the Program Logic.

Figure 4 presents a timeline showing the phases of the Pilot with key events and activities in the different jurisdictions. The timing of key UQ evaluation activities and data reporting periods covered by this evaluation are depicted relative to the Pilot timeframes. These are overlaid with the time during which the Pilot and evaluation were impacted by the (ongoing) COVID-19 pandemic.

3.1.1 Funding and legislation

In February 2019, the Minister for Health announced funding for a pilot of THN. Implementation was originally to take place in NSW and SA; WA was subsequently added to the Pilot sites. The funding allocation was \$10 million.

A new legislative instrument to support the implementation of the PBS Subsidised Take Home Naloxone Pilot, the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019*, was signed off in November 2019. The Special Arrangement allows for naloxone to be supplied outside of the usual PBS supply arrangements in New South Wales, South Australia and Western Australia. This means that under the THN Pilot arrangements, individuals are not charged a co-payment for naloxone (i.e., it is supplied free of charge), and they do not need to visit a medical or nurse practitioner to get a prescription. The Special Arrangement also means that in addition to availability through pharmacies, the PBS listed naloxone can also be accessed from a broader range of settings such as hospitals and other authorised persons or

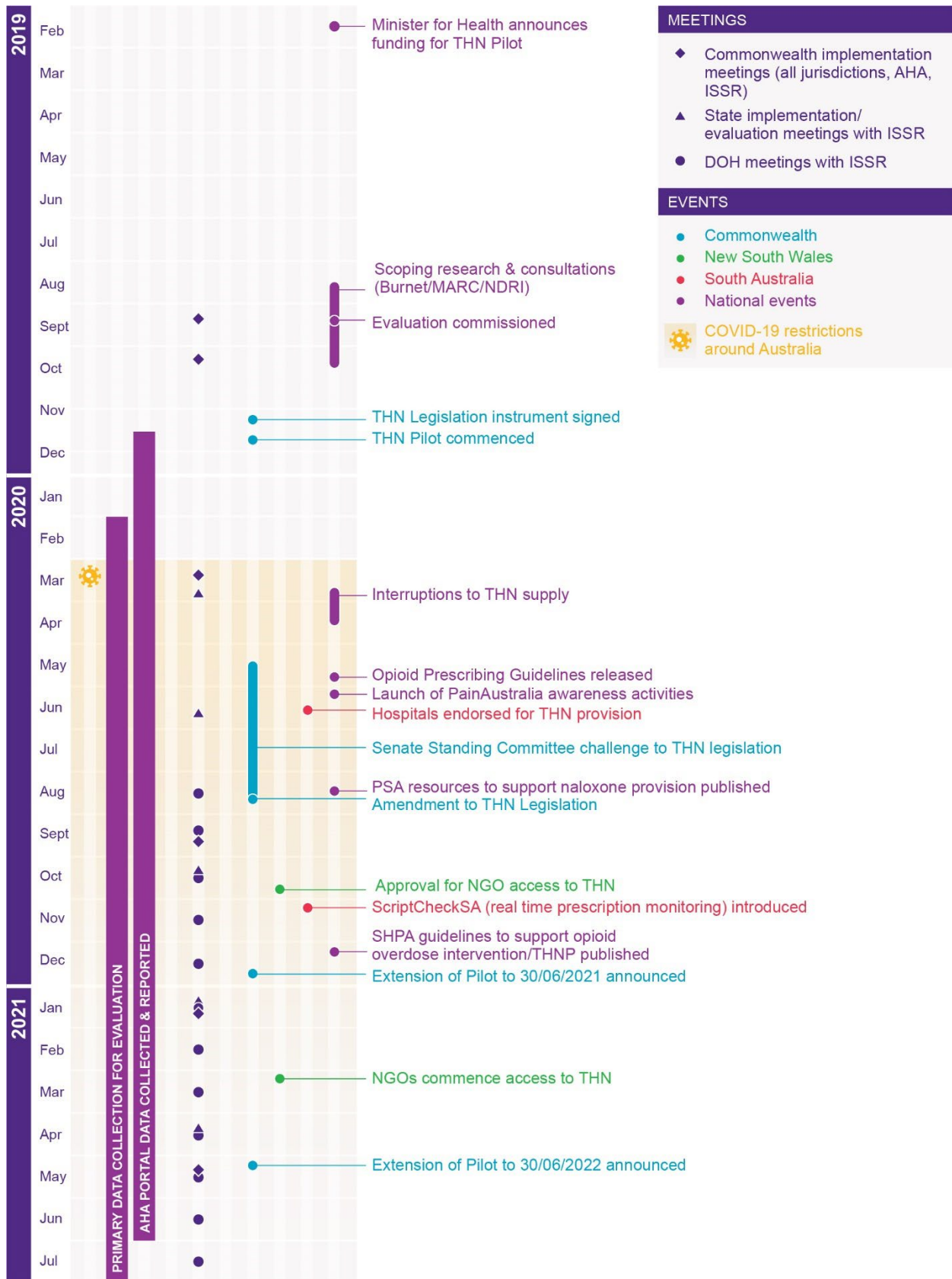
organisations such as needle and syringe programs, alcohol and other drug treatment centres or correctional release programs.

The Pilot commenced activity on 1 December 2019 in NSW, SA and WA, with the intention to run until the end of February 2021.

In May 2020, the Senate Standing Committee for the Scrutiny of Delegated Legislation wrote to the Department regarding disallowance of the THN legislation, expressing concerns about the source for legal authority for section 25 of the Instrument. Amendments were made to section 25 of the Instrument on 26 August 2020, to expressly define the powers and functions which may be authorised for the third-party administrator to perform and to provide for internal review of decisions of the third-party administrators by the Department. The motion to disallow was withdrawn on 27 August 2020 but was reported by stakeholders as creating uncertainty as to the future of the Pilot, and resulting in some reduced willingness of the implementation agencies to direct resources to the Pilot until the challenge was resolved.

In mid-December 2021, the Australian Government announced an extension of the Pilot to the end of June 2021. Legislative amendments were made in January 2021 to facilitate this extension. A further extension of the Pilot, to 30 June 2022 with funding for the year of \$3.9million, was announced on 12 May 2021 to allow continuity of naloxone supply while the findings of the evaluation were being considered by the Australian government.

Figure 4. Key Milestones of the PBS-Subsidised Take Home Naloxone (THN) Pilot



3.1.2 Key stakeholder establishment

Each participating state nominated an implementing body: NSW Health's Alcohol and Other Drug (AOD) Harm Minimisation section, SA Health's Drug and Alcohol Services SA (DASSA) section and the WA Mental Health Commission's Alcohol, Other Drug and Prevention Services section.

The Department contracted Australian Healthcare Associates (AHA) as the program administrator, to manage claims and reimbursement for naloxone supply and facilitate collection of dispensing data through its Pharmacy Programs Administrator (PPA) portal across the life of the Pilot.

The University of Queensland's Institute for Social Sciences Research (ISSR) was contracted to undertake an evaluation of the Pilot from commencement to the original end date. This was subsequently extended to cover the period until 30 June 2021.

3.1.3 Communications processes

The Department established meetings with the key implementation group, comprising representatives of NSW Health, SA Health and the WA Mental Health Commission, the program administrator (AHA), and the ISSR Evaluation Team. These meetings were held every four to six months during the Pilot establishment and implementation up to May 2021. Additional communication between members of the implementation group continued ad hoc across the period of the Pilot. Communication between the state implementing agencies and their local stakeholders was organised by the individual states. AHA provided regular electronic communications to registered access sites via the PPA portal.

3.1.4 Leverage of existing programs

In NSW and WA, the Pilot built on previous THN programs: The Overdose Response with Take Home Naloxone (ORTHN) trial in NSW and the Peer Naloxone Education Project in WA (see Appendix A). State based directives for these earlier programs had made provision for naloxone to be provided by designated health professionals at AAS sites but required prescriptions for free supply. Many of the networks and systems established for these programs were used to support the THN Pilot. SA was not operating THN programs at the time of the Pilot commencement.

3.1.5 Recruitment of access sites, stakeholders, and partners

All registered community pharmacies in the participating states were contacted through the program administrator and invited to take part in the Pilot. Self-nominating pharmacies enrolled in the Pilot by registering through the PPA portal.

AAS were encouraged by the state implementing agencies to enrol in the Pilot, initially focusing on those involved in the existing naloxone programs. In WA, these AAS were primarily alcohol and other drug (AOD) specialist services, including those provided by non-government organisations. NSW initially engaged government health services as AAS in the Pilot, again focused on AOD services. Involvement of non-government organisations (NGOs) in NSW required two Legal Authorities under Section 10(2)(b) and clause 17 of the *Poisons and Therapeutic Goods Act 1966* to allow the supply of the Schedule 3 substance naloxone by a credentialed health worker. This was approved for NGOs and private organisations in August 2020. NSW NGOs commenced THN provision under the Pilot in March 2021. Recruitment of different site types is discussed further in Chapter 6.

In SA, state-based legislation limited provision of naloxone through community pharmacies only. Other sites at which persons were identified as at risk of witnessing or experiencing an

overdose were able to provide the requisite brief education about overdose and naloxone, and a voucher for recipients to redeem naloxone at a participating community pharmacy was issued.

The number of site registrations increased steadily across the period of the Pilot to a total of 1,480 sites as of 30 June 2021; 57% of these sites (n=846) provided THN on at least one occasion during this period. The Administrator sent communications to non-active sites on several occasions to encourage more active participation. This is discussed further in Chapter 4.

3.1.6 Credentiaing & training processes

Pharmacies registered via the PPA portal and no further credentiaing process was required. Formal training was not provided for pharmacy staff, recognising their existing skills in advising on medication safety, but information sheets including Portal User Guides were made available through the administrator's website⁹. Program guidelines and other resources were also made available through the administrator's site.

Additional training and support materials for pharmacists were later developed independently and promoted by the Pharmacy Society of Australia (PSA) and the Society of Hospital Pharmacies of Australia (SHPA) and distributed through their respective memberships and more broadly to all Pilot participants by the Pilot administrator.

Credentiaing of AAS and training of staff were state-based requirements for participation and were not stipulated or required from the Department. Training was intended to prepare AAS staff to deliver the brief intervention/education for people receiving THN that included recognising the symptoms of overdose and how to administer naloxone. These are discussed in Chapter 6.

3.1.7 Promotion of THN pilot

At the commencement of the Pilot, communications about the Pilot were sent to all community pharmacies and to the Pharmacy Guild (the Guild) and the Pharmaceutical Society of Australia (PSA). The Department designed and distributed initial promotional material for access sites to promote naloxone and the Pilot in early 2020 and established a dedicated Pilot page on the Department of Health website. Refreshed promotional material was released in early 2021.

PainAustralia was engaged to provide communications and promotion to individuals with chronic pain, and services that supported them, to reach people who regularly used prescribed opioid medications. Reports from PainAustralia indicate these promotion activities commenced on 5 June 2020. Activities included posts on Facebook and Twitter including reference to THN, a feature article on THN in their newsletter, and several blog posts mentioning naloxone.

NSW Health, SA Health and the WAMHC each established dedicated Pilot pages on their websites including information on the Pilot, overdose awareness, and links to the Department of Health's Pilot web page and the PPA portal.

The Pilot was not publicly launched, and no public awareness campaign took place.

3.1.8 THN supply chain

Participating pharmacies in all states ordered naloxone stock through their existing suppliers according to usual ordering practices. In WA, the WAMHC acted as a bulk supplier and distributed stock directly to AASs. In NSW, government health services ordered naloxone through existing approved suppliers and protocols. Some hospital pharmacies acted as bulk

⁹ <https://www.ppaonline.com.au/naloxone-pilot>

suppliers and provided naloxone to other services within their LHD; the Justice Health & Forensic Mental Health Network provided this function for NSW correctional facilities. NSW Health engaged a distributor to enable stock ordering and delivery to NGOs; this was finalised in early 2021. Registered Pilot sites could claim back the cost of naloxone supplied to consumers through the PPA portal; this portal was also used to collect data for the evaluation where recipients provided consent.

Payments for naloxone under the PBS THN Pilot arrangements are made in accordance with the rates determined under the relevant section of the National Health Act for supplies made by section 90 (Approved Pharmacists – approved to dispense pharmaceutical benefits from particular pharmacy premises (approved premises)), 92 (Approved Medical Practitioners) and 94 (Approved Hospital Authorities) suppliers (i.e., the same rates as usual PBS arrangements). The amount reimbursed for supplies in non-pharmacy settings (i.e., from Alternative Authorised Suppliers) are the equivalent of the approved ex-manufacturer price (AEMP).

The TGA website officially registered a stock shortage of the intranasal spray formulation (Nyxoid®) between 26 March 2020 and 16 April 2020, due to an unexpected increase in demand. This critical shortage was declared resolved as of 17 April 2020. Low stocks of all formulations were noted about this time, primarily due to slowing of imports by COVID-19 closures of international and state borders and jurisdictions worked collaboratively through the National Naloxone Reference Group to support supply during the shortage period. No other stock shortages have been experienced over the duration of the Pilot.

Impact of COVID-19 on Pilot activities

In March 2020, community restrictions were enacted in an effort to combat the COVID-19 pandemic. This affected people's ability to access health services and pharmacies; many services and pharmacies restricted operating hours and/or reduced the time spent interacting with clients to reduce the possibility of viral transmission. Such practices and resulting time pressures also impacted the provision of naloxone through the Pilot. Subsequent easing of restrictions in the Pilot states during the latter half of 2020 allowed more consistent access to THN and the services through which it was available, but re-imposition of restrictions may again impact naloxone provision.

The public health focus on COVID-19 made it difficult for other, non-COVID, health messages (such as opioid overdose awareness and THN) to gain traction.

3.1.9 Examining key assumptions and external factors

The Theory of Change for the Pilot articulated a series of key assumptions on which it was based, as listed below. Table 3 below briefly outlines the extent to which the evaluation findings support these assumptions.

Table 3. Assumptions for the Theory of Change

Assumption	Key findings	Data source/s
THN Pilot activities in each state will align to the Pilot objectives and to best practice	Pilot activities focussed largely on people who use illicit opioids (PUIO) rather than people using prescription opioids (PUPO)	Staff interviews Implementation meetings Roundtable discussions
An adequate supply of naloxone is available for distribution	Supplies adequate (apart from COVID disruption); wholesale/distribution arrangements varied for pathways outside of existing PBS supply chains	Supply data Implementation meetings Roundtable discussions
Funds are adequate to supply naloxone to all credentialed access points	Funding was sufficient for supply of naloxone for reimbursement of purchase; funding did not cover cost of distribution to sites for pathways outside existing PBS supply chains	Implementation meetings
Access sites have appropriate resources for storing naloxone, providing brief interventions, and dispensing naloxone	Dispensing resources were sufficient in pharmacies State based credentialling process instigated to ensure sufficient storage; some effort required for NGOs to comply with requirements Limited coverage of staff training reduced Pilot availability on some occasions Brief intervention provision varied across sites where staffing was limited	Consumer and staff interviews Roundtable consultations Mystery shopping
Promotion of THN among people who use opioids (prescription or illicit) will encourage them/their significant others to obtain naloxone in case of overdose	Some evidence of uptake of naloxone by previously naïve populations Limited public promotion of THN Established peer networks among PUIO supportive of Pilot	Consumer and staff interviews Roundtable discussions
Removal of cost, increased number of access sites and promotion of THN pilot will encourage consumers/witnesses to obtain naloxone	Cost removal regarded as positive Increased number/type of sites regarded as positive Earlier removal of prescription requirement positive but resulting price was identified as barrier; combination of cost/prescription removal positive	Consumer interviews Supply data and PBS data Roundtable discussions
Consumers/witnesses will use THN to counteract opioid overdose after obtaining it from access sites	Use of THN to counter overdoses was reported across Pilot	Consumer interviews Supply data
Use of THN will protect consumers from unintentional opioid overdose death	Consumers reported using THN to counter opioid overdoses; literature including previous Australian THN program evaluations support this	Consumer interviews

In constructing the Program Logic, a number of external factors were identified as having the potential to exert a major influence on the implementation or effectiveness of the Pilot and documented as part of the Program Logic. Table 4 outlines the observed effect of these factors.

Table 4. Potential external factors and observed effect on the THN Pilot

Potential external factors	Key findings	Data source/s
Changes in availability of ongoing funding and/or Australian Government support for the THN Pilot	Challenge to the legal instrument supporting the Pilot (May-August 2020) created uncertainty among stakeholders Uncertainty about end date and succession planning for the Pilot and multiple extensions (December 2020 announcement for February 2021 and May 2021 for July 2021) reduced stakeholder confidence	Roundtable discussions Implementation meetings Supply data
Changes in the strength of illicit opioids/introduction of new and emerging opioids may increase overdose (OD) rates	Limited bulk intrusion of new/higher-strength illicit opioids into Australian market but some contamination of other illicit drugs with opioids noted Some evidence of reduced heroin availability during COVID-19 restrictions	Environmental scanning (NSW Health drug alerts; forensic analysis reports) IDRS
Role of other agencies in prevention of overdose-related deaths may affect impact of THN Pilot	Ambulance services continue to administer naloxone under existing state base funding responsibilities, but not supply naloxone for take home purposes	Roundtable discussions Supply data
Impact of existing naloxone programs may affect Pilot outcomes	Existing programs had raised awareness of naloxone among some sectors; supported early uptake of THN	Roundtable discussions Interviews (with staff) IDRS
Changes in policies and procedures regarding opioid prescribing practices may affect OD risk landscape	Changes in PBS subsidy and TGA ^h regulatory changes to opioid access introduced June 2020; may have reduced some opioid prescribing Implementation of real-time prescription monitoring programs in SA too recent for impact to be evident State/Territory changes to takeaway OAT supply in response to COVID restrictions; no evidence to date of increased OD.	Environmental scans

^h In June 2020, the Therapeutic Goods Administration (TGA) implemented regulatory changes in order to reduce harms from opioid prescription medicines; these included smaller pack sizes for immediate-release opioids for short-term pain relief, additional warning statements added to Product Information sheets for all opioids and updating of prescribing indications for opioids.

Potential external factors	Key findings	Data source/s
Other opioid-related initiatives in place or implemented during the course of the THN Pilot may affect Pilot outcomes	Projects such as Overdose Lifesavers ⁱ increased awareness of illicit opioid-related OD; may have assisted with awareness/uptake of THN	Environmental scans
Adequacy of workforce & infrastructures to support THN Pilot	Workforce training required in AAS and some pharmacy sites; current hospital infrastructures not yet supportive of THN supply under Pilot conditions	Roundtable discussions Interviews (with staff)
Previous experience of consumers and witnesses in accessing and using naloxone	Prior awareness of THN among PWID helpful in facilitating uptake	Interviews (with THN consumers) IDRS
Existing community attitudes towards overdose death prevention	Stigma about opioid overdose remained an issue; may have slowed uptake of THN	Interviews (with THN consumers) Roundtable discussions
Lack of storage among certain population groups (e.g., homeless persons)	Reported as a concern by consumers	Interviews (with THN consumers)
Consumers living/using opioids without witnesses present to administer naloxone	Increase in solo use highlighted during COVID-19 restrictions; may have increased OD risks	IDRS OD data for 2020 not available

One major external factor that could not have been foreseen at the commencement of the Pilot was the COVID-19 pandemic. Please refer to 'Impacts of COVID-19' in section 3.1.8 for discussion of the impact of COVID-19 on the Pilot operations.

3.2 Were sufficient resources available to assist with implementation of the THN pilot?

This section outlines issues related to system-level resourcing for the Pilot; service level resourcing and the impact on individual access sites are discussed in Chapter 6.

3.2.1 Were the existing workforce and infrastructures adequate to support the Pilot implementation?

3.2.1.1 Workforce

Under the agreement with the Australian Government, funding was provided to fully subsidise the cost of naloxone, the Program administrator, and the evaluation. Australian Government funding covered dispensing fees and mark ups applicable to PBS supply at participating pharmacies, but not activity costs for the other Authorised Alternative Suppliers (AAS). The participating states were to support the implementation and coordination of the Pilot.

In practice, implementation of the Pilot heavily relied on the activity of 'champions' at state, local and access site levels, who engaged in the range of work necessary to implement, coordinate

ⁱ <https://overdoselifesavers.org>

and promote the Pilot, either as part of their current roles or in addition to their existing workloads. This work was not resourced as part of Australian Government funding for the Pilot but relied on existing local funding and resources, on which the scaled-up activity level of the Pilot placed significant pressure. Roundtable participants noted this entailed a significant investment by State governments and the AASs providing THN. State governments may have been in a position to divert funding previously used to support the cost of naloxone; non-government AAS may not. Planning for future programs, particularly expanded activities, should include consideration of these resourcing needs and identify mechanisms to support implementation costs.

3.2.1.2 Policy and System Infrastructure

As noted in section 3.1, legislation was enacted by the Australian Government to allow the supply of naloxone in a broader range of approved settings. State provisions were also required to authorise supply by non-medical personnel. These measures were in place in NSW and WA to facilitate their pre-Pilot programs, but not in SA. It was deemed that the development of such legislation in SA would not be possible in time to implement the Pilot, hence the restriction of THN provision to pharmacies in that state. New policy directives were also required in NSW to authorise THN supply through non-government organisations (NGOs). Development of such directives required significant time, for example NGO participation was finally approved in NSW in October 2020. Similarly, governance approval for pharmacists to supply THN directly in SA hospitals did not occur until June 2020 despite the absence of legal barriers. Round table participants noted that protocols for direct supply of naloxone by pharmacists within the hospital involved coordination and agreements between numerous divisions and services across the hospital. This is discussed in more detail in Chapter 6.

The Australian health system which divides each state into a number of Local Health Districts (LHDs in NSW), Local Health Networks (LHNs, in SA) or Health Service Providers (HSPs in WA) means that multiple independent structures must be navigated in order to operationalise new 'universal' health programs. Diversity among these structures requires significant ongoing effort and multiple strategies to engage with the necessary range of stakeholders on-the-ground, placing further pressure on existing staffing resources of the central implementing agencies.

Implementation of a THN program in any new jurisdictions are likely to require considerable time to establish the necessary state based legislative environments and then to develop the multi-level health system approvals and protocols to support activity.

3.2.2 Was the Pilot sufficiently promoted to generate demand and allow implementation to work as envisaged?

In order to achieve these aims, promotion to a number of target audiences was required: professionals and sites who would be needed to dispense naloxone, consumers who knew about naloxone and would want to access it more easily, and the general public who may not be aware of the need for naloxone as a response to opioid overdoses. We analysed communications logs, feedback from roundtables, environmental and media scanning for evidence of promotional activity and approaches that targeted each audience type.

3.2.2.1 Health practitioners

The Department made significant attempts prior to the Pilot's commencement to engage a range of national peak organisations, representing medical practitioners, pharmacists and consumers, with some resulting agreements to support the Pilot by sharing key messages. State implementing agencies also approached state branches of these organisations, with some more active engagement and support forthcoming.

The Chief Medical Officer sent letters in December 2019 to all community pharmacies and private hospitals in all three states and to public hospital pharmacies in SA and WA to advise them about the Pilot. This was followed by circulation of an editorial by the Chief Medical Officer to stakeholders (including peak bodies and primary health networks) along with information on how to register. The Minister for Health also wrote to each of the participating State Health Ministers.

The Pharmaceutical Society of Australia (PSA) and Society of Hospital Pharmacists of Australia (SHPA) both actively promoted the Pilot to their membership, and created supporting resources to guide THN provisionⁱ. The Pharmacy Guild of Australia was less active at national level but did provide some support in SA. Despite this, awareness of the Pilot among community pharmacies was not universal. Mystery shopping visits found staff were aware of the Pilot at only 10 of 24 sites visited (a further six said that the Pilot was not mentioned during the transaction and in another four, no comment was recorded).

The Department developed a dedicated website for the Pilot, with information for the general public and identifying a broad range of potential naloxone recipients. The Administrator's website also held information on the Pilot, sent information broadcasts to registered sites, and operated a help desk to assist with registration enquiries. Promotion of the Pilot was also undertaken through web pages on the sites for the WAMHC and SA Health under 'resources for health professionals' and for NSW Health under the AOD programs section. Each of these were for health practitioners and appeared to focus on naloxone for people who use illicit opioids and their family/carers.

The absence of dedicated funding for promotional activities by the implementing agencies may also have impacted on awareness and opportunities for cross-communication within professional communities about the Pilot.

So, in terms of promoting the access to free naloxone, that could be done a lot better in this jurisdiction. There isn't a lot of communication between services that are providing take home naloxone. (Roundtable Participant, NGO, WA)

Roundtable consultations also showed that in some other regions, local champions acted independently and actively promoted the Pilot among their service networks, inter-agency working groups and local community organisations. This resulted in increased awareness and more active participation by registered sites within those areas, and in some cases providing unanticipated benefits from local connections in that a broader range of potential access sites were identified and subsequently recruited into the Pilot. Consumer participants in such networks also provided peer-to-peer promotion, including into carer and other potential witness groups. Health promotion and community development practitioners were identified as key actors in such circumstances, typically being aware of local community health concerns, potential activity partners and available communication channels. Building these activities into a large-scale roll out of THN, incorporating existing knowledge and practices from these networks into specified roles, could provide local boosts to awareness raising and increase participation.

PainAustralia was contracted by the Department to undertake promotional activities to the chronic pain sector, both practitioners and patients; these promotional activities were launched in June 2020. PainAustralia reported in September 2020 on a reach of 20,000 for Facebook/Twitter posts on pain management that included links to THN, and cumulative reach of 22,000 for a feature article on THN in their newsletter. Environmental scanning by the

ⁱ <https://www.shpa.org.au/news/new-guidelines-support-opioid-overdose-intervention>; <https://my.psa.org.au/s/article/Naloxone-S3-guidance-document>

evaluation team subsequently detected some social media from these activities but not widespread further broadcast of the messages. Pain clinics and practitioners contacted during the evaluation to participate in consultations or interviews were largely unaware of the Pilot.

3.2.2.2 People who use illicit drugs

Data from the Illicit Drugs Reporting System (IDRS) show that a large proportion of people recruited from capital cities who inject drugs were aware of naloxone prior to the Pilot (39). Nationally, over 80% of 2019 participants reported awareness of naloxone, and 57% knew about THN programs. These figures were lower in SA, where programs had not recently operated (61% knew about naloxone, but only about 21% about THN programs). This background awareness and appetite for THN along with existing knowledge of THN among workers in the AOD sector, may have meant that uptake by this group was influenced more by THN availability and communication through AOD services than public campaigns may have achieved.

A lack of standardised promotional materials suitable for all access sites was noted. Each state produced their own branded resources for consumers (fact sheets), typically to accompany the brief intervention/education provided along with naloxone at access sites. The information contained was similar but not standardised.

3.2.2.3 General public

Despite funding for the Pilot having been announced broadly in February 2019 during the 2019 election campaigns, subsequent broad promotion was not undertaken at national level and the Pilot was not publicly launched at commencement in December 2019.

The Department provided some ongoing promotional materials for display at access sites: posters, window decals and 'countertop' stickers. Mystery shopping visits subsequently identified these at only four of 24 sites visited. COVID-19 restrictions and infection control practices resulted in many pharmacies removing display materials from counters to reduce infection risks.

Low levels of wider-community awareness of naloxone, or the risk of opioid overdose among people other than those who use illicit drugs, meant that considerable public awareness raising would be required to generate increased demand for naloxone among people who do not use opioids themselves but could become trained active witnesses in the event of an overdose. Such a campaign would also need to normalise the use of naloxone as a lifesaving medication in case of overdose or adverse reactions. We found no evidence of such a campaign.

Promotion of the Pilot was instead heavily dependent on pharmacists actively broaching the subject of naloxone with potential recipients as part of their clinical practice. This was in turn dependent on pharmacists' judgement of whom it was appropriate to approach, which may not include people likely to witness someone else's overdose.

3.3 What effect did the supply/distribution mechanisms have on the uptake of THN?

This section examines the extent to which the distribution mechanisms in place for the Pilot ensured efficient delivery, adequate stock and reimbursement for dispensing at access sites.

3.3.1 Delivery

Pharmacy settings and NSW government health services continued to use existing ordering mechanisms to order stock and arrange delivery. The Commonwealth paid the distribution costs

in these circumstances under existing standard PBS arrangements. Such existing arrangements limited the introduction of additional distribution costs from the Pilot.

WA AAS obtained stock through the WAMHC, which acted as a wholesaler and distributor and continued to support distribution costs as it had done under previous arrangements.

Since I last spoke to you, the Mental Health Commission has contacted us regularly, and whenever they are putting in orders, they ask us how much we would like, so we've managed to always have naloxone on hand. (WA, NSP staff member, Interviewed May 2021).

No existing mechanism was in place to support distribution to non-government AAS in NSW. As NSW Health was not permitted to act as a wholesaler, NGOs in NSW were required to order stock through a wholesaler/distributor contracted by NSW Health. Distributors were initially reluctant to provide the projected low volumes for NGO distribution, resulting in a significant delay in contracting and subsequent commencement of NSW NGO participation in the Pilot. Establishment of these new supply chain mechanisms meant that the distributor charged additional costs per unit as well as delivery fees, adding further to the THN implementation budget for NSW.

3.3.2 Adequate stock

Interruption to supply was noted in March 2020 due to COVID-19 related international delays and interstate transport disruptions; this created some uncertainty around Pilot viability but was resolved quickly (April 2020). No further supply interruptions were reported during the evaluation period.

I guess the only thing that's really impacted on our distribution has been to do with the fact that there is a global pandemic and we've had a couple of periods of lockdown... Distribution levels at the moment are pretty much on a par with what they were before March last year, but there's been a lot of fluctuation over the last year (WA, NSP staff member, Interviewed May 2021).

Pharmacies were less willing to order large quantities of stock ahead of establishing demand as they were concerned that the cost of unused stock would not be reimbursed through the Pilot.

Well we never really sold it before this, that is the thing. Like we never knew it was an option. Like we knew it became a pharmacist only medication a while ago, but we never had anyone coming in asking for it. Like we never gauged the demand of people buying it (NSW, Community pharmacy staff member, Interviewed April 2020).

Commercial wholesalers were also reportedly reluctant to hold significant quantities of stock due to uncertain demand. These led to instances of delay in supply to pharmacies and AAS, as reported during staff interviews and roundtable consultations.

Not all registered pharmacies were found to stock naloxone; while stock could be ordered within 1-2 days, consumer interviews described lack of stock availability or delays in supply as a real barrier to access, potentially being discouraged after making unsuccessful attempts. Mystery shopping visits showed that pharmacies without THN in stock were not always willing or able to suggest a local alternative supply venue.

..... the conversation ended when they discovered they were out of stock. Felt awkward having to ask if they could get some in. Encouraged to try elsewhere but

no information on where else stocked it. Pharmacist had his back to me during this whole part of the conversation. (Mystery shopping, Community pharmacy, NSW, August 2020)

They did not have the stock, at least useable ones. They did not offer any alternatives or provided me with information so that I can acquire the naloxone I needed. (Mystery shopping, Community pharmacy, NSW, February 2021)

Similar observations were also reported by stakeholders during round table consultations. Where consumers contacted the implementing agencies or the administrator to indicate a lack of stock, especially at sites listed as participating in the Pilot, information on local alternative supply sites was provided.

Uncertainty regarding the duration of the Pilot led to reports in December 2020 of stockpiling of naloxone by some sites, with the resulting risk of holding out-of-date stock, which would not be reimbursed if not dispensed. Non-ordering and non-promotion occurred at other sites who were concerned about generating a demand for THN that would not be met after conclusion of the Pilot, slowing the provision of THN in the community.

3.3.3 Reimbursement processes

Pharmacies were familiar with reimbursement procedures from other programs and reported few difficulties navigating the process. AAS in WA and NGOs in NSW did not require reimbursement and so experienced no challenges arising from this system.

NSW LHDs reported that the reimbursement model was not aligned with existing processes and recording systems for stock management and transfer, particularly within larger health sites such as hospitals. The resulting multi-step processes for ordering, reporting and reimbursement created barriers for staff. Similar issues were noted for hospital settings in other states.

Implications

- Adequate resourcing of coordination and implementation activities, in addition to subsidising naloxone itself, will be critical for implementing THN programs at scale
- Systems for encouraging pharmacies to stock naloxone consistently may assist with increasing uptake of THN
- Alignment of authorising systems within jurisdictions may smooth the adoption of THN protocols in non-pharmacy sites
- Establishment of consistent supply systems across jurisdictions may provide leverage to develop a more sustainable distribution system for non-pharmacy settings
- Extensive promotion of the Pilot into non-AOD services and client groups will be needed to encourage uptake of THN by a broader range of consumers and witnesses.

4. Did the THN Pilot achieve improved access?

Key points

- More occasions of naloxone supply were recorded: 27,955 supplies over 18 months of the Pilot compared to 3,579 supplies through the PBS in the previous 2 years.
- 1480 sites registered for the Pilot but only 846 (57%) provided THN during the evaluation period; active participation rate for AAS was higher (82.5%) than that of community pharmacies (52%).
- More settings provided THN; pharmacies, specialist alcohol and other drug (AOD) services, justice and correction settings, and general health services such as hospitals.
- The majority of non-pharmacy THN sites were providers of AOD services; specialist pain clinics did not engage with the Pilot.
- More people received naloxone during the Pilot, both at risk of experiencing opioid overdose and people who may witness an overdose. Most identified as using prescribed opioids.
- The proportion of people at risk from pharmaceutical opioids who received naloxone increased from 0.15% to 1.63%.
- Consumers accessed naloxone close to home, 55% within their home postcode, and THN was available in city, regional and very remote areas.



THN was **supplied**
at least

27,955 TIMES
to individuals

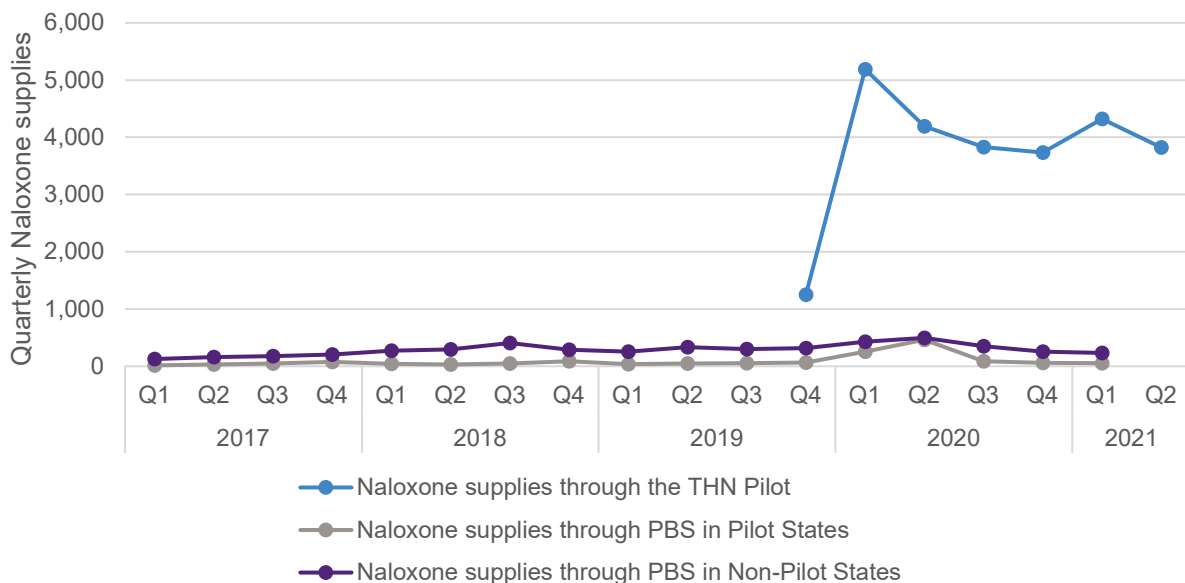
4.1 Did access to naloxone increase during the Pilot?

Between 1 December 2019 and 30 June 2021, 27,955^k naloxone supplies through the Pilot were recorded. Supply peaked in February 2020*, followed by a marked reduction during March/April 2020 (potentially linked to the introduction of COVID-19 restrictions), and then a relatively steady rate of supply across subsequent months. There was some reduction during November 2020, followed by increases from December-February 2021 after announcement of extension of the Pilot.

This averaged out to approximately 1,399 new supplies during each month of the Pilot, or 4,197 per quarter, across the three Pilot states.

This is an order of magnitude higher than the total supply of naloxone^l via the PBS over the two years prior to commencement of the Pilot (mean = 347 per quarter), and higher than provision via the PBS in both Pilot (164 per quarter) and non-Pilot states (342 per quarter) during the Pilot period (Figure 5). By examining dispensing patterns prior to and during the Pilot for naloxone, prescription opioid medicines and an unrelated class of medicines (statins), we were able to see that this increase in naloxone supply was specific to naloxone. It was not related to patterns of opioid dispensings (little change in this period)^m or provision of statin medicines in general (see Figure 22, Appendix D).

Figure 5. Comparison of naloxone supplies under the THN Pilot with PBS-based supply



Source: PBS data, PPA portal data, supply data collected by AAS; PBS data for Q2 not available at time of report

*Examination of detailed supply data from the PPA portal showed that the very high February 2020 peak was largely accounted for by a small group of linked pharmacies in one local area. Consultation with staff revealed that they had initially offered naloxone to every patient receiving opioid medications. This was confirmed by a mystery shop visit.

^k This includes supplies recorded via PPA portal as individual supply (23,876 with ethics clearance; 1,608 without ethics clearance) and manually by WA Mental Health Commission (2,471).

^l Naloxone dispensed as prescriber's bag excluded.

^m Regression coefficient=0; p<0.001

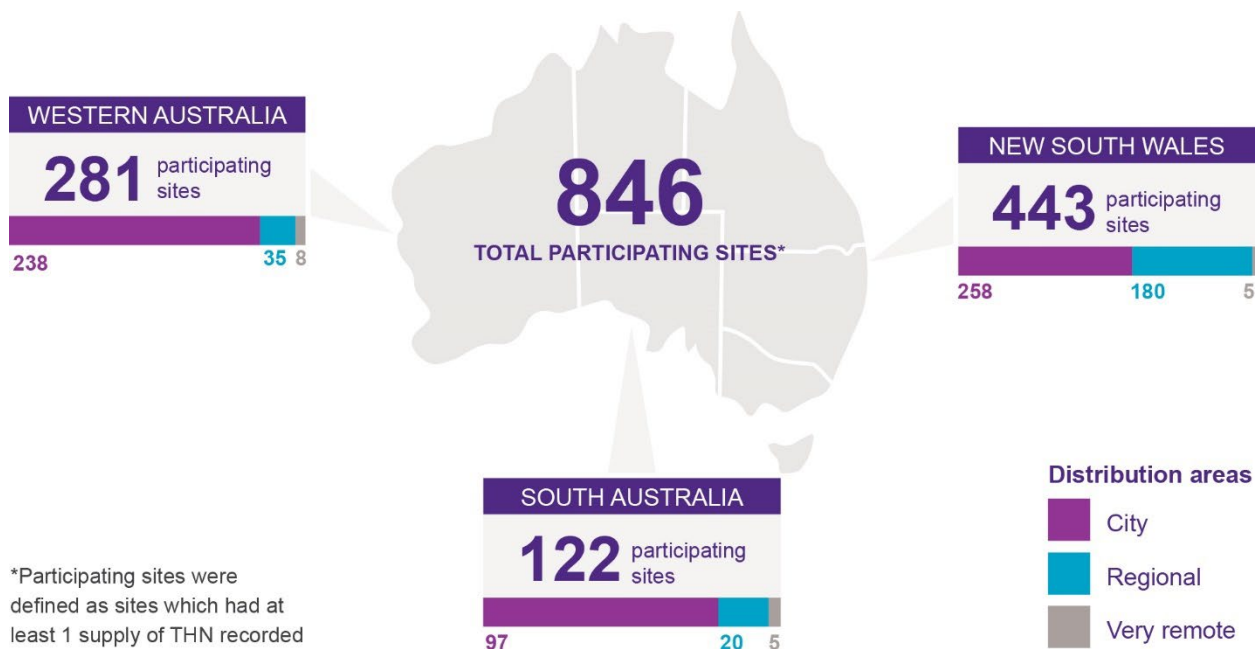
4.2 Which aspects of access changed?

4.2.1 Was naloxone available in more locations?

At 30 June 2021, 1,480 sites had registered to provide naloxone under the Pilot. Of these, 846 (57%) supplied naloxone to individuals on at least one occasion during the evaluation period and so were considered 'participating' sites.

Most of the participating sites were in NSW (n=443, or 5.5/100,000 populationⁿ), but SA (n=122; 6.9/100,000) and particularly WA (n=281; 11.0/100,000) were also well served. Figure 6 below shows that the majority of participating sites were located in cities (70%), followed by regional and remote areas. NSW was found to have wider reach in regional areas (40%) compared to other two participating states (<20%).

Figure 6. Distribution of participating access sites by remoteness



About half of the Pilot participants for whom we have postcode data (55%; n=5,434) accessed naloxone from within their home postcode, and 73% from within 5 postcodes of their home^o. These figures were slightly less for WA (34% and 55% respectively), but this may reflect the number of participants who accessed naloxone from an outreach service whose registered postcode was different to that in which the outreach operated.

4.2.2 Was naloxone available in more settings?

In NSW and WA, the Pilot allowed provision of THN through (s90) community pharmacies, (s92) approved medical practitioners, (s94) approved hospitals and authorised alternative suppliers (AAS), which included other health services (e.g., Justice Health, community health centres), needle and syringe programs (NSPs^p), alcohol and other drug (AOD) support services, outreach programs and non-government organisations. In SA, legislation only allowed dispensing of

ⁿ Using 2020 population figures from the Australia Bureau of Statistics (ABS)

^o Consenting participants (n=9,905) provided their home postcode at the point of provision to help us estimate whether they had to travel to access the naloxone. Access site postcodes were recorded at registration.

^p Clean Needle Programs (CNPs) in South Australia

naloxone by pharmacies (hospital or community); other site types used vouchers to refer clients to participating pharmacies. Existing arrangements allowed Drug and Alcohol Services South Australia (DASSA) to act as an AAS.

Registered sites (n=1,480) included 1139 community pharmacies, 49 approved hospitals and 292 AAS. No s92 approved medical practitioners registered for the Pilot.

Of the registered sites, 846 (57%) provided THN at least once during the evaluation period and were thus regarded as “participating sites”. This comprised 605 pharmacies (594 community and 11 hospital-based) and 241 AAS.

After the sharp peak in February 2020, monthly supplies at pharmacy sites maintained a relatively stable trajectory, and AAS a gradual upward trend.

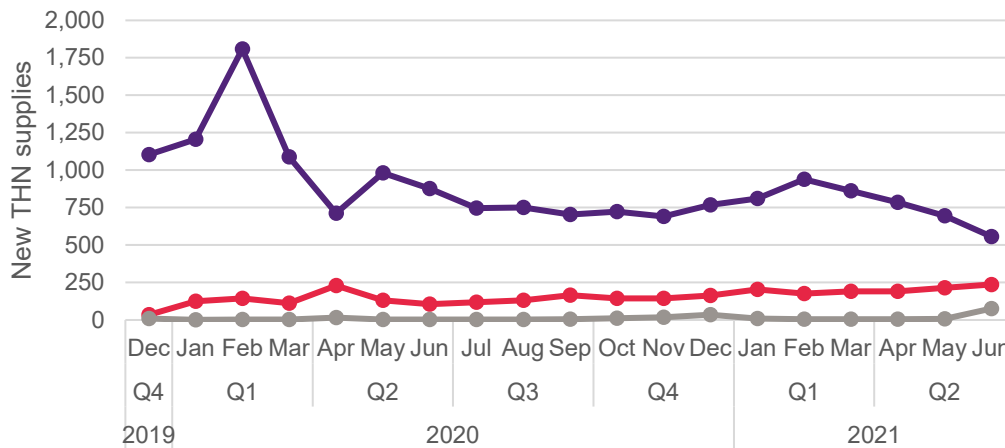
An apparent downward trend among city pharmacies was mainly due to a drop in NSW monthly supplies after the February 2020 peak; monthly supplies rose for city pharmacies in SA and WA.

Monthly supplies in regional pharmacies and AAS showed a gradual upward trend compared to city sites. Regional sites recorded an average of 156 THN supplies per month through pharmacies and 50 per month through regional AAS (see Figure 7).

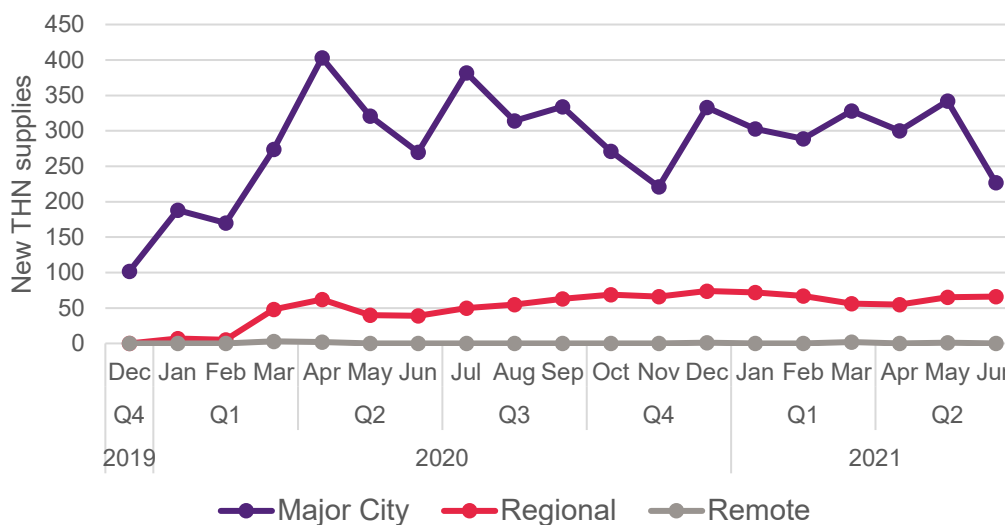
The increase in supply among AAS was primarily seen in NSW sites, both city and regional, including government AOD services and justice health settings. The majority of AAS supplies in WA (98.5% of 2,423 supplies) occurred at city sites with a stable trend of 126 supplies per month.

Figure 7. THN supplies December 2019 to June 2021, by access site type and remoteness

(a) Pharmacies (Community and Hospital Pharmacies)



(b) Authorised Alternative Suppliers (AAS)

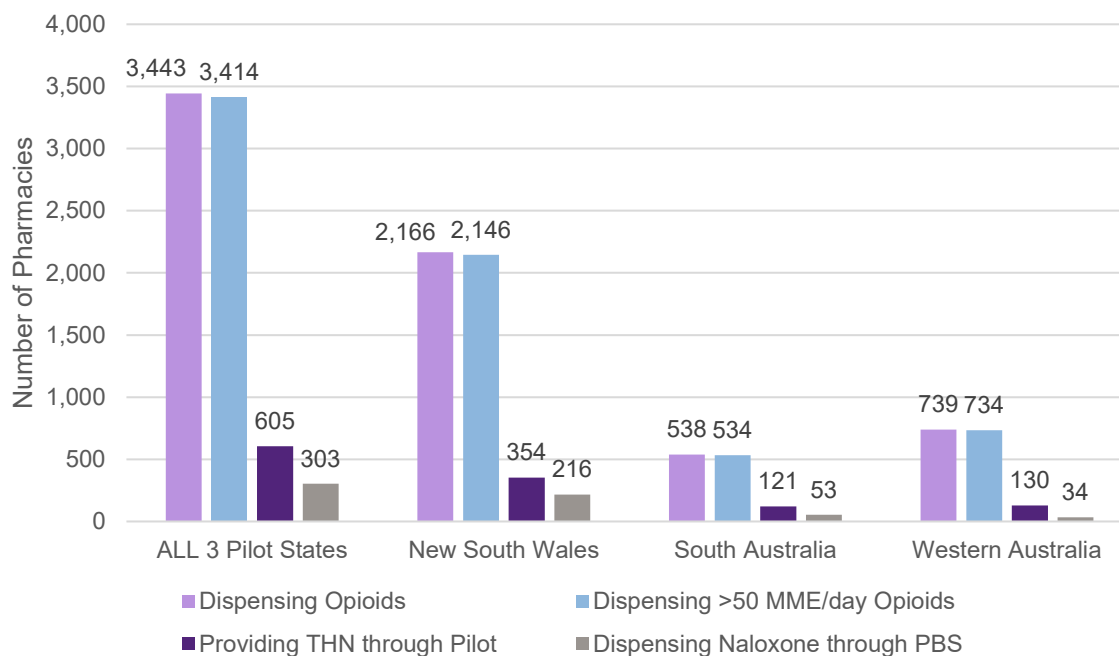


4.2.2.1 Participating Pharmacies

Figure 8 shows that during the Pilot period, twice as many pharmacies dispensed naloxone through the Pilot (n=605) than via the PBS (n=303). The difference was most marked in WA, where four times as many pharmacies dispensed THN through the Pilot than through the PBS.

We also found that the number of remote pharmacies providing THN via the Pilot was four times that of PBS-based naloxone providers.

Figure 8. Pharmacies dispensing naloxone and opioids in NSW, SA and WA, December 2019-June 2021



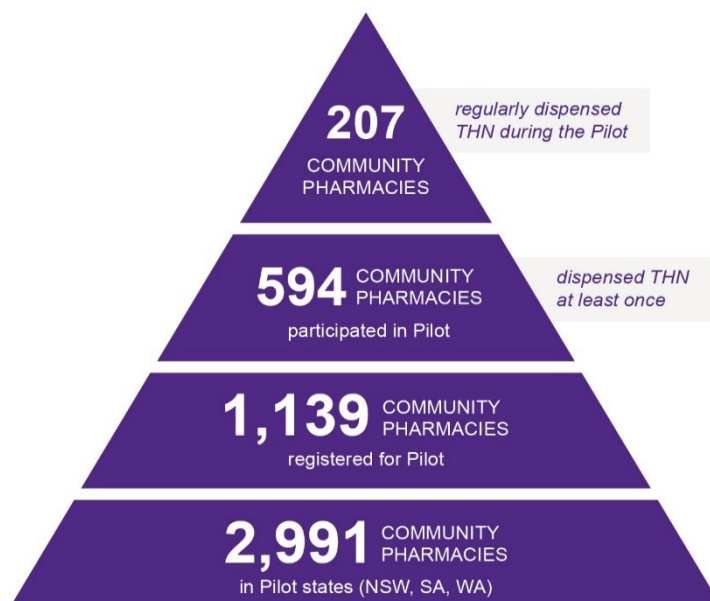
These participating sites represent 17.5% of all pharmacies that dispensed opioids in the Pilot states during this time (2,166 in NSW, 538 in SA and 739 in WA), most of which dispensed opioids comprising a potential overdose risk (i.e., >50 MME/day) to at least one person each month. This is significantly higher than coverage achieved through the PBS (8.8%).

This coverage estimate was slightly higher in SA (22.5%) than NSW (16.3%) and WA (17.6%), and in regional areas (21.2%) than in major city (16.4%) or very remote (15.8%) areas.

Participating pharmacies were mostly community (s90) pharmacies. A total of 1,139 community pharmacies registered for the Pilot, which accounts for nearly 40% of all community pharmacies in the three Pilot states⁹. Of those registered, 52% (n=594) participated (supplied naloxone once), but only 18% (n=207) made at least one supply per month after registration (Figure 9).

⁹ Source: <https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pb-expenditure-and-prescriptions-report-1-july-2019>

Figure 9. Active participation in the Pilot by community pharmacies



4.2.2.2 Participating Authorised Alternative Suppliers (AAS)

A range of AAS were approved in NSW and WA to provide naloxone directly to consumers as part of the Pilot. These included a range of health settings:

- Hospital services including emergency departments
- Alcohol and other drugs (AOD) treatment services (government and non-government)
- Needle and syringe programs (NSP); called Clean Needle Programs (CNP) in SA, including outreach settings
- Justice Health services and/or custodial release programs (NSW and WA[†])
- Community based health support organisations.

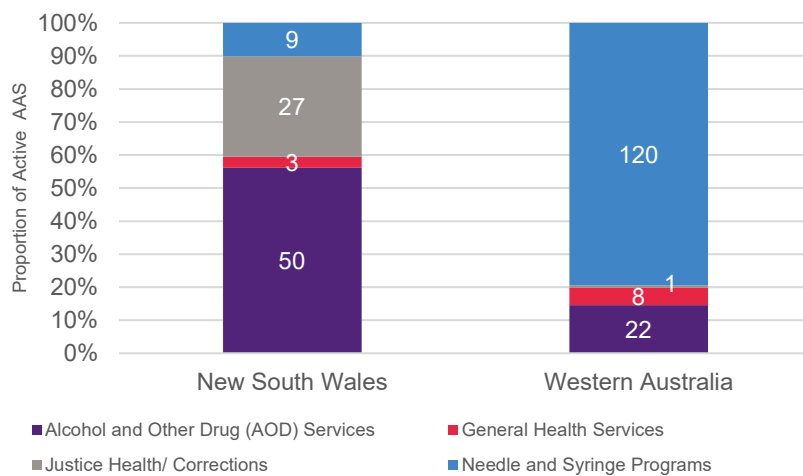
Of the 292 AAS registered for the Pilot, 241 (82.5%) provided naloxone at least once during the Pilot. Some very-newly-registered NGOs in NSW had yet to provide THN by 30 June 2021, but the participation rate for AAS was higher (82.5%) than that of community pharmacies (52%).

Figure 10 shows the participating setting types in NSW and WA, comparing sites that specifically target people who use illicit drugs (AOD services), justice settings where those leaving custody are at recognised risk of overdose, and general health services (hospital and community based) that offer broad, non-AOD services and reach broader populations. In both states, the majority of sites targeted people who use illicit drugs.

In SA, only DASSA was approved as an AAS for direct provision of THN. Other sites instead provided consumers with a voucher identifying the setting, to be redeemed for THN at a participating pharmacy or DASSA. Voucher data recorded at point of THN provision (n=778) shows referrals through other pharmacies (62.3%), CNPs (23.5%), other AOD services (7.8%), hospitals (3.2%), private prescribers/GPs (1.5%), peer networks (1.4%) and prison/post release programs (0.3%).

[†] Although justice settings in WA had been approved in late 2019 for Pilot participation by the then Deputy Commissioner Offender Services, administrative issues precluded active naloxone provision during the evaluation period. (Please refer to Section 6.6)

Figure 10. Participating Authorised Alternative Supply sites in NSW and WA^s, by setting type



NB: Numbers represent the number of active AAS in each setting type

The supply of naloxone in non-pharmacy settings continues to expand and evolve. The Royal Flying Doctors Service in NSW registered as an AAS, facilitating provision of THN in remote communities that may not otherwise be able to access the Pilot. A new initiative with the WA Police Force will see personnel carrying naloxone to administer in case of opioid overdose; this commenced in July 2021 and so was excluded from the evaluation. This is discussed further in Section 6.7. Similarly, an initiative with St John Ambulance WA will allow ambulance personnel to leave THN with overdose patients who refuse transport, commencing in October 2021.

4.2.2.3 Which site types showed limited engagement?

Despite being permitted to take part in the Pilot, some site types were not well represented among the participating AAS:

- No (s92) authorised medical practitioners participated actively in the Pilot; this may indicate communities had convenient and efficient access to naloxone from a PBS approved pharmacy.
- Specialist pain clinics did not appear to have engaged with the Pilot – none were registered, and knowledge, awareness and interest were limited when canvassed by the evaluation team.
- Hospital clinics and Emergency Departments (ED) showed limited activity. Some provision occurred through one WA hospital ED and some activity in a NSW hospital ED was described during roundtable consultations but not recorded in Pilot data.
- Mental health settings were not a targeted service type in the Pilot, but the mental health clinic at one WA hospital provided some THN during the Pilot.

Factors limiting participation by these site types are discussed in Chapter 6.

4.3 Did the Pilot reach the intended target groups?

The Pilot was intended to reach people at risk of experiencing an overdose, due to their use of opioids, either prescribed or illicit, and those who were likely to witness an overdose. In this

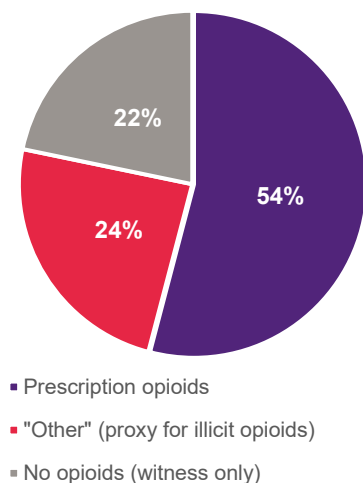
^s In SA, THN was primarily supplied under the Pilot by pharmacies. DASSA, as the sole registered AAS, was excluded from this graph. The large number of sites in WA represent individual service locations that each registered as separate access sites.

section we consider the characteristics of people who accessed THN through the Pilot to assess whether these target groups were reached.

At the point of naloxone supply, consumers were asked for consent to collect additional data for the evaluation. They were asked whether they identified as using prescribed opioids, as a witness only (no use of opioids), or an 'other' category (as a proxy for people who use illicit opioids, or PUIO). They were also asked about other medicines consumed, and whether they had previously accessed THN through the Pilot. Providers also recorded the consumer's estimated age group and gender. Consent and these additional data were collected for just under half of supply events (48%; n=13,525).

Over half of the consenting participants (58%) were male, and the estimated age ranges were predominantly 18-40 years (43%) and 40-60 years (44%). Data from the PBS indicate that these proportions are similar to people in Pilot states who had received naloxone via the PBS prior to the Pilot. The SA Pilot participant profile was slightly different: more were female (52%) and older (27% estimated at 60+ years), with fewer (30%) in the 18-40 years age range.

Figure 11. Opioid use nominated by participants at point of THN access



Of the consenting Pilot participants, just over half (54%) identified as using prescribed opioids (Figure 11). However, analysis of their other medications data provided showed that this group included people receiving opioid agonist therapy (OAT) and some who also used illicit opioids, as well as those using only pain medications. Just over one in five participants (22%) identified as potential witnesses (no use of opioids), and 24% identified as “other”. We were not able to determine whether there are differences between the consenting and non-consenting THN recipients, but it is possible that people who use illicit opioids may be over-represented in the non-consenting group.

4.3.1 People at risk of experiencing overdose

Using data from the PBS for 2019, we estimated that over 3 million Australians were dispensed prescribed opioids between 2015 and 2019. This is consistent with other findings.⁽⁴⁾ Using the opioid dose thresholds discussed in Section 1.1, we calculated that at least one in five (22%) people who were dispensed prescription opioids were at risk of overdose (average of 51-100 MME/day; 13.4%) or high risk of overdose (average of >100 MME/day; 8.5%)[†]. A small decrease in dispensing of opioid prescriptions was seen in 2020, but the proportion of people at risk remained high (23%) (refer to Figure 12).

These figures suggest that approximately 690,000 Australians were at risk of overdose from prescribed opioids in 2019.

People who use illicit opioids such as heroin are also at risk of experiencing overdose. Although as noted earlier, figures are likely to be a very significant underestimate. The proportion of Australians who reported recent use of heroin in the 2019 Household Survey (0.1% of the 2019 population) approximates to 25,000 people[‡]. Figures for people receiving opioid agonist therapy (OAT) are more robust (approximately 51,000 people[‡] in 2019) (40-42). These numbers are also shown in Figure 12, not for direct comparison (due to concerns regarding the estimates) but to illustrate differences in scale for the at-risk populations.

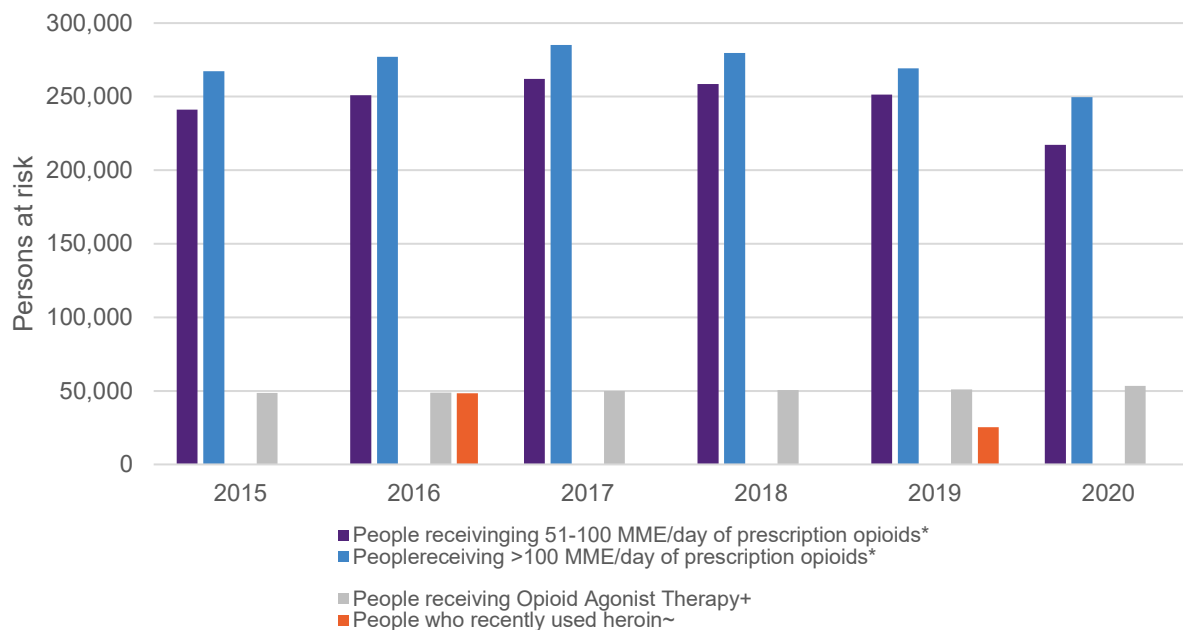
[†] Derived using PBS data. Estimates pertain to the number of patients receiving >50 MME/day dose of opioids in a month. Patients receiving both 50-100 MME/day and >100 MME/day in a month were counted in the latter category. Opioids for OAT are excluded.

[‡] Data from 2019 National Drug Strategy Household Survey

[‡] Data from the National Opioid Pharmacotherapy Statistics Annual Data

Due to likely overlap between these populations and concerns regarding underestimation of people at risk due to illicit opioid use, it is not possible to estimate a total 'population at risk'. Despite this, the potential need for naloxone to counter overdose remains significant for all.

Figure 12. People at risk of opioid overdose in Australia, 2015-2020



Sources: *Derived using PBS data; excluding opioids for OAT; +National Opioid Pharmacotherapy Statistics Annual Data; ~Derived using 2016 and 2019 National Drug Strategy Household Survey data

In order to understand what proportion of people who were at risk from prescribed opioid overdose received naloxone, we calculated a naloxone access rate^w: the number of people receiving naloxone relative to the number of people assessed as at risk (i.e., receiving opioid doses of >50MME per day).

Prior to the Pilot (January 2017 to November 2019), the average naloxone access rate^x was low: 15 per 100,000 population at risk in any given month across the Pilot states and 72 per 100,000 population at risk across the non-Pilot jurisdictions (refer to Figure 13). The higher naloxone access rate in non-Pilot jurisdictions was mostly in Victoria and the ACT, where active provision of naloxone through existing THN programs was recorded through the PBS as it required a prescription to be subsidised.

During the Pilot, the naloxone access rate rose substantially for participating states: from pre-Pilot (average over 35 months, January 2017-November 2019) rates of 15 per 100,000 people at risk to 1,630 per 100,000 during the Pilot^y (average over 19 months, December 2019-June 2021; Figure 12). NSW access rates peaked at 3,112 per 100,000 (or 3.1%) during February 2020, while the other Pilot states showed a gradual increasing trend: recent naloxone supply rates of 1,396 per 100,000 (or 1.4%) were noted in SA and 2,089 per 100,000 (or 2.1%) in WA.

^w Naloxone access rate is calculated by dividing the monthly number of naloxone supplies by the number of individuals who have been provided >50 MME/day opioids each month via PBS.

^x Pre-Pilot access rate calculated using PBS data only

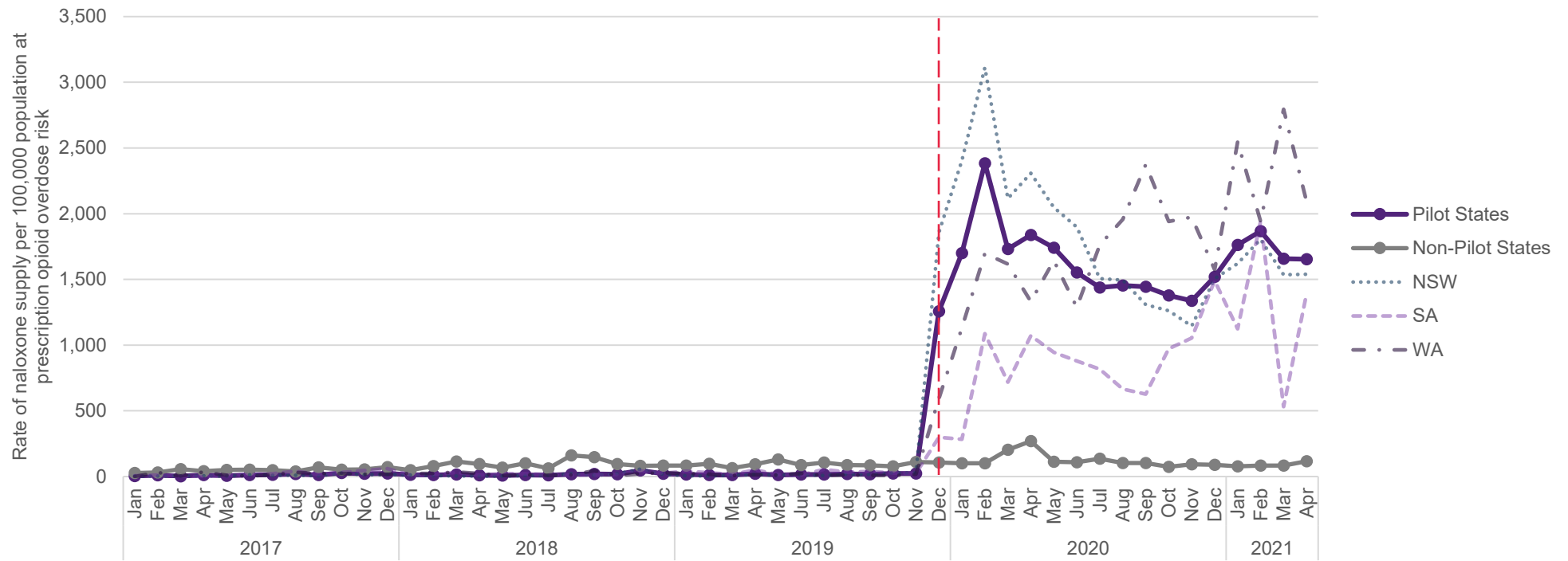
^y During-Pilot access rate calculated using PBS and Pilot data for naloxone provision for participating states

These access rate increases took place *before* the introduction in June 2020 of the TGA regulatory measures which restricted some opioid supply (refer to external factors discussed in section 3.1.9), suggesting the changes in access rates were not due to a decrease in opioid supply.

Similar increases in access rates were not seen in jurisdictions not participating in the THN Pilot, supporting the link between increased access rates and the Pilot.

It is important to note that while the Pilot has significantly increased naloxone access, the rates of people who access naloxone among people receiving prescription opioids for pain at doses that place them at higher risk of overdose are still relatively low (refer to Figure 13).

Figure 13. Changes in the naloxone access rate for individuals at risk of prescription opioid overdose in Australia^z during the THN Pilot



Note: Vertical red line indicates start of THN Pilot

Source: PBS and PPA data

^z Naloxone access rate is determined on the basis of best available data but may overestimate the number of naloxone supplies and underestimate the population at risk of prescription opioid overdose. Naloxone supply (numerator) includes all naloxone supplied through the Pilot and dispensed via PBS. Number of people at risk of prescription opioid overdose includes individuals dispensed with prescription opioids (excluding OAT medicines) at an average dose of >50 MME/day in each calendar month.

Although people who use illicit opioids are at a recognised risk of experiencing overdose, and earlier Australian THN programs specifically targeted this group, only 24% of consenting Pilot participants identified at the point of THN supply as “other” (a proxy for use of illicit opioids). This may be a significant underestimate of their participation in the Pilot: people who use illicit opioids may be less willing to provide consent for this information to be collected, and may also reflect the sites from which people accessed naloxone. In WA, more consumers than other states fell into the ‘other’ category (45%). This larger proportions of “other” consumers in WA mostly accessed THN from AAS, most of which were alcohol and other drug services. Conversely, in SA, where all consumers accessed THN at pharmacies, more (87.5%) identified as using prescribed opioids and fewer as “other” (4%).

Due to uncertainties regarding both the number of people at risk of overdose from illicit opioids and the proportion of THN recipients in the Pilot who identified as using illicit opioids, we were not able to calculate a naloxone access rate for this group.

However, other studies suggest that although earlier THN Programs specifically targeted people who use illicit opioids, naloxone access for this group of people had not reached saturation. Data from the 2020 IDRS indicate that only 46% of the PWID interviewed in NSW, SA and WA who regularly use opioids had accessed THN in the last year (39); in 2021 this was still only 52%. Similarly, the ETHOS Engage study, of people who used illicit opioids and/or were receiving OAT in 2018-2019, showed that even of people who had recently experienced an overdose, only 35% had accessed THN (10).

4.3.2 People likely to witness an overdose

Of the THN recipients who provided evaluation information, 22% identified as people who did not use opioids, indicating they were likely to witness, rather than experience, an overdose.

All consenting consumers were also asked directly whether they considered themselves at risk of experiencing an overdose. Although many of the “other” consumer group nominated themselves as at risk of *witnessing* an overdose rather than experiencing one, our assessment^{aa} of factors such as their opioid consumption and/or polypharmacy indicated that 80.7% were at risk of experiencing an overdose. Under-recognition of overdose risk is not uncommon, even among people who regularly use illicit opioids, and may limit people’s motivation to access THN for themselves (43).

Despite being at risk themselves, people who use illicit opioids also comprise a key pool of potential overdose witnesses, whose uptake of naloxone may allow them to support others in an overdose event.

Additional information characterising THN recipients was obtained through interviews of consumers recruited at the point of THN provision (n=213 individuals). Many reported they were actively involved in looking after their own health and supporting others, and as such would be well placed as potential witnesses to use naloxone in case of overdose. Three quarters (78%) reported being always or mostly in control of their own healthcare, and over half (52%) provided healthcare support for a partner or family member, and 18% for friends/neighbours. About one-third (30%) received healthcare support from their spouse/partner or relatives. The presence of

^{aa}We re-assessed the overdose risk for all participants (including those who identified as ‘not at risk’ or as witnesses only) using additional information:

Type of opioid used. Participants who declared use of prescribed opioids as well as ‘other’ types of opioid (e.g., illicit) were classified as at risk.

Other medications consumed. Participants who declared use of illicit opioids (e.g., heroin), opioids such as morphine or suboxone, benzodiazepines or poly-substance use, in addition to their prescribed medications, were classified as at risk.

In this ‘assessed overdose risk’ measure, we categorised an individual as at risk of overdose if they perceived themselves at risk or they were assessed as at risk using the information above.

such support networks reinforces the potential for this group to use naloxone to counter an overdose should they witness it, and suggests viable opportunities for peer-to-peer THN awareness programs as are active in some jurisdictions for people who use illicit drugs (10).

Implications

- Expansion of the Pilot in regional and remote areas should continue to maintain and to expand its reach in these locations.
- Underestimation of overdose risk should be challenged by targeted awareness raising for people who use prescribed opioids and friends/carers; despite the increase in THN access, <2% of the population at risk of pharmaceutical opioid overdose received naloxone through the Pilot.
- Ongoing expansion of AASs into the non-AOD space (such as pain clinics) should be a priority to further target people who only use prescription opioids and those who do not use opioids but may witness an overdose.
- Ongoing site-level monitoring mechanisms would be beneficial to encourage continued active provision of THN and resolve management stock issues.
- Inclusion of overdose awareness messaging as part of brief intervention/education may be an opportunity to increase awareness among those at risk. Consumer peer networks may be helpful to improve awareness of overdose; professional networks may help promote awareness of THN programs.

5. What impact did increasing access have on the uptake and use of THN?

Key points

- More naloxone was provided to individuals: 43,212 units of THN were supplied in NSW, SA and WA during the Pilot, compared to 4,495 across Australia over the preceding 4 years
- Nasal spray comprised 84% of THN supplied and was the preferred formulation, but pre-filled syringes remained in demand, particularly for refills.
- Having naloxone accessible at services outside the AOD sector (e.g., community pharmacies) provided opportunities to raise awareness of overdose risk among people who did not use illicit opioids but were themselves at risk or likely to witness another person's overdose.
- One in five people who received THN refilled their supply at least twice in a year; 65% of refills were due to use to reverse an overdose.
- The Pilot has enabled at least 1,649 overdose reversals, the equivalent of 3 reversals per day.

THN SAVES LIVES

“...one of them had some heroin and obviously she had too much, she ... dropped. Thankfully I had naloxone on me downstairs, so I ran down and got it, administered the spray, she came to and um everything was sweet.

“Well it felt good for me ... saving somebody's life. ...Overdoses shouldn't happen because it's preventable.

“I was out with a friend [in the] back streets of Kings Cross and the MSIC was closed. We come across someone who was in obvious opiate overdose distress, 'cause I can recognise the symptoms... we just swung into action. My friend and I knew what to do.

“... he just lost his wife, she died of cancer and he told me he was going to try and kill himself, and I looked at him and he was gray, and yeah gave him naloxone and brought him back.

“... Grab the naloxone, we're going to have to administer a dose. We rang an ambulance and then commenced CPR... What we did was fantastic... [I felt] like a responsible citizen of the community.

“...[my hubby] suffers from short term memory, and he's ... on a very strong painkiller Oxycodone...he would forget how much he's taken ... So, he doubled up on it... I knew that he'd taken an overdose... I gave him one dose of naloxone in the nose and within 10 minutes he started to improve...

DURING THE PILOT...

THN SAVED AT LEAST



Between 1 December 2019 and 30 June 2021, 43,212 units of naloxone were recorded as supplied through the Pilot to people at risk of experiencing or witnessing an opioid overdose in NSW, SA and WA^{bb}. In comparison, only 4,495 units of naloxone had been dispensed across Australia through the PBS during the 4 years leading up to the Pilot (January 2015 – November 2019). Supply through the Pilot was thus 10-fold higher in the 18 months of the Pilot than in the previous 4 years.

Eighty percent of the Pilot naloxone (34,494 units) was provided through community and hospital pharmacies. AAS supplied a further 8,718 units (20%). The majority of people who accessed THN from pharmacies identified themselves as using prescription opioids (63%); only 13% identified as using illicit opioids. At AAS, people accessing naloxone were more likely to have used illicit opioids (58%) than prescribed opioids (28%). People who identified as witnesses were more likely to approach a community pharmacy to access THN (24% of THN consumers) than an AAS (14%).

This is consistent with data from the 2020 IDRS that show that PWID in NSW were more likely to access naloxone from an NSP or drug treatment or health service (71%) than a pharmacy (2.4%) or other health service (22%). In WA, access was similarly focussed on drug-related services (53%, vs 38% from pharmacies and 7% other services). Naloxone access in SA was very low (16%) and evenly split between pharmacies and drug health services (44% each). These proportions did not change in 2021.

5.1 Did increasing the range of site types make it more likely that consumers found a site with which they were comfortable?

For community members who may not immediately recognise the relevance of overdose risk to themselves or as a potential witness, familiar pharmacy settings may provide an opportunity to open the conversation around naloxone:

One woman, who said she felt she didn't need it, accepted the naloxone anyway because [the pharmacist] convinced her it was a good precaution to have on hand. [The pharmacist] said the lady came in a couple weeks later and said she saved her son's life from an overdose with the naloxone. [The pharmacist] said this news was very motivating and boosted her efforts to keep giving out the naloxone. (Community Pharmacy, SA)

This opportunity for naloxone to be offered however depended on pharmacists recognising the need for naloxone being broader than people who use illicit drugs and being willing to open the conversation with the appropriate clients.

Many consumers interviewed preferred the familiarity of a known AOD service where naloxone was a routine part of harm reduction, as they felt that staff were less likely to discriminate against them:

It is easier when you go to the fit place, the clinics where you dose. I don't know. The people are trained different too, they are more relaxed and accepting of the person... here they are friendly. Because they want to get you the right equipment. They want you to be safe. That is what they are trained in, so they are doing the

^{bb}Data from PPA portal and manual systems from AAS in WA recorded the number of naloxone units provided on each occasion of supply. On each occasion, a consumer could receive up to two naloxone units: nasal spray, pre-filled jets, ampoules, or a combination of these. One 'unit' comprised a pack of two nasal sprays, a single pre-filled jet or a pack of five ampoules.

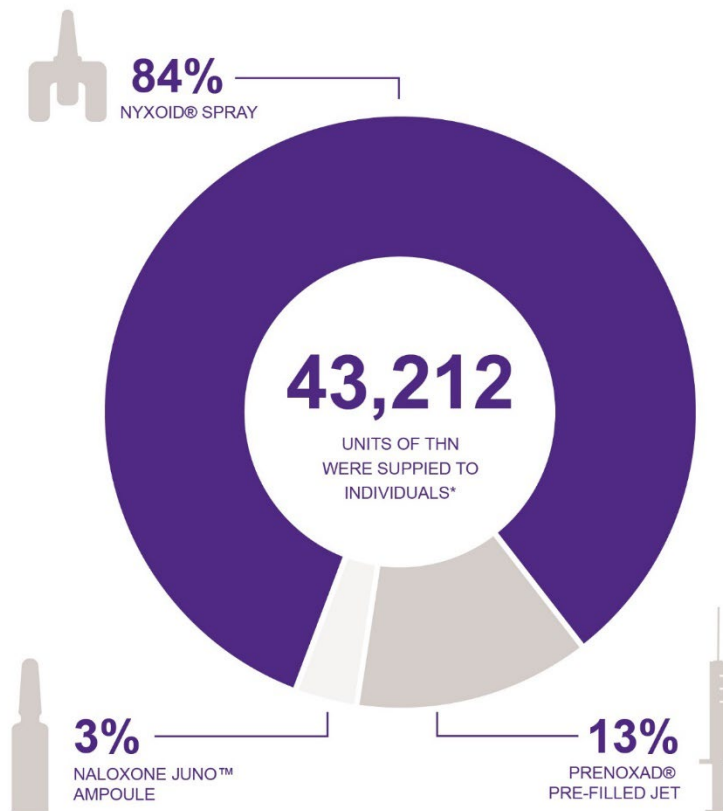
right thing. But at a chemist they look at you funny all the time. (NSW, PUIO, Recruited from Community Pharmacy, Interviewed December 2020)

Many consumers who also reported that they used illicit drugs felt most comfortable being able to obtain THN from peer organisations:

Very comfortable. If it was a chemist, I am not sure about a chemist or a hospital. There is discrimination and stigma that comes along with it, that would put me off. But trying to save someone's life or being able to provide that in my community sort of overrides the discrimination that usually comes along with their use. (NSW, PUIO, Recruited from NSP, Interviewed December 2020)

5.2 Did the availability of different naloxone formulations affect uptake and use?

Most sites offered consumers a choice between nasal spray (up to two units, each containing two actuations, per supply), pre-filled jets (up to two units of one jet each) or one unit of each. In staff interviews and roundtable consultations, some sites (primarily corrective service health sites) noted that only one formulation was available for consumers, and in the majority of cases this was Nyxoid®, often due to organisational policies regarding needles and syringes. The majority (84%) of naloxone supplied across the Pilot was the nasal spray formulation (Nyxoid®), followed by pre-filled jets (Prenoxad®; 13%) and ampoules (Naloxone Juno™, 3%).

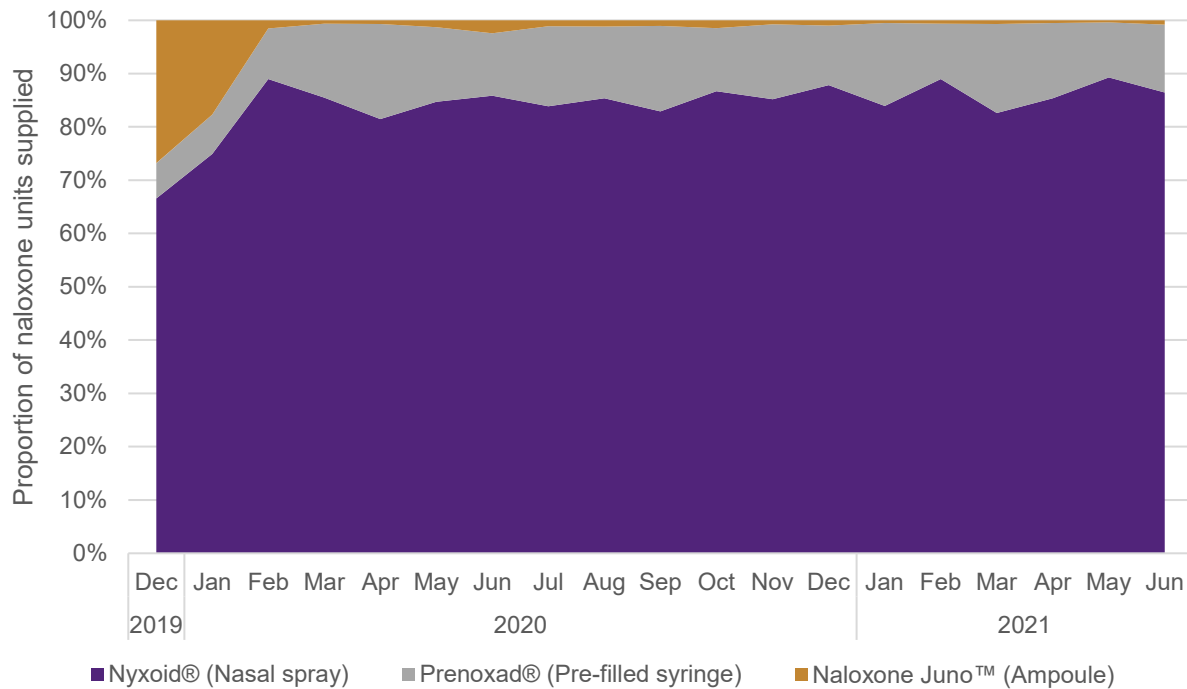


*May underestimate by 5% where individual data not available.
Naloxone HCL and Junalox® are not shown because they comprised less than 0.1% of total naloxone supplied

The proportion of Nyxoid® remained between 85%-89% between February 2020 and June 2021, while the proportion of Prenoxad® showed a steady increase from December 2019 until

April 2020, after which its trend has fluctuated between 10%-18% (refer to Figure 14). Naloxone Juno™ dropped from 8% in April 2020. Naloxone HCL and Junalox® formulations comprised less than 0.1% of the naloxone supplied during the Pilot.

Figure 14. Proportion of naloxone units supplied by formulation during the Pilot

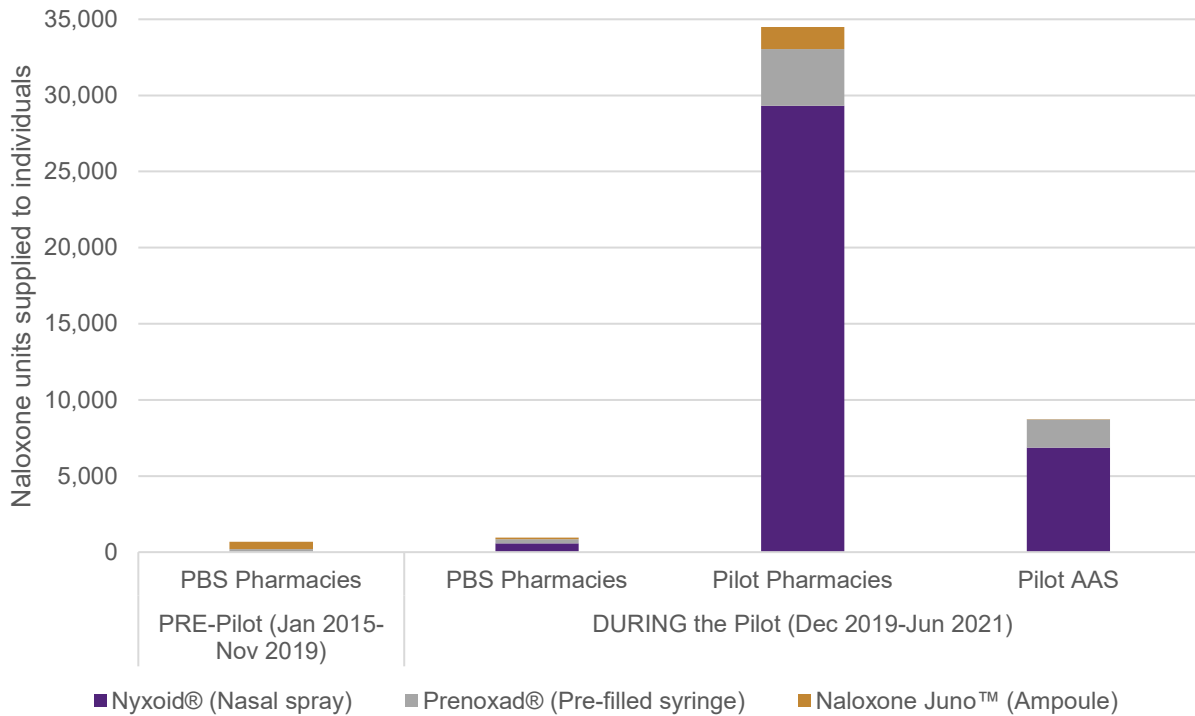


Note: Naloxone HCL and Junalox® formulations not shown; <0.1% of units supplied

Figure 15 shows that the nasal spray (Nyxoid®) was the most supplied formulation in both Pilot pharmacies (85%) and AAS (79%), as well as in PBS-only pharmacies in the Pilot states (60%). As shown below, the distribution of naloxone formulations shifted from DBL® Naloxone HCL® before the Pilot to the nasal spray, which became more widely available during the Pilot.

In Pilot data from the PPA portal, the predominance of nasal spray as the preferred naloxone formulation was consistent across type of opioid use. More of those who identified as using illicit drugs (35%) obtained prefilled syringes compared to those using prescription opioids (9%) and witnesses (17%) ($\chi^2 = 17.98; p = 0.006$). This is reflected in supply data where 31% of PUIO obtained Prenoxad®, compared to 10% of people using prescribed opioids and 14% of witnesses. No specific supply pattern was found by age or gender.

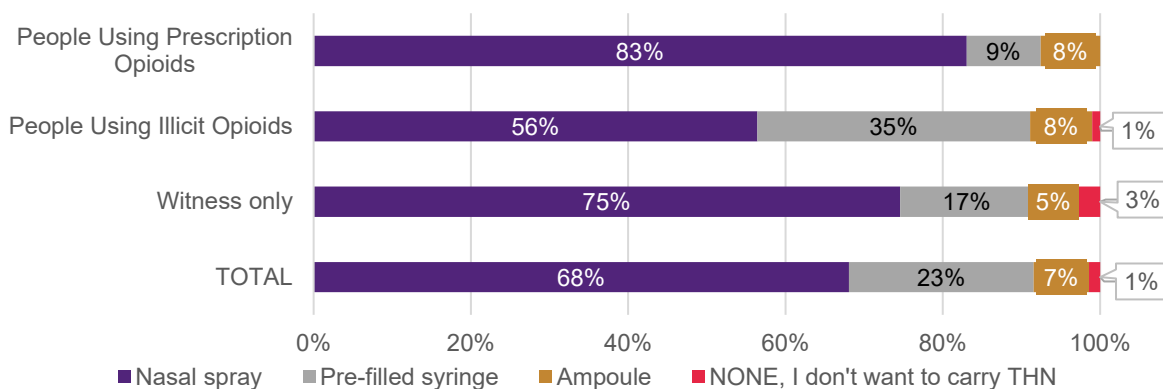
Figure 15. Naloxone units^{cc} supplied in participating states, before and during the Pilot, by access site type and formulation



Note: PBS data include naloxone supplies up to April 2021.

For the purposes of the evaluation, 213 individual consumers who accessed THN as part of the Pilot were interviewed to obtain more in-depth information as about their access and use of naloxone. These data confirmed a preference for nasal spray among consumers (Figure 16), again with no difference in preference by age or gender.

Figure 16. Preferred naloxone formulation, by type of opioid use^{dd} (n=213)



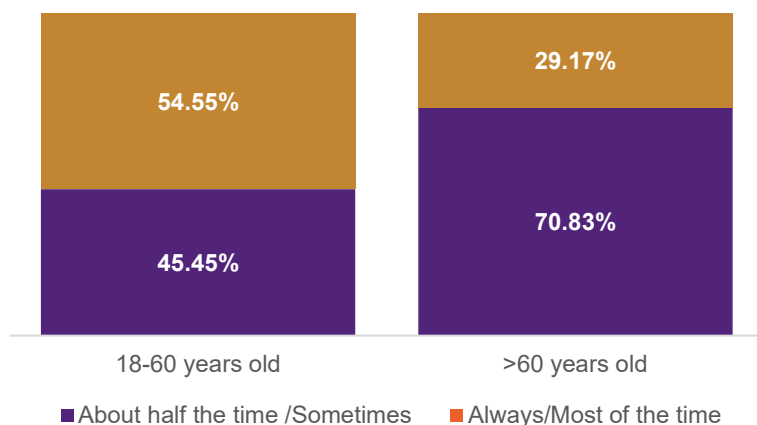
Participants were asked “How frequently would you carry naloxone?”

^{cc} This refers to the number of units supplied to individuals.

^{dd} Using the most recent interview of each participant

Older participants (aged 60+) were more likely to report they would carry their nasal spray irregularly (i.e., about half of the time/sometimes) compared to younger age groups (45%) ($X^2=5.16$; $p=0.023$; Figure 17).

Figure 17. Frequency of carrying nasal spray THN by age group (n=213)



For other naloxone formulations, similar proportions responded 'Always/Most of the time' and 'About half the time/Sometimes' ($X^2=0.318$; $p=0.853$). These patterns did not vary by type of opioid use, age or gender.

In the qualitative interviews, the majority of consumers noted that their preferred form of naloxone was the nasal spray, Nyxoid®, due to its perceived safety and ease of use.

Well it's easier, it's much less complicated especially for people that may not be used to handling ... injecting equipment. Because the other one ... you need to use the ampoule, you need the needle tips, you need to find the place to inject someone, that sort of thing. That, that can be overwhelming... in an overdose situation possibly never, you know, in your life and all of a sudden you've got to do something with a needle. That could be really overwhelming for people. Yeah so, yeah that's why I would say the nasal spray. (SA, PUIO, Recruited from NSP, Interviewed January 2021)

The nasal spray because I don't want to inject, some people hate the injection and that's why I prefer because the spray might take a little bit longer where the injection takes you much quicker really. (SA, PUIO, Recruited from NSP, Interviewed January 2021)

Like it is a very safe drug to have around. No one can get hurt or anything like that (NSW, PUIO, Recruited from NSP, Interviewed October 2020).

Amongst some consumers, the nasal spray formulation was considered 'less harsh' than injectable formulations, which many referred to generically as 'Narcan'. Many noted that Narcan was perceived negatively because of the effect that it could have on the pleasurable effects of opioid intoxication. For example:

Narcan has always had this sort of reputation of being a lifesaver, for sure, but also not a very pleasant experience, yep. Especially if you just paid \$100 for your wack and you're enjoying your stone even if you might be dying in the process, then suddenly you're snapped right out of it, you know? (SA, Witness, Recruited from NSP, Interviewed February 2020)

Nevertheless, the enhanced efficacy of injectable formulations of naloxone was still appreciated by many, with a minority noting that they would prefer to have this option, particularly the pre-filled syringe.

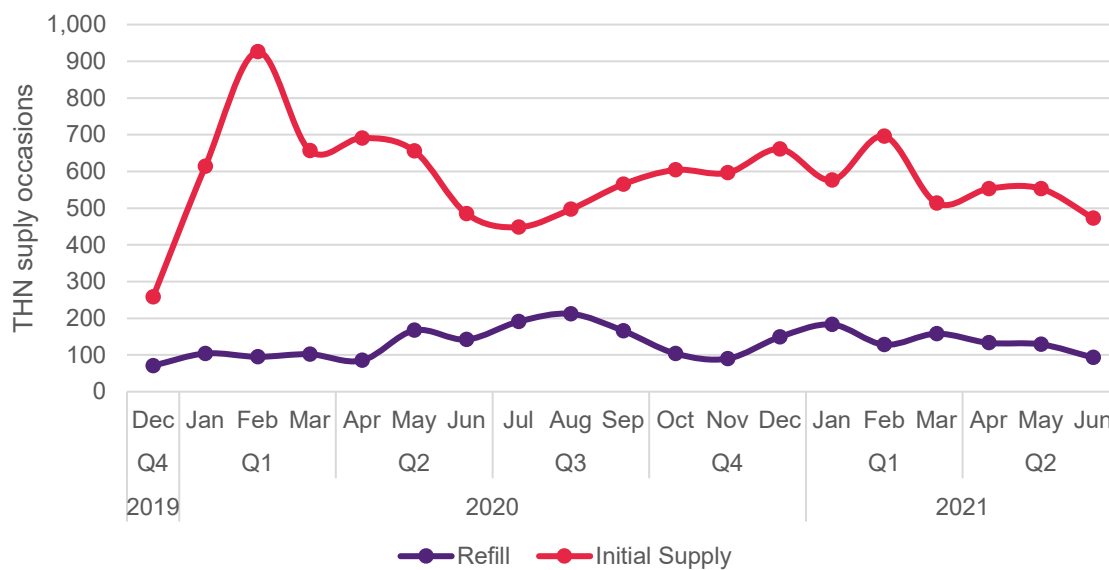
Because it's- well for me, just personally, it's just easier to whip it open and then just, ... into somebody's leg or arm or through clothing, ... just as preference. (SA, Witness, Recruited from Community Pharmacy, Interviewed January 2021)

5.3 Repeat access to THN

Of those supply occasions where evaluation data were captured (n=13,525 or 48%), a total of 11,023 supplies were reported as 'initial supply' (82%) while 2,502 (18%) were 'refills' or repeat supplies. In the participating states, the proportion of refills was higher during the Pilot than it had been prior to the Pilot through PBS supply (14%, n=93; p<0.001). Refill supply during the Pilot was mostly reported through AAS (54%); much of this was in WA. In NSW, the majority of refill supplies were through pharmacies (78%). Of the refills, 65% were reported as due to use to reverse an overdose (see section 5.4), with 35% being due to THN having been damaged, lost, or given to another person.

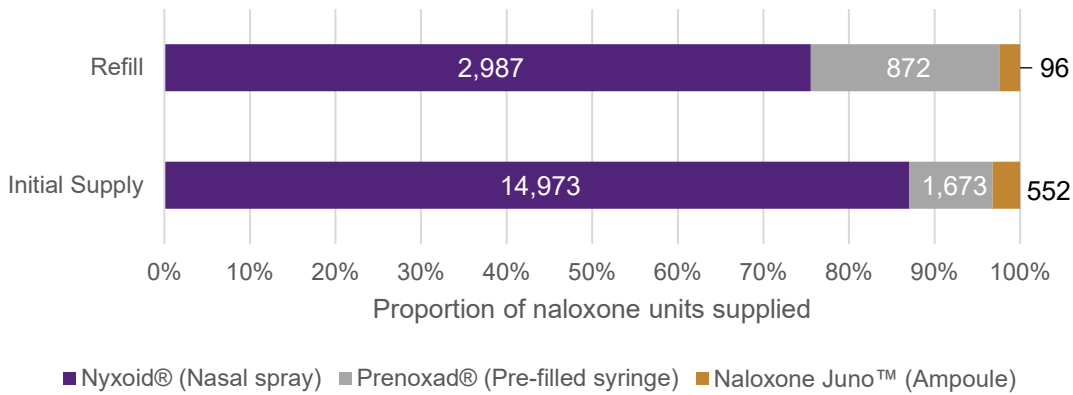
Figure 18 shows that monthly proportion of refills fluctuated between 10% and 30% during the Pilot, with no obvious increase in monthly rate over time. We also found minimal rate change over time when disaggregated by state, type of opioid use, type of access site and location.

Figure 18. Number of initial and refill supply occasions, December 2019 – June 2021



Nasal spray was the formulation most commonly provided for both initial (87%) and repeat (76%) supplies (Figure 19). Pre-filled syringes comprised a higher proportion of refills than they did of initial supply. This indicates that although Prenoxad® was less popular than Nyxoid®, it remains a preference for some consumers, and so it is important that both remain available to consumers.

Figure 19. THN formulation supplied as initial supply and refill

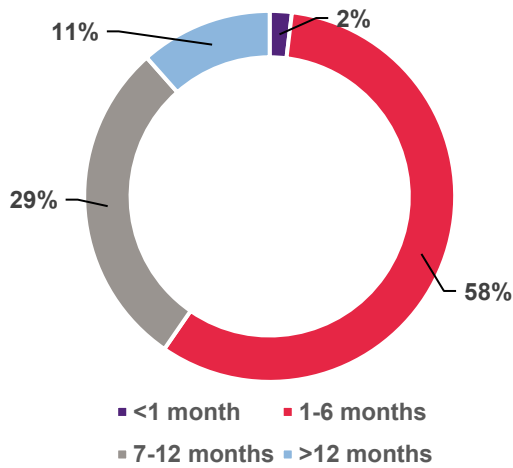


Source: PPA data

From interviews of THN recipients, we estimated how frequently consumers obtained a new supply of naloxone, i.e., the time between refills.

Of 83 individuals who were interviewed at least twice, 52 (63%) reported at least one refill event. Figure 20 shows that over half (58%) obtained their THN refill 2-6 months after previous supply while one third (29%) refilled after 7-12 months.

Figure 20. Estimated interval between THN supply (refills) using interview data (n=52)



Most interviewees had obtained their THN refill from community pharmacies; this aligns with data from the PPA portal, where the majority of THN refills were from community pharmacies (50%) and NSPs (42%).

Source: Interview data

5.4 Use of THN for overdose reversal

Naloxone recipients who reported their supply as a refill were asked whether the previous supply had been used to resuscitate someone. Of the supply records with evaluation data (n=13,525; 48% of supplies), 1,649 (12%) reported their previous supply had been used to reverse an opioid overdose during the Pilot. Other studies show comparable findings: data from the 2019 IDRS showed that of PWID who had accessed naloxone through a take home program, 12% had used it to resuscitate someone. A 2015 international meta-analysis estimated that 9% of naloxone units distributed to people who use illicit drugs would be used within three months to resuscitate someone (44).

This estimate is the equivalent of approximately **3 opioid overdoses reversed per day^{ee}** across the entire period of the Pilot (Figure 21). As it is based on data from only 48% of supply occasions, this is likely to be a significant **under-estimate**.

Figure 21. Use of naloxone during the Pilot

DURING THE PILOT...



The number of refills due to use recorded at access sites each month fluctuated considerably over the course of the Pilot, with the largest numbers seen in WA. However, there was a gradual increase in the monthly figures for NSW and SA from December 2019 onwards.

Most were reported from cities, but even so, 94 overdose reversal events (6% of the total) were recorded by sites in regional and remote areas. In NSW most refills due to use were from community pharmacies (79%) while in WA these were from AAS (84%).

Overall, nearly one third (31%) of people obtaining refills after use identified as witnesses. There was some variation between the states: in NSW, 41% were witnesses, in SA 24% and 18% in WA. People who identified as using prescribed opioids comprised 21% and PUIO, 48%.

Of the consumers interviewed (n=213), one third (29%) reported at least one overdose reversal using THN in the last 12 months, with 12% reporting 2-4 occasions and 1% more than 4 occasions.^{ff} Of those who used their THN on others, 56% and 46% administered nasal spray and pre-filled syringes, respectively. Ten interviewees reported that they were resuscitated

^{ee} Calculated by averaging the total number of refill supplies attributed to use of previous THN supply to avert an overdose event across the number of days of the Pilot (total of 573 days) to 30 June 2021.

^{ff} Where participants were interviewed multiple times, we used the most recent interview.

using their own THN at least once in the last 12 months. Most reported having used illicit opioids. Five were resuscitated using a pre-filled syringe and two with nasal spray.

Seven were resuscitated by friends, neighbours and/or bystanders, again reinforcing the importance of witnesses as agents of overdose reversal.

Many consumers reported that they liked to carry naloxone in case they witnessed an overdose:

I always keep Naloxone on me, wherever I go, in the car or in my bag, wherever...just in case I need it (WA, PUIO, Recruited from NSP, Interviewed May 2021).

Yeah I just know it's really handy having this stuff around. It saves people's lives (SA, PUIO, Recruited from Community Pharmacy, Interviewed August 2020).

Because I lived in a housing commission building where people used drugs and stuff in the fire escape. So I always make sure I have plenty of naloxone at home (NSW, Witness, Recruited from AOD/NGO, Interviewed September 2020).

Yeah they just asked me, would I be interested in it? And I said "well yeah". I've lost a few mates that've overdosed and I often bump into someone who overdosed somewhere, you know, so, it'd be a good thing (NSW, Witness, Recruited from AOD Service, Interviewed October 2020).

Detailed stories of overdose reversal from consumers are discussed in the section below.

5.5 Stories of overdose reversals from THN Consumers

THN SAVES LIVES

“...one of them had some heroin and obviously she had too much, she ... dropped. Thankfully I had naloxone on me downstairs, so I ran down and got it, administered the spray, she came to and um everything was sweet.

“Well it felt good for me ... saving somebody's life. ...Overdoses shouldn't happen because it's preventable.

“I was out with a friend [in the] back streets of Kings Cross and the MSIC was closed. We come across someone who was in obvious opiate overdose distress, 'cause I can recognise the symptoms... we just swung into action. My friend and I knew what to do.

“... he just lost his wife, she died of cancer and he told me he was going to try and kill himself, and I looked at him and he was gray, and yeah gave him naloxone and brought him back.

“... Grab the naloxone, we're going to have to administer a dose. We rang an ambulance and then commenced CPR... What we did was fantastic... [I felt] like a responsible citizen of the community.

“...[my hubby] suffers from short term memory, and he's ... on a very strong painkiller Oxycodone...he would forget how much he's taken So, he doubled up on it... I knew that he'd taken an overdose... I gave him one dose of naloxone in the nose and within 10 minutes he started to improve...

More than 60 stories of overdose reversals were recounted by participants during the qualitative interviews. Interview participants reported administering naloxone to others more often than receiving it during resuscitation events.

We were sitting in the lounge room at home, I was on one lounge he was on the other had mine then he had his and then I thought nothing of it and went to the toilet, and then he started, his eyes were rolling, I didn't think nothing of it, then his eyes shut, then one minute he started getting purple that's why I knew straight away then I ran to my room got it put it straight in the nose then a couple minutes of after he came around and got a bit wild with me, but that's ok. (NSW, PUIO, Recruited from Community Pharmacy, Interviewed March 2021).

Some participants did report that they had been resuscitated using naloxone supply acquired under the Pilot:

You mentioned that you were resuscitated BY someone since the last time you were interviewed, can you tell me more about that?

Yeah my wife, came home after work and found me in a bad way, the needle still in me. She said she panicked and remembered she has one on her and done it the way that I showed her how to administer it and then she said I came around, she also called the ambulance and she said make sure that never happens again (NSW, PUIO, Recruited from an NSP, Interviewed March 2021).

The most commonly used form of naloxone used during these events was the nasal spray.

It all came automatic, I just thought back to what he said and once my sister and myself had worked out that he was non-responsive we stuck it up his nose and pushed the button [laughs] and because it's a longer acting one that's what we pick up now, is the nasal one. (SA, PUIO, Recruited from Community Pharmacy, Interviewed January 2021).

However, despite being the most favoured form from a functional perspective (e.g. easy to carry, no need for refrigeration), the nasal spray was said to take longer to take effect during a resuscitation event, and frequently needed to be administered more than once.

I did it once and then waited five minutes and you could see they had come around a little bit, but not very much but then, I gave them the second package...the second nasal spray that's in the box because it comes in two lots..., so I continued to administer the second... after five minutes they started to wake up.... They were awake and fine. ... After that, they were totally fine (WA, PUIO, Recruited from NSP, Interviewed March 2021).

Likewise, one participant had a similar report of the nasal spray being administered to them during a resuscitation event.

Yeah, they used the nasal spray on me. They had to use two of them as well. It still took a while for me to come to. So maybe the injection is a bit more effective (WA, PUIO, Recruited from NSP, Interviewed January 2021).

However, despite the fact they do administer naloxone when required, and the majority (65%) also called an ambulance, not all participants enjoy administering it, nor do they stay after the recipient has been revived.

I administered it to a random person who was in the toilet. There was nobody helping.... I just did what I needed to do. I injected him with it and he came around straight away after we tried CPR and other things. Then I got out of there pretty quickly. He was in shock, embarrassed, I think. It sucks... I hate resuscitating people in general, so even more random people. I waited until the ambulance arrived and that's why when I just sort of left {WA, PUIO, Recruited from Community pharmacy, Interviewed March 2021).

The main reason cited by participants for disliking administering naloxone is the fact many recipients become angry once they regain consciousness.

*They dropped. I saved them. I woke them up and they didn't like it. They were *** angry because they wasted their money to get high and I brought them back to life (WA, PUIO, Recruited from Community pharmacy, Interviewed February 2021).*

Despite the reactions of recipients, most reported a positive feeling after a resuscitation event.

Yes, we had a friend over who started falling asleep, nodding off as we call it. We were able to arouse him by calling his name, tapping him on the face. He assured us he was fine but the next time we looked at him, his lips were blue. I said to my partner to grab the naloxone, we're going to have to administer a dose. We rang an ambulance and then commenced CPR...then commenced the nasal spray followed by CPR. The ambulance people arrived, assured us that yeah, they weren't actually required. So what we did was fantastic, they made us feel very comfortable with us calling the ambulance and with us using the naloxone. [I felt] like a responsible citizen of the community (WA, Witness, Recruited from NSP, Interviewed May 2021).

Another participant noted a feeling of relief after having saved someone's life using THN:

Interviewer: And how did you feel?

Participant: Um, I was actually well...how did I feel about saving his life? Relieved. (WA, Witness, Recruited from NSP, Interviewed May 2021).

Overall, consumers expressed overwhelmingly positive opinions of the Pilot and THN, with a large number noting that THN 'saves lives'. For example:

I just, personally I think it's a brilliant thing, you know? That saves someone from dying, pretty much, at the end of the day (SA, PUPO, Recruited from Community Pharmacy, Interviewed October 2020).

I believe that they should provide to everyone who uses drugs, you know it's a good thing to save lives. And yeah, I appreciate that they're doing it, it's great (SA, PUJO, Recruited from NSP, Interviewed August 2020).

Like to me it sounds like sheer common sense. Any person who dabbles with you know, hard drugs like that, um, particularly if you're doing it intravenously, um, yeah, you'd like to have that nearby (SA, PUJO, Recruited from Community Pharmacy, Interviewed September 2020).

Further stories of the use of THN to reverse overdoses are included as Appendix E.

Implications

- The Pilot should continue to expand its reach among at risk populations where there has been limited uptake of THN, such as people who use opioids to manage chronic pain, peer/family and carers who may witness another person's overdose.
- Encouraging staff at existing supply sites to engage with these groups, and expanding site types to include pain clinics and carer organisations may help with this.
- The Pilot should also consider leveraging peer/family/carers networks to reach people who are not currently connected with services that may refer them to THN.
- People should be encouraged at the time of their initial supply to obtain a refill once the previous supply is used, damaged/expired or given to someone else.

6. What was the impact on access sites participating in the pilot?

Key points

- Most staff interviewed were very positive about the THN Pilot, noting the positive effects it had on their organisation's ability to provide THN.
- Most pharmacy staff found the THN Pilot's impact on their workload was minimal, and successfully incorporated it into existing workflows and processes.
- Most staff believed the training and credentialing systems equipped them with knowledge and skills to distribute naloxone to clients. Many expressed a preference for online training, or a choice of online or face-to-face where possible.
- Staff in AOD services and community pharmacies considered providing THN to be part of their core role, but organisations new to THN commented on the lack of funding to assist implementation.
- The impact on access sites differed by state, and by the different types of access sites that were engaged and credentialed as part of the Pilot.
- There was limited engagement by hospital pharmacies in some jurisdictions, due to barriers to implementation in these settings. There was also limited engagement by pain clinics, primary care, and mental health settings.



This chapter assesses the impact of the THN Pilot on access sites. The chapter first addresses the broader regulatory environment around access site involvement in the Pilot, followed by a discussion of the broad impacts of the THN Pilot on access sites including the development of organisational policies and procedures, workforce and impacts on workload, and training for staff. Following this broad discussion, the chapter focuses on impacts for specific types of access sites: community pharmacies, AOD services, NGOs, NSPs, Corrective Services Health Settings and Police. The chapter concludes by examining some of the factors that limited engagement in the Pilot by some types of access sites.

6.1 Regulatory environment

Each jurisdiction involved in the Pilot has a different state regulatory environment governing the supply of THN by alternative access sites.

In NSW and WA, existing THN programs facilitated the engagement of alternative access sites.

Under the ORTHN trial, the NSW Ministry of Health had initiated changes to regulatory mechanisms to allow appropriately trained, authorised health staff to provide naloxone.

In August 2020, the NSW Ministry of Health issued a Policy Directive that allowed for alternative access sites to supply THN. Under Clauses 170 and 171 of the Poisons and Therapeutic Goods Regulation 2008 (Regulation) the Secretary of Health authorised (for the purposes of the Act) credentialed health workers employed in a Local Health District, Justice Health & Forensic Mental Health Network, St Vincent's Health Network or the Medically Supervised Injecting Centre (MSIC) in NSW to supply Schedule 3 medications under clause 17 of the Regulation. The authorisation applies only to naloxone supplied under the intervention described in these Procedures. This policy directive was later amended to allow the inclusion of NGOs.

In Western Australia, changes to allow alternative access sites were initiated under the WA Naloxone Projects 2018-2020 through a Structured Administration and Supply Arrangement (SASA) under the Medicines and Poisons Regulations 2016. This allowed appropriately trained, authorised staff (including volunteers) employed by selected services to supply naloxone given they satisfy a number of conditions, such as staff having appropriate First Aid and other certificates, staff undertaking training in prevention of opioid overdose and administration of Naloxone from the Mental Health Commission, and other conditions (45).

In South Australia, there were no pre-existing THN program and policy frameworks to facilitate the introduction of regulatory mechanisms to include alternative access sites in the implementation of the Pilot. Consequently, to allow for timely implementation of the Pilot and commencement of the provision of THN, the implementation process in this jurisdiction did not include activity or regulatory mechanisms allowing for alternative access sites to provide THN free of charge without a prescription. Community pharmacies were the key focus for the implementation of the THN Pilot in South Australia.

6.2 Organisational policies and procedures

The implementation of the THN Pilot required organisations, particularly AAS, to implement their own policies and procedures to integrate THN provision into their organisational workflows.

The majority of access site staff noted that the organisations that they worked for needed to develop or adapt their own policies and procedures for a range of activities related to operationalising the THN Pilot in their organisation. These included: receipt of stock; storage; identification of appropriate clients to offer naloxone; how to approach clients and how to have the conversation with them about naloxone; and entry of data relating to THN provision. Receipt of stock, secure storage of naloxone and data entry were newer activities for AAS, but core

business for pharmacies; however, some pharmacists did note that their organisation had to develop their own policies about identifying and approaching appropriate clients for THN.

Practices for approaching clients and discussing naloxone were more likely to be “business as usual” for AAS if they were an AOD-focussed organisation such as an NSP. Some access sites were provided with policy and procedural documentation by implementing agencies including the Ministry of Health in NSW, but most still reported that they needed to develop their own policies to fit the Pilot into their own organisational workflow. Where access site staff had to develop their own policies to implement the Pilot, many reported that it was difficult to easily access information that would have helped them. They also noted problems with some of the information on implementing agencies’ websites, particularly lists of pharmacies where THN was available under the Pilot being out of date or inaccurate.

Many access site staff noted that some clients either did not consider themselves at risk of opioid overdose, or were not interested in discussing their own potential risk of overdose. Some staff noted that framing conversations with clients around responding to overdose risk for *others* rather than themselves was successful in encouraging client uptake in these cases:

But interesting, a lot of people are really keen to take it if you talk to them about risk to others, not so keen when you talk about their own risk. (Roundtable Participant, Prison Health, SA)

Many of the access site staff described using existing promotional material such as Overdose Awareness Day and visual promotion materials (posters, postcards) to display around their sites to promote THN and initiate conversations with clients. Staff also described drawing on existing resources in the form of research, guidelines, and information sheets produced about THN.

6.3 Workforce and impact on workload

The impact on access sites varied depending on the setting. For community pharmacies, the THN Pilot had minimal impact on staff workloads and was easily integrated into existing workflows; this feedback was consistent across jurisdictions.

The existing frontline workforce in AOD settings (including treatment services, NSPs, and AOD NGOs) regarded THN as a core part of their role in harm reduction. Many staff were pleased that they were able to provide THN to their clients to assist them.

...the key thing in aspect of how we operate the service, take home naloxone is considered core-business. (NSW, NGO/ AOD staff member, Interviewed July 2021)

Many staff were pleased that they were able to provide THN to their clients to assist them.

Most access site staff interviewed reported that the incorporation of THN into their existing duties had caused minimal disruption, however some access site staff (particularly those in AOD NGOs in WA) noted that they would have appreciated funding for implementation.

Although they reported some impact on their workload by administration and other activities related to the THN Pilot, this was not viewed in a negative manner. The majority indicated that the average time for each THN provision was 10-15 minutes.

State implementing agencies provided support to access sites with aspects of the Pilot such as registration and using the PPA portal. Although information was available on the PPA portal to assist with these functions, the implementing agencies reported receiving a significant number of requests for clarifications and assistance, creating some pressure on workload at state coordination level. The additional support was however positively regarded by the site staff interviewed.

6.4 Site credentialling and staff training

Although not mandated by the Department as part of the Pilot, credentialling of AAS and training of AAS health workers were instituted in WA and NSW. In WA this was undertaken by the WA Mental Health Commission (WAMHC)⁹⁹, again following on from previous arrangements. NSW Health initially contracted training for health workers from South East Sydney Local Health District (LHD), following on from the ORTHN trial. Subsequent iterations of training, including for NGOs, were provided by St John Ambulance. Credentialling processes were managed by NSW Health^{hh}.

The majority of access site staff interviewed indicated that the training equipped them with the information that they needed to distribute naloxone to consumers, and was practical. This was consistent across all three states. Very few interviewees felt they needed more training or that they were unsure about how to explain the use of naloxone to clients. The staff training and credentialling process differed by state, and there were some jurisdiction-specific issues.

Many of the interviewees in New South Wales commented that the initial credentialling process being face-to-face resulted in some difficulties in sufficient numbers of staff being able to attend and complete the training. However, once the training was moved online due to COVID-19, this created greater opportunities for more staff to complete the training.

The main negative comments about the training and credentialling process for NSW access sites revolved around the time it took to get approved in their own organisational system once they had done the training.

There was also confusion for some workers about the purpose of the credentialling and training system in NSW. One staff member in New South Wales noted that they were uncertain whether the credentialling process meant that they could use naloxone themselves or whether they were only able to provide it for others to use:

I would need some clarity around being a healthcare worker, so not medically trained, and um utilising naloxone on a health site. I had one health district saying if witnessing an overdose always call for staff who were medically trained, and then I had another workplace while witnessing an overdose there was a paramedic present for another client present asking me to utilise naloxone... Yeah am I able to utilise it myself or is my credentialling is it around just supply. (NSW, AOD staff member, Interviewed October 2020)

Training in WA was mainly delivered face-to-face, and interviewees reported the outcome of this as positive. There was also an online tool that was described as comprehensive, but perhaps not practical in all situations:

The take home naloxone education tool that the Mental Health Commission provided, I think would work really well if you were in a clinical setting like if you're in a doctor's appointment, you can open up that that tool on your desktop but it's rather lengthy. It contains a lot of information that consumers don't really need or want to know about...and in practice, we don't use that tool... we couldn't use the tool on the way that we work. (WA, NSP staff member, Interviewed May 2021)

One CP worker suggested basing the training on an existing model in WA:

⁹⁹ <https://www.mhc.wa.gov.au/reports-and-resources/resources/health-professional-resources/take-home-naloxone/>

^{hh} <https://www.health.nsw.gov.au/aod/programs/Pages/naloxone-public-health-services.aspx>; <https://www.health.nsw.gov.au/aod/programs/Pages/naloxone-ngo-and-private-service.aspx>

What might be a good idea is [to have it] similar to the CPOP (Community Program for Opioid Pharmacotherapy) training. For example, there is an online module that you can do. Often these modules also give CED points or continuing education points which you know as a pharmacist you need to make sure that we get enough throughout our practising year, so people are quite eager to do these small courses, because it gives some points and at the same time, you know, you are able to get that information out there to make sure that it has actually been processed (WA, Community pharmacy staff member, Interviewed June 2021)

Finally, a suggestion by an NSP worker related to standardisation of training:

Um, probably [have training] generally standardised across all sites in Australia so it's a consistent approach, that probably would be helpful. But the training we received was appropriate. (WA, Community pharmacy staff member, Interviewed July 2021)

Similarly in SA, the majority of comments from access site staff about the training was positive. Staff commented that it was concise and easy to understand, as well as informative and useful. DASSA had used a train-the-trainer model, holding a workshop early in the Pilot. Participating NGOs reported holding brief update sessions for frontline staff during regular meetings to refresh knowledge or upskill new staff.

6.5 Impact on select access site types

6.5.1 Community Pharmacies

In all jurisdictions, the community pharmacy sector has been the main pathway of the THN Pilot rollout. In South Australia, community pharmacies have been the central access point for THN under the Pilot, and the only type of access site where clients could directly access naloxone. Completion of training was not required of pharmacist as a condition of registration, but information sheets and access to training were available through the PPA portal.

Community pharmacy staff mostly reported being engaged to participate in the pilot through an expression of interest:

It was through expression of interest through either the PSA or the Guild, but there was an expression of interest and then obviously through the PPA as well (WA, Community pharmacy staff member, Interviewed May 2021).

Other pharmacists heard about the Pilot through word of mouth. One community pharmacy staff member described how they became involved:

I was approached by one of the pharmacists who was looking after all the claiming and pharmaceutical services and I believe he was approached to participate in the trial, but I personally was not involved. I was asked if we want to participate and... and we decided that it's the right thing for us to do (WA, Community pharmacy staff member, Interviewed June 2021).

Pharmacists described developing their own procedures around identifying appropriate clients, and how and when to approach them to offer them naloxone:

But when we're approaching, basically we're trying to identify appropriate candidates based on a number of rough criteria about who might be at risk of

overdose, and then trying to make sure that there's an appropriate place to discuss it... So there's thoughts given to privacy, and then it's basically just a brief counselling session. (SA, Community Pharmacy staff member, Interviewed April 2020)

Interviews with consumers and staff indicated that many of the community pharmacies that were active in the Pilot were also delivering OAT. This informed how they developed their own policies and procedures, with many noting that they offered THN to all of their OAT clients. For example:

So we usually identify people who are on the methadone program, or are heavy opioid users. So obviously when we are interacting with them we can identify those patients pretty easily. If we are dispensing a script for them, or handing out methadone doses. We will just mention it to them and say hey, there is this free product you should have. Keep it with you, show somebody who is with you how to use it, that way you have it on hand. That's pretty much it. I give them the option of having one with them. (NSW, Community Pharmacy staff member, Interviewed April 2020)

Other access site staff members offered THN to people using prescription opioids more generally:

Well prescription opioids or on the opioid substitution program, I guess I have not come across people on heroin – not that they tell me. So yeah mainly it is our regulars that I have approached, that I know are on prescription or opioid substitution program. (NSW, Community Pharmacy staff member, Interviewed May 2020)

For community pharmacies, the majority of staff noted that the resources and infrastructure, as well as requirements, for the THN Pilot fit well into their existing business. The use of the PPA Portal for claiming and reimbursements was already a standard feature of workflow in these settings.

Conversations with pharmacists revealed strategies used to encourage uptake of THN in their practice:

- One noted that all the pharmacists were encouraged to remember to have a discussion about naloxone with all of their regulars who present with an opioid prescription. If a new customer comes in with an opioid prescription, the pharmacists around at the time sometimes remind the pharmacist serving the customer to offer the naloxone if [they] forget to themselves. (Community Pharmacy, SA)
- An independent community pharmacy that also provided OAT reported that all the staff were trained, and they had added a pop-up note in their pharmacy's dispensing system to alert and remind them to dispense and discuss THN when they dispensed opioids. (Community pharmacy, SA)
- Others talked to all their OAT clients and those who collect fits pack about the Pilot, and used the "it could be useful to help save a friend or family member" approach when talking about THN, to reduce potential resistance from clients who may not see naloxone as relevant to themselves. They reported having had a few clients who have saved friends from an overdose with THN from this Pilot and using this positive feedback to promote THN to other clients. (Community pharmacy, WA)

- Some had developed a strategy around counselling their clients, having in-depth conversations with their clients who could be at risk of an overdose. Discussing their use of the opioids and what's happening, for both PWID and people using prescription opioids. They had taken a "slowly, slowly" approach to these conversations around the use of opioids and in educating their clients, not rushing in. (Community pharmacy, NSW)
- One pharmacy reported they have decals (the blue ones distributed by the Department) stuck to the counter at point of sale and they would point to this and ask the client "Do you know this is available?" "Do you know it is free"? (Community pharmacy, WA)
- Others linked up with allied organisations, noting close links and "cross-referral" with outreach and homelessness services (Community pharmacy, NSW). Another described having dispensed THN to local Council Workers to put in the security vehicles that drive around at night, in case they come across an overdose (Community pharmacy, WA).

Some of the pharmacists were also mindful of the importance of their role in encouraging widespread awareness of the pilot:

[A primary goal was] to really let everyone know that this is more of an awareness... like an 'awareness programme', as well as being a first aid tool that basically can come in handy in life changing circumstances (WA, Community pharmacy staff member, Interviewed May 2021).

In addition to ensuring widespread awareness of the pilot generally, the importance of disseminating information to people who may not believe they require naloxone was acknowledged. To this end, procedures were established to identify a specific cohort:

So basically, we have a flagging system where if someone's been prescribed in opioids or if we have another one of our regular customers who always gets high strength opioids, we will just offer [naloxone] to them (WA, Community pharmacy staff member, Interviewed April 2021).

In such cases, another staff member reported using a gentle approach in interactions, in an effort to address any potential defensiveness due to stigma:

We currently have a lot of chronic pain patients who we've talked to and given a flyer, just for them to have a read, because quite often they are not in the right frame of mind to be discussing a lot of information with us, if they're in chronic pain. We do explain it in such a way that they're not feeling judged or any negative connotation regarding opioid use. It's more about keeping them safe and providing them with an opportunity to recognise if perhaps they've taken their medication inappropriately you know, in a desperate need of pain relief, [it could lead to] a potential overdose and these are things that can assist (WA, Community pharmacy staff member, Interviewed May 2021).

The impact on daily workload caused by the pilot in terms of administration and customer consultation was minimal and not problematic. However, some reported initial issues with the supply of naloxone:

I guess the only problem we had was it expiring before we could hand it out. Maybe we just need better control on our ordering procedures, like how much is going out so we're not having any wastage. We had a few that were expired (WA, Community pharmacy staff member, Interviewed April 2021).

The training was reported as practical and useful by the majority of pharmacists. A minority of staff members felt there was not enough training, and felt they needed to do outside research because it was not something they had pre-existing knowledge about. One pharmacist suggested that the training could be improved if “*we have a drug representative who comes to pharmacies to show us physically how to use it, it would stick in our memories for longer*” (SA, Community pharmacy staff member, Interviewed January 2021).

6.5.2 AOD Services

A range of AOD service types were engaged in the Pilot: these included NSPs, residential and outpatient treatment services, OAT programs, peer and outreach programs, and hospital-based services. Where there are specific issues for a site type, this is discussed in the relevant sections following this one.

6.5.3 NSPs

Staff of NSPs were supportive of the Pilot, and in those states where they have been able to hand out naloxone directly, they appreciated the opportunity to provide this directly to their clients.

Yeah, I've worked in drug and alcohol for like 30 years, and this is one of the best things I have ever seen implemented, yeah, it's great! (NSW, NSP Access site staff member, Interviewed June 2021).

Existing clients of NSPs had overwhelmingly positive perceptions of staff at the NSPs, describing interactions with staff as friendly, and free of stigma or judgement.

Staff from NSPs in NSW described implementing policies and procedures to facilitate operationalising the Pilot in their organisation. For example:

I think some of it was just, making sure we had, um, register people when they came in, getting their consent, making sure that was- and the storage of the naloxone...And other things such as making sure we- if the supplies were getting low we replenished it, had enough stock. (NSW, NSP Access site staff member, Interviewed June 2021).

One of the staff members from an NSP in NSW described how policy was developed at organisational level and filtered down to team members:

I think that was done at a managerial level, like, at the beginning of the pilot, and that was just fed down to us through team meetings (NSW, NSP Access site staff member, Interviewed June 2021).

Consistent with reports from other sectors, NSP workers said each ‘supply’ of naloxone to a customer took between 10-15 minutes:

Oh, between- if they've been trained before, around 5 minutes, if they haven't been trained before, 10-15 and that depends on, you know, how many questions and, um, to make sure their comfortable with all the information. (NSW, NSP Access site staff member, Interviewed June 2021).

The NSP staff members from NSW felt that there was minimal impact on their workload, and they felt positive about providing THN:

Look, not much at all, like, it's yeah, it doesn't impact our workload at all. It actually feels good to know that you're doing something worthwhile, not just handing out a needle, you're actually- I feel like you're doing something worthwhile with the clients. (NSW, NSP Access site staff member, Interviewed June 2021).

NSP staff members from NSW discussed their approach to brief education for consumers. One staff member described providing clients with a printout on overdose management on the outside of the naloxone pack:

...so we have to train them in overdose management, um, we train them on how to use naloxone, we give them the printout sheet – we actually wrap it round the outside of the take home naloxone instead of on the inside, because we think that it's better for them to know what they're doing before they have to open it (NSW, NSP Access site staff member, Interviewed June 2021).

This worker described offering the brief education to consumers every time the client received THN:

Um, their name, age, postcode, whether their aboriginal or Torres Strait Islander, whether they've had previous- oh their drug of choice, um, whether they've had previous training and whether they- we train them each time, we go over it each time – and age (NSW, NSP Access site staff member, Interviewed June 2021).

Amongst those interviewed, NSW NSP staff did not report any issues with supply. In WA, an NSP worker reported being engaged by a GP:

Dr [name] who is one of the consultants in addiction medicines asked me if we would like to be recruited [for the pilot] (WA, NSP staff member, Interviewed July 2021).

NSP workers described the pilot's impact on their daily workload as minimal. One staff member reported that their workplace collected information from their staff and found "the vast majority took 10 minutes or less" when supplying naloxone (WA, NSP staff member, Interviewed May 2021).

Of those interviewed, it was unanimously viewed as time well spent:

"it's not onerous... I think its valuable. For an extra two to 10 minutes, I think it's part of the role" (WA, NSP staff member, Interviewed July 2021).

In terms of procedures related to the pilot, one staff member commented that they already

"had policies in place to assess risk and overdose in any regard, but basically [the Pilot prompted] a gentle reminder to provide the naloxone if required" (WA, NSP staff member, Interviewed July 2021).

Some access site staff from WA suggested that the ordering processes for THN could be simplified:

Going through a third party rather than just asking for it directly added an unnecessary amount of communication and unnecessary level of bureaucracy for the process. (WA, NSP staff member, Interviewed May 2021).

In South Australia, NSP (called Clean Needle Programs in SA) sites were informed by DASSA about the Pilot, and then provided with vouchers to provide to their clients along with an information sheet on how to use naloxone.

The impact on workload for CNPs was mainly limited to provision of the voucher and information to clients, along with time for the brief education. This was considered a core part of their role:

Interviewer: And does this have an effect on other work obligations?

Participant: Nah it is part of my work. It is a core part of my work. (SA, NSP/CNP Staff member, Interviewed April 2020)

Some access site staff tried to quantify the percentage of their workload that was dedicated to the THN Pilot:

So that 10% includes developing resources, it includes training up staff, it includes training the workforce as well. (SA, NSP/CNP Staff member, Interviewed April 2020)

In SA, NSP staff reported that they then developed their own policies about what information to tell their clients, and would help clients select an appropriate pharmacy from the list of registered pharmacies or would provide clients with a printout of the lists of chemists that had registered for the Pilot. A roundtable participant described how they targeted clients for THN:

So because all of us peer educators are probably - being familiar with naloxone for years anyway and favourable about it, we just mainly had to be informed before the actual specific steps that we were to employ when we were promoting it to clients.

It's easy obviously when clients come in and list heroin or opiates as their drug to be injecting, then they are the people that you can instantly raise the option of naloxone and give them vouchers. (Roundtable Participant, NSP/CNP/Peer organisation, SA)

One NSP in SA explained how receiving the voucher at an NSP and then attending a community pharmacy differs from the client just attending the community pharmacy:

Well it is anonymous. They don't have to provide their name. They don't have to provide their Medicare card or anything. They don't even have to give a reason. As long as they have that orange voucher that says they have had an intervention at the NSP, then they take that voucher to one of the pharmacies that we know are participating in the program. (SA, NSP/CNP staff member, Interviewed March 2020).

So even where NSPs were unable to directly distribute THN to clients, having the vouchers available at access sites to provide to consumers still served an important function in promoting the Pilot in SA.

6.5.4 NGOs

The impact on non-government sites varied by jurisdiction, given that each state implemented different arrangements for the THN Pilot for NGOs.

Staff of NGOs in the AOD sector expressed very positive perceptions of the THN Pilot, but also hoped for continuity and permanency of free THN provision:

Oh, extending it so it becomes a permanent thing! As I said, this is a lifesaving program for us, uh, it is something that we have been pushing for years, and finally it has come to

fruition so I just hope it becomes extended and becomes rolled out permanently (NSW, AOD NGO staff member, Interviewed June 2021).

As noted in Chapter 4, NSW has formalised their involvement of NGOs in the provision of THN. Distribution of THN has been included as a Key Performance Indicator in some Ministry of Health funding agreements.

For those organisations that had previously been involved in the provision of THN in NSW through the ORTHN program, the pilot allowed them to expand and extend their delivery of naloxone to clients. One access site staff member in New South Wales described the Pilot as *'one of the key changes that, uh, really, um, allowed us to scale up our delivery of Take Home Naloxone to vulnerable clients who are at high risk of overdose.'* (NSW, AOD NGO staff member, Interviewed July 2021)

In WA, one NSP worker explained how his workplace was asked to participate in the pilot:

We'd been involved in distributing naloxone to lay people to respond to overdose in the community since 2013 and so when the pilot was extended to include WA, we were asked if we would be involved (WA, NSP staff member, Interviewed May 2021).

In South Australia, non-government sites continue to distribute vouchers to clients to encourage them to access take home naloxone from a pharmacy. This allowed them to promote the Pilot and provide the brief education about THN, but still required a second step before consumers could access naloxone.

Access site staff from NGOs in NSW noted that their supply and reimbursement system worked well. For example, this access site staff member described their system in the following way:

So, it works very well, so all we need to do is we need to, according to the new NGO procedures, - I've only had to do it once I think, let me think – so we literally just fill in a form with our, um, whatever our case number or site number is to the manufacturer and were allowed 60 units of each time we order and then they arrive within two days later. And then we send the invoice to the ministry of health, who then, um, pays for it. So it works – we've only done it once – but it works seamlessly. (NSW, AOD NGO staff member, Interviewed July 2021).

In WA, one staff member described how streamlining in their workplace procedures occurred during the implementation of the pilot:

Initially we had a nurse practitioner on our health team who would prescribe naloxone and we had peer workers who'd been trained and authorised by our CEO to provide the education to the consumers who should be receiving naloxone. So the education would be done by one of our peer workers and then our nurse would do the health assessment and the prescription of naloxone. Once the SASA (Structured Administration and Supply Arrangement) came into place [which is] similar to how they authorised registered nurses to provide vaccinations in remote area clinics], we no longer needed the nurse practitioner to be involved, we could just have the peer workers who were doing the education authorised under that SASA arrangement. (WA, AOD NGO staff member, Interviewed May 2021).

In WA, NGO staff noted that there was no funding for their distribution of naloxone:

As a not-for-profit organisation, there were - we're just provided with the naloxone; there is no funding to support the distribution of the naloxone.

So in effect, our core funder, which is not the Mental Health Commission, is subsidising the provision and rollout for our consumers of this Commonwealth take home naloxone program. (Roundtable Participant, NGO/NSP, WA).

Some WA access site staff members felt funders relied on the fact that NGOs consider THN part of their core business to negate the requirement for extra funding for implementation:

... quite often NGOs are expected to go above and beyond their requirements, that the people that may be funding decisions... they just sort of go, 'ho but that's just part of your normal business'. 'That should just be done as part of your core business. That should just be done, because you care about the consumers' (WA, NSP/NGO staff member, Interviewed February 2020).

This highlights the differences between the jurisdictional models for involving NGOs in the implementation of the THN Pilot.

Overall, frontline staff in NGOs generally expressed fewer concerns about addition to their workload through THN provision, however senior service representatives noted that additional work regarding development of policies and procedures, training of staff, and storage of naloxone had required additional resources of the organisations.

6.5.5 Corrective Services Health Settings

The extent of engagement of correctional settings in the THN Pilot differed in each state.

In New South Wales, NSW Justice Health had been involved in processes for the earlier ORTHN programs and so were able to engage early in the process of implementing the Pilot. Naloxone is provided on release from custody to clients of an AOD program. As one staff member described:

... during the initial assessment for a patient who's going to be on [AOD program], I identify any history of opioid use or prescribed opioids, or if they're going to be released into an area where they could be witnessing an opioid overdose, taking into account current drug warnings that could increase their risk of overdose, and then, providing the education. So, doing the brief intervention, doing the video with them and completing the form. Um. And then it's a matter of- in this particular center it's a matter of getting the naloxone to them on release. (NSW, Justice Health Service staff member, Interviewed May 2021)

At the commencement of the pilot, Connections Transition coordinators from Justice Health NSW completed training and became credentialed as an AAS. Access site staff noted that paperwork for implementation of the Pilot is "really extensive":

So, we fill out the ORTHN form, and that has to be signed by the patient they completed and then scanned to our naloxone pathways generic email which is managed by drug and alcohol at Justice Health. And then we have to- the form goes into the patients hard copy file, and then you have to enter the appointment into our appointment booking system for justice health and then you have to add it into a spreadsheet as well – I guess just for us to keep track of, um, how many people are getting it, and then the person who is following up on the patient following their release, they'll find out that whether they got the naloxone on their release and update the spreadsheet to make sure they actually got it. And, yeah, so it's a bit lengthy. (NSW, Justice Health staff member, Interviewed May 2021)

Furthermore, in some settings, there was a two-step process where the health staff member providing the THN was not the same staff member expected to provide the THN to the client upon release:

So, I don't actually see them collect it, I just put it with corrective services and they put it with their release paperwork. But, I mean, most of the time, they get it, um, - how do I explain this – so, if the patients don't get it, it's nine times out of 10, because the corrective services have forgotten to give it to them. (NSW, Justice Health staff member, Interviewed May 2021)

Staff in correctional health settings noted that the Nyxoid nasal spray was the only formulation they offered to clients.

In South Australia, Correctional Health settings provide naloxone on exit from custody but through the PBS, rather than through the THN Pilot. At the commencement of the Pilot and after the development of the vouchers, SA Prison Health provided vouchers to people exiting prison so that they could access naloxone from a community pharmacy. As vouchers identified their source, there were potentially stigmatising effects for people receiving them from Correctional Health:

There was some feedback from the consumers about not wanting to take the voucher, it clearly indicated prisoner on it and they didn't want to take that. (Roundtable Participant, Prison Health, SA)

In Western Australia, custodial settings can provide naloxone on exit by prescription. The WA Department of Justice has not implemented the Pilot as yet. The following information was provided by the WA Department of Justice:

Whilst Corrective Services was unable to participate in the Take Home Naloxone (THN) Pilot, they are advocates for the dissemination of intranasal naloxone to prisoners (who are known to inject drugs), upon exit from prison.

Mental Health, Alcohol and Other Drugs (MHAOD) have advised that in late 2019, prior to the global COVID-19 pandemic, the former Deputy Commissioner Offender Services, and Director Health Services, supported a proposal and communication plan to commence the roll out of THN in WA prisons, with training to be delivered by external parties. Unfortunately, due to an internal restructure of Health Services and MHAOD, and the Department's major focus being on managing the COVID-19 pandemic, the project stalled. It is noted that the Deputy Commissioner Offender Services also resigned in this time.

MHAOD have advised that, whilst there are approximately 400 doses of THN currently stored at the Hakea Prison Pharmacy, the provision of THN to people exiting WA prisons has yet to occur, as additional staff training/education sessions, and planning discussions with prison Superintendents, are required. MHAOD also advised that the Mental Health Commission recently delivered some training to staff at Bandyup Women's Prison, and that discussions are ongoing in regards to whether THN packs can be distributed from Casuarina Prison.

6.5.6 Police

Western Australia is the only jurisdiction to involve police in THN Pilot activities. Western Australia Police Force has worked in conjunction with WAMHC to develop a trial of naloxone deployment by police officers. Training was provided by the WAMHC, with naloxone to be sourced through the Pilot. The following information was provided by WA Police Force:

On 1 July 2021, the WA Police Force commenced the 12-month trial which will see select police officers from the Perth metropolitan area and one regional location equipped with Naloxone.

The trial locations were selected based on several drug-related indicators including WA Health data and the results of wastewater analysis.

The trial will also include officers from several specialist units, who have been selected due to the frequency in which they seize and process large amounts of illicit drugs.

It is expected there will be approximately 300 police officers involved in the trial.

Law enforcement agencies in Europe, the UK and the US have undertaken similar trials however the WA Police Force is the first law enforcement agency in Australia, and the southern hemisphere, to take part in a Naloxone trial.

As first responders it may provide an opportunity for officers to save the life of someone who has overdosed, before medical help arrives.

In many cases police officers are the first on scene in response to 'welfare checks' or other tasks that result in a drug-impaired person being located, sometimes unconscious, and will likely be best placed to provide the early medical intervention.

There is always a risk police officers could be exposed to highly illicit toxic opioids in the course of their day to day workⁱⁱ. Taking part in this trial is another way in which we can better protect officers in the work they do protecting the community.

6.6 What factors prevented participation by some site types?

There was limited engagement in the Pilot by some types of access sites originally expected to take part. This section briefly discusses the factors that prevented participation by some site types.

6.6.1 Hospital pharmacies and emergency departments

There was relatively limited engagement from hospital pharmacies, and many barriers were noted in trying to implement the THN Pilot in Hospital Pharmacy settings. The requirement to enter data into the PPA portal presented an issue due to responsibilities for medicine provision, recording and stock control being spread across different departments rather than resting with the individual who dispensed the naloxone. There appeared to also be some confusion and differences in interpretation of the scheduling legislation, as to which health professionals are able to supply Schedule 3 medicines and their requirements to do so.

In NSW, THN was introduced into hospital settings, however there were a number of barriers encountered – including the requirement for additional credentialing to distribute THN for pharmacists within NSW Health settings who would ordinarily be able to supply a Schedule 3 medicine. This was mentioned by a number of participants. Entry of data into the PPA portal was also cited as a barrier; staff from the implementing agency provided assistance where possible (46).

In WA, participants described examples of introduction of THN in hospital settings:

...we've introduced take home Naloxone throughout the hospital. Initially we did a lot of education in the emergency department because we reckoned that the primary place that people would present to hospital would be in ED, but we certainly get admissions or referrals from people on medical wards and ICU, and

ⁱⁱ This risk is regarded as relatively small: https://www.acmt.net/_Library/Positions/Fentanyl_PPE_Emergency_Responders_.pdf

we've given them out to patients who've also been in the mental health unit as well [following] potentially opioid overdoses. (Roundtable participant, Hospital, WA)

In SA, at the time of writing, there had been limited movement towards introducing THN into hospital pharmacy settings. Roundtable participants noted that there had been a lack of clear ownership within the hospital system in terms of responsibility for implementing the Pilot, and there were multiple state approvals needed from different Local Health Network bodies that govern the different hospitals. Challenges were also encountered in terms of the order of these approvals and conflicting requirements, where hospital sites declined approval before the state-wide approvals, however the state-wide approval bodies wanted details from sites about how the program was going to work before approving.

Furthermore, difficulties around the requirement for labelling of medication within hospitals created barriers:

But within the hospital system there is no precedent for supplying a medicine that's not actually charted by a medical officer and there's no stock control mechanism. (Roundtable participant, Hospital pharmacy, SA)

The same participant noted that having a state system that is more flexible would help get more health professionals involved in dispensing THN.

6.6.2 Pain clinics

Pain clinics had limited engagement— there were no registrations by pain clinics and limited knowledge and awareness of the Pilot when canvassed by the evaluation team. Given their lack of involvement in the Pilot and our subsequent inability to interview staff from this group, this report can make limited comment on the factors that limited their participation.

6.6.3 Primary care

There was limited engagement with the Pilot by primary care facilities, and limited engagement by Approved Medical Practitioners (s92) who were able to provide THN under the Pilot rules. This is to be expected given the small number of dispensing doctors across Australia (15 in 2019-2020) (47).

6.6.4 Mental health settings

There was limited engagement in the THN Pilot by mental health settings, although there were some site registrations and distribution by select sites. Mental health settings are a prime opportunity to expand THN provision, as people with chronic pain and substance use problems commonly experience mental health problems.

Implications

- The Pilot had different impacts on different types of access sites. Recommendations need to be specific to the type of access site and may include allocating staff or space to provide naloxone and the brief intervention/education.
- Sites were able to implement their own policies to facilitate integration of THN into existing work practices. A national roll-out of THN should facilitate the coordinated sharing of learnings about policy and practices to assist with implementation of THN at organisational levels.
- Raising awareness of overdose risk among the professionals who work in other practice areas (emergency medicine, in-home care, mental health, primary health) may encourage uptake by a broader range of access sites.
- Training should be consistent, available universally and on-demand (i.e., via web-based platforms) and have versions suitable for different professional skill levels (GPs, pharmacists, retail staff, non-health service staff).
- A national or large-scale program should consider allocating resources for staff training, policy and procedure development, and time for naloxone provision.

7. Were there any barriers to increasing access and/or uptake of THN? How could these barriers be overcome?

Key points

- The Pilot addressed or partially addressed a number of barriers to access and/or uptake of THN, including: cost, availability in a range of settings, access to naloxone through a range of sites, consumer knowledge of how to use naloxone, and staff knowledge of THN.
- Barriers that still need work to address include: stigma about people who use opioids, consumer and community awareness of THN, awareness of overdose risk, availability of THN at desired locations for access, and other barriers to carriage of naloxone such as fear of police response to naloxone, and negative perceptions about naloxone.
- Recommendations from consumers and access site staff to overcome barriers included public awareness campaigns and advertisement, maintaining and expanding access sites and modes of access of THN, and use of peer networks.
- Key facilitators of success of the Pilot included: the removal of cost as a barrier to naloxone; the broad appeal of Nyxoid® nasal spray formulation enhancing uptake; the activities of local and state level champions for the Pilot and local health promotion networks in promoting the Pilot; cross-sectoral collaboration to engage with potential THN consumers; increased staff knowledge and ability to provide THN; and the increased range of settings for access of THN introduced through the Pilot. Additionally, effective engagement of the AOD sector, acceptance of naloxone within the sector and the effective work of peer organisations, networks and word of mouth helped engagement with the Pilot.

THN BARRIERS

Barriers addressed by the pilot

1. Cost

Making THN available for free to consumers removed a significant barrier to opioid overdose prevention.

2. THN access without a prescription

Removing the need for a prescription for THN reduced barriers of time, convenience and cost for consumers.

3. Access through a range of different sites

Making THN available through a range of different sites, including community pharmacies, NSPs, and other AOD services (although this differed by jurisdiction), increased its accessibility for a range of consumers.

4. Consumer knowledge about how to use Naloxone

Providing the brief education as part of THN supply increased consumer knowledge and confidence to use Naloxone.

5. Staff knowledge of THN

Under the Pilot, training in overdose response and how to supply naloxone was available to staff of registered access sites, increasing staff knowledge of THN.

Barriers that still need work to address

1. Stigma about people who use opioids

Stigma about opioid use (illicit and prescribed) was mentioned by a majority of participants as an ongoing barrier to THN.

2. Consumer and community awareness of THN and the Pilot

Limited consumer and community awareness of THN is an ongoing barrier to uptake.

3. Awareness of overdose risk

Many consumers are unaware or underestimate their own or others' risk of overdose from opioid use.

4. Availability of THN at desired access location

THN was not always available where consumers would prefer to access it from.

5. Having naloxone on hand in the event of an overdose

A range of factors affected consumers' willingness to carry naloxone regularly in case of overdose.



This chapter summarises the key barriers to increase and uptake of THN, and the extent to which these barriers were addressed through the Pilot. The chapter also discusses mechanisms to mitigate the effect of these barriers, drawing on suggestions from participants and by identifying key facilitators of success in the Pilot.

7.1 To what extent were these challenges resolved during the THN Pilot?

Consumers interviewed noted a range of different barriers to uptake of THN. Some of these have been addressed or partially addressed through the Pilot, however some remain. This section discusses the barriers to uptake of THN based on a synthesis of the qualitative data from consumers, access site staff, and roundtable consultations.

7.1.1 Barriers addressed by the Pilot

7.1.1.1 Cost

Price was consistently mentioned by many consumers as a barrier to THN.

Because a lot of money is used to fund your habits, having to purchase new syringe kits and then after having to purchase naloxone, just on the chance somebody overdoses, you know I mean (WA, PUIO, Recruited from Community pharmacy, Interviewed March 2021).

Many expressed appreciation that the Pilot had allowed them to obtain THN for free. For example:

The Pilot has been a huge step in that direction to provide it for free (SA, PUIO, Recruited from Community Pharmacy, Interviewed June 2021).

Yeah, I do think the fact that they're free as well was obviously a very big thing because otherwise people wouldn't be paying for them (WA, PUIO, Recruited from NSP, Interviewed May 2021).

Consumers also noted that a key part of the Pilot was being able to access naloxone free without a prescription.

7.1.1.2 THN access without a prescription

As noted in the Penington Report on the Australian Naloxone Access Model, while naloxone is currently available over the counter outside of the Pilot, in many instances it also comes at a larger cost (e.g., \$50-80) than if the naloxone is prescribed and supplied through the PBS (\$6.60 for concessional beneficiaries and \$41.30 for general beneficiaries) (48). However, the requirement for a prescription for this reduced cost presents potential issues: the GP may not be willing to prescribe it, time spent attending a doctor, cost of the visit if it is not bulk billed, as well as transportation costs to attend the visit, along with the additional step of then having to attend a pharmacy to have the prescribed naloxone dispensed.

Many participants considered that accessing naloxone without a prescription was an important feature of a THN program, for example:

And the fact that it is not mandated, it should be in every chemist available and we shouldn't need a prescription, you should be able to just go in and say, 'look I need some naloxone'. (NSW, PUPO, Recruited from NSP, December 2020 interview)

Participants appreciated that they could access the THN directly from the pharmacy or other access site (except in SA) without a prescription, reducing this extra step and saving time, cost and providing convenience.

7.1.1.3 Access through a range of sites

The ability to access naloxone through a range of sites is important to enhance reach and uptake of naloxone. In NSW and WA, the Pilot increased the range of access sites through which consumers can access naloxone.

I mean, the more pharmacies the better, because people aren't going to [needle] exchanges if they don't use, so it's a good thing it's in pharmacies (WA, PUJO, Recruited from NSP, Interviewed May 2021).

It should be available at all chemists on all desks or all counters, so yeah, it shouldn't be just one or two of the chemists. It should be everywhere (WA, Witness, Recruited from Community pharmacy, Interviewed June 2021).

An exception to this was those participants in SA who received a voucher from their access site and then had to obtain their THN from the pharmacy. This is discussed more below in section 7.1.2.4.

7.1.1.4 Consumer knowledge about how to use naloxone

Part of the Pilot design involved the delivery of a brief intervention/education component to consumers upon access to THN (this could be at either the point of provision of THN directly, or provision of the voucher in SA). Access site data and interviews indicated that 99% of consumers received the required brief intervention/education and/or resources when they were given naloxone.

Mystery shopping visits also confirmed this, but noted some variation in the thoroughness of the instructions provided. Of the 20 sites where naloxone was available, 19 reported receiving product information when obtaining naloxone. The majority of respondents for the mystery shopping visits (13/20) reported that they felt they received sufficient brief intervention/education and felt they had knowledge about how to use naloxone:

I was given instructions on how to use the naloxone nasal spray. They asked me if I wanted instructions on how to use it and I said yes. The pharmacist assistant told me to call 000 in an emergency. When I see the patient unresponsive, she gave me a few examples, to put them on their side and administer the naloxone nasal spray. They reassured me that I didn't have to worry about the px inhaling the naloxone as it will be absorbed. There were no other pamphlets provided with the naloxone. (Mystery shopping, Community pharmacy, NSW)

For some of the mystery shoppers at pharmacies, the product information was the main source of information given about naloxone:

She said "administer this after you have called an ambulance. It's very easy and all the instructions are inside the box. Just take care with the use by date printed on the top." (Mystery shopping, Community pharmacy, WA)

Amongst the consumers interviewed for the evaluation, 77% were provided with brief intervention/education or a written resource when they obtained their THN. Of those who weren't provided with this information, more than half mentioned that staff (i.e., pharmacist)

knew of their current knowledge on how to use THN, while only 13% said that they were expecting it but the staff didn't explain or provide information. A few (7%) said their supply was given by a friend who also didn't provide advice on method of use.

Most consumers responding to the qualitative interviews for the Evaluation noted that they were offered the brief intervention/education, regardless of access site type. The following participant described how they felt more equipped to administer naloxone because of the training:

In the beginning I get this 'should I do it or should I call the police, or the ambulance, and stay with the person'. But then the training kicks in, and I think if that was me I would want someone to act straight away (NSW, Witness, Recruited from AOD/NGO, Interviewed September 2020).

The majority of consumers noted that they felt comfortable during the brief education/intervention, and most considered the information provided during the brief intervention/education to be practical. For example:

Interviewer: What made it comfortable for you?

Participant: He explained it to me a couple times there, and knowing I've got something there if my husband does go into this um unconscious state, to know I do have something there to help straight away

Interviewer: Yep. And how practical do you think that instruction was for you?

Participant: Fine, it was practical, I could understand it straight away, it was good how it was laid out and written. (SA, Witness, Recruited from Community Pharmacy, Interviewed April 2021)

It was, it was very practical, as I said I care for my daughter who is on prescribed drugs and I thought it was very important that I know what it's all about, yeah. (SA, PUIO, Recruited from Community Pharmacy, Interviewed February 2021)

7.1.1.5 Staff knowledge of THN

Under the Pilot, training in overdose response and how to supply naloxone was available to staff of registered access sites, increasing staff knowledge of THN.

The majority of consumers expressed that they felt comfortable during their interaction with staff, and that they felt that they received practical information about how to use naloxone, indicating that most staff they interacted with were knowledgeable about THN. Participants described using their training during resuscitation events, and this was thanks to increased staff knowledge of THN. For example:

The advice I was given was very good and thorough. I could have used obviously three or four times in the last year. I used the advice probably five times in total over the last two years and I had to use naloxone and one of them had to go to the hospital. They were OK within the hour. So I feel that the advice I was given was as good as it could have been and if it wasn't, then I wouldn't have been successful with the incidents I had. (WA, PUIO, Recruited from NSP, Interviewed May 2021).

The mystery shopping results aligned with these findings, with the majority of mystery shoppers reporting that staff were knowledgeable about THN (12 knowledgeable and 9 somewhat knowledgeable). These results were recorded across community pharmacies and AOD/NSPs. In most community pharmacy settings, it was the pharmacists, and not the retail staff, who were

reported as knowledgeable about THN. They provided information on how to use naloxone, information on how to identify an overdose, and reminders to call an ambulance.

However, of the sites visited only 10 reported knowledge of the pilot (a further six said that the pilot was not mentioned during the transaction and another four, no comment was recorded).

The attendant seemed highly knowledgeable about Naloxone and the pilot. I asked if I could come back for more Naloxone, and he said I could until the pilot ended early next year. (Mystery shopping, Community Pharmacy, SA)

He knew what the pilot was and also knew of other pharmacy providers in the area. He kept the information simple and to the point which I think would make it easy for people to follow. (Mystery shopping, Community Pharmacy, SA)

She was very knowledgeable about the product. She didn't mention anything about the pilot though. However, I was a bit surprised that she told me that people on heroin could become very, very aggressive after being administered with it. (Mystery shopping, AOD service, WA)

Very knowledgeable and skilled in explaining potentially complex information. (Mystery shopping, NSP, NSW)

7.1.2 Barriers that need more work to address

7.1.2.1 Stigma about people who use opioids and overdose

The stigma surrounding people who use drugs was mentioned by a majority of participants as a barrier to THN. For example:

I also think there's a real stigma around opioids, so whenever you mention that you're on an opioid to a doctor or anything like that, usually I don't say anything in public and most people I know don't say anything in public, but there's a real stigma to acknowledge that ...often I've been to hospitals and have taken in my prescription and they kind of judge you as 'oh, you must be addicted to opioids if you're doing this', so I think that's probably why people don't ask for it, because they feel like they're going to be judged at the fact that they could overdose and also the fact that they're taking opioids in the first place (WA, PUPO, Recruited from Community pharmacy, Interviewed March 2021).

Stigma about people who use drugs is an ongoing issue of significant complexity, and in the context of THN stigma, results in multiple, inter-related barriers for consumers and other stakeholders. For example, potential consumers may feel that they are being judged for accessing naloxone, they may fear mistreatment by staff, or they may actually experience mistreatment because of stigma. At a structural level, the stigma of criminalisation of drug use results in another cascade of barriers related to enforcement of laws, such as THN consumers not wanting to carry naloxone because they fear confiscation by law enforcement (discussed in more detail below), or services and organisations may be less likely to offer THN to consumers because of this stigma.

For people who use prescription opioids, including OAT, stigma also meant that some consumers were reluctant to ask for or receive THN from their pharmacist, in case this was perceived as indicating that they were 'abusing' their medicines.

7.1.2.2 Consumer and community awareness of THN and the Pilot

The lack of awareness of naloxone and lack of awareness about the Pilot amongst consumers was one of the key barriers mentioned by a majority of participants.

Naloxone really needs to be... a lot more people need to know about naloxone. A lot more people need to know that it can save lives, and has (WA, PUJO, Recruited from NSP, Interviewed September 2020).

They don't know where to get it. They don't know that it's free, and they probably don't know that it's readily available. I've met a few people that didn't know you can get it from pharmacies, or from doctors, and alcohol and drug services (WA, PUJO, Recruited from NSP, Interviewed May 2021).

7.1.2.3 Awareness of overdose risk

A lack of awareness of overdose risk was noted as a key ongoing barrier to THN amongst consumers – this was consistently communicated as a barrier across the consumer interviews, access site staff interviews and roundtable participants.

I think a lot of people are scared to admit that they can take too much without realising. (WA, PUJO, Recruited from Community pharmacy, Interviewed March 2021).

Some consumers reported that even where the risk of overdose from opioids was understood, people may still not believe they themselves are at risk:

I think a lot of people don't think it's gonna happen to them. [They think] this kind of thing always happens to somebody else, but they don't realise... (SA, PUJO, Recruited from Community pharmacy, Interviewed August 2020).

This was reported as being an issue even for some whilst in a situation presenting as an overdose:

The only thing is that people that need it the most are the ones that are overdosing and I don't know if they want it because they don't want to come out of that hit. I had to speak to one guy who had the nasal spray used on him and he seemed quite cross about it because he believed that he wasn't overdosing...he just...you know, was enjoying his high, but to everybody else, he looked like he overdosed - (WA, PUJO, Recruited from Community pharmacy, Interviewed September 2020).

Some staff members that were interviewed noted that some consumers could become defensive when offered THN:

Some of the methadone people are like oh no I am right I am right. Just because they think we are accusing them of different things. But yeah most people are fine with it, they understand it is just there as a precaution (NSW, Community Pharmacy staff member, Interviewed May 2020).

This indicates that awareness of opioid overdose risk is an ongoing barrier that will need to be addressed in a national roll-out of THN.

7.1.2.4 Availability of THN at desired location for access

Consumers noted that a barrier to uptake of THN was the lack of availability of THN at some locations.

Many consumers also noted that THN was still not available from other access site types that they would like to access it from. This was particularly common amongst SA participants, where participants are only able to directly access THN from a pharmacy.

Well it would make it easier if they could just get it from the clean needle program. Or from their drug and alcohol counsellor, or their social worker, or their welfare worker or their DV worker or, you know, any of those services that they access instead of having to get a voucher and take the voucher to the pharmacy and, you know, trying to find out which pharmacy is that's participating in the program, and then going there, and then the pharmacy might not have it in stock so they have to go back. It would be so much easier if when they come in and get their injection equipment, they can get naloxone instead of a voucher (SA, PUIO, Recruited from NSP/CNP, Interviewed August 2020).

As indicated above, some consumers noted that they had attempted to attend pharmacies that were listed as THN Pilot pharmacies, however when they attended staff had been unaware of the Pilot or no naloxone was available.

I went in with my voucher and the first person I spoke to didn't know anything about it. She then took it to, I guess, the head pharmacist. He knew about it. Even if the pharmacies are participating, not all staff are informed about it, so people might get turned away because the staff aren't informed, and that's something I've actually heard has been happening (SA, PUIO, Recruited from Community pharmacy, Interviewed March 2020).

This issue was noted for some large chain pharmacies, where a Head Office representative had registered all their subsidiaries, but the information had not been communicated at individual pharmacy level and naloxone was not in stock.

Access site staff members noted that stock expiry could present one barrier to pharmacists stocking THN, but acknowledged it was an issue that could be addressed through stock management procedures:

I guess and the only problem we had was it expiring before we could hand it out. Maybe we just need better control on our ordering procedures, like how much is going out so that we're not having any wastage (WA, Community pharmacy staff member, Interviewed April 2021).

I know in theory it expires this month and I know in practical terms the shelf life is a lot longer than that, but I think that's maybe something to think about, the expiry date (SA, Community Pharmacy staff member, Interviewed January 2021).

7.1.2.5 Barriers to carriage: Perceptions about THN and overdose response

A range of barriers to carriage of naloxone were highlighted by consumers, focused particularly on negative perceptions of naloxone, fear of police response to naloxone, and negative perceptions of naloxone. These barriers to carriage are discussed below.

7.1.2.5.1 Fear of police response to naloxone

For people who use illicit opioids in particular, the fear of law enforcement presented a barrier to carriage of THN.

The main [barrier] would be the law. The possibility of coming under the police's attention, attention of the police, and discrimination (NSW, PUPO, Recruited from NSP, Interviewed December 2020).

I think some drug users feel paranoid that they ...that their details will be given to police or other, that they will somehow get in trouble for their drug use, I think that is the main problem (WA, PUIO, Recruited from NSP, Interviewed September 2020).

Fear of repercussions from police interactions was also cited as a potential barrier to carriage:

Another barrier could be the same reason why some people don't want to carry equipment on them - if they get pulled up by the police, [the police] might be like 'why do you have this on you?' (WA, PUIO, Recruited from Community pharmacy, Interviewed September 2020).

Some participants (from multiple jurisdictions) reported that their Prenoxad[®] was seized by the police, as the officers thought that it was illegal. Recent training provided to the Police Force in WA is likely to counter this and would be helpful in all jurisdictions.

It is not within the scope of this report to comment in detail about Good Samaritan legislation, however this was raised by a number of access site staff, roundtable participants and consumers, and is also an issue identified in the literature.

People are worried about getting into trouble ...you give out an injection that saves a life and they could end up suing you, or if it doesn't save a life, you could be done for manslaughter. There are just, so many grey areas with it. I've seen people walk past people who overdose because they just don't want to be involved because it might get them in trouble which is a sad thing when it comes to a human life, but you also look at their point of view. They could be professional people. They don't need to drag their life down. I know lot of people are concerned to help people because there will be repercussions later (WA, PUIO, Recruited from Community pharmacy, Interviewed March 2021).

[The biggest barrier is] probably getting in trouble with the police. Like if they stay with that person if that's gonna get them done for being intoxicated or whatever (SA, PUPO, Recruited from Community pharmacy, Interviewed November 2020).

Fear of law enforcement not only impacted on willingness to carry naloxone, but also willingness to perform the full opioid overdose response, including calling an ambulance. Consumers noted that either they or people within their social networks had expressed some hesitancy about calling an ambulance for fear that police would accompany the ambulance.

I'd be fearful of ringing an ambulance and police turned up and searched my car and found naloxone in the glovebox... it's that stigma that as soon as the police see something like that, you're a druggie (SA, PUIO, Recruited from Community pharmacy, Interviewed January 2021).

But a lot of people hold the fear that once the ambulance are called then the police are going to come and the law is involved. (NSW, PUIO, Recruited from NSP, Interviewed May 2021).

7.1.2.5.2 Negative perceptions about naloxone

Many consumers noted that naloxone, particularly Narcan, had a reputation for reducing the positive or desired effects of the opioid. This could contribute to a reluctance of others to use naloxone in situations where the receiver may become angry:

A lot of people don't wanna use it on an opioid addict, because it's gonna put them into opiate withdrawal and they're not gonna thank you for it, even though you just saved their life. I think that's the only resistance addicts have on using it (WA, PUIO, Recruited from NSP, Interviewed September 2020).

Mystery shopping also noted this issue. During two mystery shopping observations, the mystery shopper was warned by staff that recipients of naloxone could become angry or aggressive:

He warned of the reaction of someone who had been brought back from a great \$200 high and would be very unhappy and possibly angry and aggressive (Mystery Shopping, Community pharmacy, WA).

I then asked her if there were any side effects and she said: "People can get very very angry if they have taken heroin and enter into withdrawal.". However, she said that the priority was to save a life before anything else (Mystery shopping, GOV AOD, WA).

7.1.2.5.3 Other barriers to carriage

Consumers reported that factors such as temperature requirements, or living situations could prevent them from carrying naloxone on their person:

Some people probably are stable, so that's okay... but for homeless people, it's a bit harder for people like that to carry a regular supply of it (SA, PUIO, Recruited from Community pharmacy, Interviewed June 2021).

Some consumers mentioned logistical factors as key barriers to carriage: for example, some consumers reported that they were concerned about keeping THN in their car due to temperature requirements, and others reported logistical barriers to carrying it on their person at the required times (for example if they did not have a bag or pocket to carry the THN).

7.2 What mechanisms should be established to mitigate the effect of these barriers?

7.2.1 Suggestions from interview participants

Consumers and access site staff were asked about their recommendations for improving the Pilot. A range of suggestions were made, with those mentioned consistently summarised in Table 5 below. Please note that in Chapter 10 we discuss recommendations for the national roll-out of THN in more detail.

Table 5. Participants' suggestions for overcoming barriers to THN

Barrier	Participants' suggestions for overcoming barrier
Cost	Continue to provide naloxone for free to consumers
Availability of THN at desired locations	Maintain and continue to expand the types of sites where THN is available, including: <ol style="list-style-type: none"> 1. Increase pharmacy coverage 2. Availability of health services consumers regularly attend 3. Availability from GPs 4. Delivery of THN 5. Vending machines 6. Online ordering and booking systems
Stigma and embarrassment	Public awareness and targeted campaigns with a considered, sensitive message about opioid use and naloxone Increase anonymity and ease of access through online booking and ordering systems, vending machines Clear and consistent signage about the Pilot at access sites
Public awareness of naloxone	Large scale advertisement on TV and other media, buses, and social media Signage at access sites
Awareness of THN amongst those at risk of opioid overdose	Targeted campaigns about opioid overdose risk Inclusion of THN as part of standard operating procedure
People who use prescription opioids may not consider themselves to be at risk of opioid overdose	Development of targeted resources for people who use prescribed opioids, resources were launched in August/September 2021 (Burnett Roundtable, NNRG)
People who use opioids that are not in touch with services are difficult to reach	Increase/formalise use of peer and social networks and outreach
Fear of police response to naloxone	Education for police

Inclusion of information about law enforcement and ambulance attendance in brief education for consumers

The discussion below expands on the most common recommendations made by interview participants, with quotes to illustrate these points where relevant.

7.2.1.1 Continue to provide naloxone for free

A number of consumers mentioned that naloxone should continue to be provided for free.

If they want it on the streets, give it for free (NSW, PUPO, Recruited from AOD, Interviewed February 2021).

Free access is positive and should be reinforced by the CNPs (SA, Witness, Recruited from Community pharmacy, Interviewed March 2020).

Participants considered that ongoing free access to THN was important, a key part of increasing carriage of THN.

7.2.1.2 Public awareness campaigns and advertisement

Given that public awareness was cited as a key barrier to the enhanced uptake of THN by participants, advertisement and promotion of naloxone was consistently suggested by many as a strategy to enhance public awareness of naloxone and its availability through the Pilot. For example, participants mentioned:

Well, there could be TV advertisements or bus advertisements on bus stops or some sort of advertisement. They could be in different chemists...they could have signage. Again, advertising which would help people read what naloxone is and how it can help (WA, PUPO, Recruited from Community pharmacy, Interviewed October 2021).

Definitely put more information out there and advertise it. Show people that have used it and are working and functioning and living normal lives (SA, PUPO, Recruited from Community pharmacy, Interviewed February 2021).

I would like it to see it advertised in a non-threatening, non-aggressive manner. It needs to be discussed in a non-invasive way. Friends talking at the table over a coffee. "My son has got an addiction problem. Oh, did you know naloxone is available. Go and talk to a pharmacy, or you can get it from a hospital, or here is an outreach services number. You don't want to come home and find him and not be able to help". Something along those lines (NSW, PUPO, Recruited from NSP, Interviewed May 2021).

7.2.1.3 Clear signage about the Pilot/THN at all access sites

Participants also noted that they would appreciate signage about the Pilot at access sites to indicate the availability of THN. Participants noted that this could alleviate some of the concerns that consumers might have in approaching a pharmacy or other access site and circumvent stigma. For example:

There was no signage there was nothing. There was no particular desk or anything like that so you just wouldn't know. So a symbol or something to give a sign that this

is a friendly accepting place we provide this, that would be really helpful. (NSW, Witness, Recruited from Community pharmacy, Interviewed March 2021).

A sign that just says “Free Naloxone”, something like that, so you don’t have to be told, you could read something then ask for it (SA, PUPO, Recruited from Community pharmacy, Interviewed November 2020).

Promotional materials disseminated at the beginning of the Pilot included window stickers and posters; continued availability of these would assist with recognition of access sites.

7.2.1.4 Maintain and expand modes of access/access sites

The second key area of recommendations to overcome barriers to THN access related to maintaining and expanding access site types, and modes of access. Consumer participants offered a number of suggestions that related to increasing the types of access sites available, and the modes of access:

1. Many noted that the lack of certainty about whether pharmacies were participating in the Pilot acted as a barrier, and so recommended increased pharmacy coverage.

To be honest having it in as many places as absolute physically possible. I mean as many pharmacies as many chemists, and just put the word out there on social media as well because a lot of people don’t know, like the nasal spray exists. [I didn’t] until my friend told me the other day, I didn’t know that so you know, if I did know, I might have it got it sooner (WA, PUJO, Recruited from NSP, Interviewed February 2021).

2. Participants (particularly those in SA) noted that THN should be provided through services that they attended regularly, such as Needle and Syringe Programs, health care and community services, and AOD services.

Being able to get it directly from the CNPs, instead of getting a voucher and taking it to a pharmacy (SA, PUJO, Recruited from Community pharmacy, Interviewed March 2020).

Consumers from other states also noted the need to expand availability of THN:

I think it should be rolled out to a lot more than just a few chemists and outreach centres, and NSPs, I think the police should have it, I think community-engaged workers should have access to it, and hospitals obviously, and maybe even vending machines where they pick up their packs from (NSW, PUPO, Recruited from NSP, Interviewed December 2020).

Also noted was the need to train more people at each access site to be able to dispense naloxone more readily:

Say like half a dozen people work at [peer organisation]. It’s really important that everybody that works there has the ability to hand out naloxone. Not just me getting it and then I have to leave the building and meet up with my using opioid friends and then I can hand it out. Because I can just do a brief intervention in the building. Train...the ability to train people there so they can have to hand it out themselves. That would be the thing that I would recommend (WA, PUJO, Recruited from NSP, Interviewed February 2020).

3. While patients are already able to access naloxone from a GP by way of prescription, many participants noted that they thought it would be helpful to have THN available directly from GPs and other primary health services. ⁱⁱ

Our consumer interviews indicated that there was a high rate of recent access of GPs and other health services: 92% had accessed a GP in the previous six months and 36% a medical specialist. Psychologists (33%) and social workers (31%) may present other opportunities to discuss or provide naloxone.

The best processes for allowing for direct provision of THN by GPs would need to be carefully considered in a national roll out of THN, but it is important to note that this was mentioned by many consumers and considered by stakeholders to be something of a gap in the current Pilot model. This is discussed further in Chapter 9.

4. Delivery of naloxone was mentioned by many participants as a way of increasing reach of naloxone and as a way of circumventing stigma as a barrier through enhanced anonymity. Delivery was also highlighted as a key recommendation for allowing access to naloxone for consumers in rural, regional and remote areas. There are however legislative and safety barriers: pharmacists are required to dispense naloxone in person, and delivery services would need to consider how to provide the necessary education to consumers on how to recognise overdose and use naloxone correctly.

Maybe if they offered some kind of delivery to people who don't have a car and they don't have a way to get to the clinic. I live quite close to one, but if you're not as close to one, it would be a bit hard if you don't have a car (WA, PUJO, Recruited from Community pharmacy, Interviewed November 2020).

5. Vending machines were mentioned by quite a number of participants as a potential way to increase access to naloxone and maintain anonymity (although it is noted that this suggestion has multiple legislative and other barriers depending on the jurisdiction).

Vending machines would be a good idea at places like at the back of hospitals and shops. That'd be a good place to be able to get them as well (NSW, PUJO, Recruited from Community pharmacy, Interviewed May 2021).

6. To facilitate the process of receiving THN and to enhance convenience and anonymity, some participants suggested that online booking and ordering systems could be used by access sites.

7.2.1.5 Further formalisation of use of peer and social networks

The lack of awareness of the Pilot amongst consumers was mentioned by participants as a barrier to THN, with participants suggesting that greater formalisation of outreach activities and peer distribution could be a means addressing this. For example:

I think face-to-face with the outreach and everything, in this area, or in the city the outreach goes on foot. Yeah, I think the face-to-face and the gentle nagging, I'll put it like that (NSW, PUJO, Recruited from NSP, Interviewed December 2020).

I see it as being a peer-based program. I think if the peers could have a greater role in being trained to deliver information and inform their networks and be able to refer peer support people into recovery or treatment or whatever the individual needs or

ⁱⁱ Note that the requirement for a prescription presents its own barriers, already discussed in Section 7.1.1.2.

requires, it would be a great place to start (NSW, PUPO, Recruited from NSP, Interviewed December 2020).

In NSW and WA, peer workers have been involved in THN programs prior to the Pilot. For example:

...the peer workers who were doing the education authorised under that SASA arrangement. So we did have a whole system of, you know, policies, procedures, and educational materials already in place before the Take Home Naloxone pilot began. (WA, NSP staff member, Interviewed May 2021).

In SA, peer workers had also been trained in THN but were only able to supply the vouchers:

Participant: Yeah, we're supplying the vouchers not the naloxone

Interviewer: yeah, right. And what makes you comfortable to do that?

Participant: because I know, because I have been really well briefed with naloxone and overdose, so I'm quite comfortable talking about it because I know a lot about it and also because I'm working with, I'm a peer so I'm working with my community... (SA, NSP/CNP staff member, Interviewed January 2021).

Consumers and access site staff that had training from peer-based organisations found it helpful and informative. Consumers that accessed THN from peer organisations appreciated interacting with people with lived experience:

I feel that the people who work at the [peer-based organisation] know what they're talking about. If I have any questions, they can answer them. And I don't...I don't feel embarrassed or whatever to ask for Naloxone. Yeah, I feel more comfortable going there than to the pharmacy to ask for it, because they're yeah, they're not judgmental and it's free (WA, PUJO, Recruited from NSP, Interviewed December 2020).

Some participants also thought the peer model could be expanded to include information provision about THN for family members and friends of people who use opioids.

This recommendation is further expanded in Chapter 9, Section 9.2.2.4.

7.2.1.6 Education for police

Some of the consumers interviewed mentioned that education for police about naloxone and the Pilot is needed:

The police, you actually have to tell them it's actually legal to have this and I don't need a prescription to have this... They don't seem to know it's not illegal if you don't have a prescription, I think they need to be given education on that (NSW, PUJO, Recruited from NSP, Interviewed December 2020).

7.2.2 What were the key facilitators of success in the Pilot?

To further inform the consideration of how to overcome barriers to THN provision, and the extent to which the Pilot addressed barriers, this section provides an overview of the key facilitators of success in the Pilot.

Table 6. Key facilitators of success in the Pilot

Key Facilitators	Results
1. Free access to THN	Enhanced reach and accessibility of THN for consumers
2. Availability of THN without a prescription	Reduced time, removed additional step and additional cost for consumers
3. Availability of Nyxoid® nasal spray formulation	Enhanced reach, acceptability and ease of administration for consumers
4. Increased staff knowledge and positive staff attitudes	Staff were more comfortable offering THN to clients Consumers felt comfortable being offered THN and during brief intervention/education
5. Standard operating protocols that included naloxone	THN becomes integrated into 'business as usual' and staff are more likely to offer THN
6. 'Champions' for the Pilot in different sectors	Enhanced promotion of the Pilot
7. Communication and collaboration across sectors	Shared learning during the Pilot, cross-promotion
8. Local health promotion networks	Broader range of site types involved, cross-promotion of Pilot between sectors
9. Use of existing resources for promotion and guidelines and development of new ones	Facilitated speedy implementation of the Pilot
10. Increased range of settings for access of THN	Greater likelihood of engaging intended target populations
11. Effective engagement of the AOD sector and acceptance of naloxone within the sector	Early uptake and enhanced reach of THN to people who are engaged with AOD and related services
12. Use of peer networks and word of mouth	Informal promotion of the Pilot within target populations.

7.2.2.1 Free access to THN

Offering naloxone to consumers for free was central to the Pilot model, and removed a significant barrier to THN uptake. Although previous research has shown that even consumers with limited income place significant value on naloxone, the most disadvantaged community members may struggle to afford naloxone at non-concession prices.

7.2.2.2 Availability of THN without a prescription

The availability of naloxone without a prescription allowed consumers to obtain it without having to see a GP, thereby removing the time involved for this step and avoiding a consultation fee.

7.2.2.3 Availability of the Nyxoid® spray

By offering a range of formulations, consumers were able to access a naloxone product with which they were familiar and confident to use. The nasal spray formulation enhanced the reach and acceptability of naloxone amongst consumers, particularly those who were unfamiliar with injecting practices or had concerns about carrying needles and syringes.

You don't really want to be sticking needles into strangers. So I think the nasal spray is fantastic alternative. (NSW, PUPO, Recruited from NSP, Interviewed April 2021)

The nasal spray is definitely more comfortable to use (WA, PUPO, Recruited from Community pharmacy, Interviewed September 2020).

7.2.2.4 Increased staff knowledge and positive staff attitudes

More knowledgeable staff enhanced consumers' comfort with being offered THN and during the brief intervention/education process.

They're very helpful, friendly. They asked me If I needed anything else, if I knew how to use it or any help with any other problems I might be having as far as safe use goes. They were very helpful...like I said they made sure that I had everything I needed, even aside from naloxone, everything else that I needed to make sure that I knew how to use it (WA, PUPO, Recruited from Community pharmacy, Interviewed November 2020).

Access site staff reported that the training equipped them with the knowledge to successfully provide THN and describe appropriate overdose response to their clients. Pharmacists noted that guidelines on assessing which clients should be offered naloxone were helpful, as were tips on 'how to broach the subject'.

7.2.2.5 Standard operating procedures that include naloxone

Staff at NSPs noted that it was easy to incorporate offers of naloxone into routine exchange activities, so that less effort was required to 'remember to do it'. Staff of one pharmacy noted they were all trained in how to offer naloxone and explain its use, and it was made clear this was an expectation of standard practice; colleagues could then remind each other to offer naloxone to suitable clients. This also ensures standardisation of approaches to THN provision within an organisation.

7.2.2.6 Champions in different sectors

Champions at multiple levels have been key to the success of the pilot and helped facilitate the implementation of the THN Pilot, as well cross-sectoral collaboration. At the state level, champions in state implementing agencies were pivotal to the success of the Pilot, acting as

central points for information, linkage agents for establishing collaborations, and advocating for change to address new challenges.

For access sites, strong management support for THN facilitated implementation of the Pilot at site level and helped encourage cross-sectoral collaboration. For example, this participant noted:

...so what we've done is we've had strong management support that this is a key intervention for the service, and we have had a number of really enthusiastic champions within the service, of which I am one but there's a few of them, on both teams to ensure that we're continually providing training, support, updates, and motivation to staff to continue rolling it out. It's also part of our regular health promotions agenda, where we have regular health promotions to promote the use of naloxone so that clients are constantly being reminded and obviously we have an onsite business rule – policy and business rule – on how to implement take home naloxone (NSW, NGO Staff member, Interviewed July 2021).

7.2.2.7 Communication and collaboration across sectors

Participants discussed several examples of cross-sectoral collaboration and information sharing across sectors in a geographic area to share learnings and enhance the reach of the THN Pilot to difficult to reach clients.

We've got a chemist out here who is so proactive in the drug health world and ... he and I actually co-hosted an overdose awareness day, pre-COVID...At an Aboriginal non-government organization. And he's just so on-board. So he's part of the program. So, we actually promote that if you need one on the weekend, go to [Pharmacy]. He's non-judgmental. He's really, you know, on board with everything (NSW, NGO Staff member Interviewed June 2021).

'There's one other that we know of that's on the Pharmacy Guild. But what our nurses are doing- there's a new promotion coming up, where the nurses are going out to the pharmacies to try to get them onboard with naloxone and with dried bloodspot testing (NSW, NGO Staff member, Interviewed June 2021).

One pharmacy discussed a collaboration with local outreach and homelessness services, where pharmacy staff would visit with outreach teams, establish rapport with clients and encourage them to visit the pharmacy for naloxone.

7.2.2.8 Local health promotion networks

These networks were instrumental in promoting the Pilot to a broad range of local stakeholders within a region and helping to enhance capacity of services to provide THN. As such activity is a key focus for health promotion, incorporating promotion of THN and the Pilot into the agenda did not require a significant shift in thinking. A health promotion officer from one NSW LHD described how health expo days and regular local network meetings provided continual opportunities to promote the Pilot across sectors, ensuring a broader range of avenues for THN access and development of a 'no wrong door' approach for THN in that community.

7.2.2.9 Use of existing resources for promotion

Access site staff reported using Overdose Awareness Day and visual promotion materials (posters, postcards) to stick around access sites to promote THN and initiate conversations with clients. Access site staff also reported that they used resources developed by others, and at times developed their own resources, to aid implementation of the THN Pilot in their

organisation. For example, a community pharmacy staff member in SA noted that they provided the Penington Institute resources on naloxone to consumers:

Because that's the whole idea is that you've got quick access to it. Then we provide the front and back page from the Penington Institute, the naloxone one-pager. Sometimes, the preventing overdose page as well, from Penington. So those are the two resources that we'll provide in writing (SA, Community Pharmacy staff member, Interviewed April 2020).

Use of existing collateral reduced costs and established links between THN and other health behaviours, working towards de-stigmatisation.

7.2.2.10 An increased range of settings

A broad range of setting types through which consumers could access naloxone contributed to enhanced reach of the Pilot, particularly in regional areas where limited coverage by specific services (e.g., NSPs) may otherwise have precluded access to THN. Consumers may also feel more comfortable engaging with different service types; those not familiar with AOD treatment services found pharmacies less daunting to approach, while some already linked to treatment services preferred familiar venues where they were confident of staff attitudes. More generalised health services such as carer organisations or family support groups allowed staff to offer THN to clients more likely to witness an overdose than experience one.

7.2.2.11 Effective engagement of the AOD sector

The majority of initial Pilot implementation targeted the AOD sector in each jurisdiction, to positive effect. The existing AOD workforce were already familiar with and supportive of THN programs. They were also committed to harm reduction and skilled at supporting vulnerable clients. Existing acceptance of naloxone within AOD sector contributed to the goodwill of staff to promote and implement the Pilot.

7.2.2.12 Work of peer organisations, networks and word of mouth

Peer networks were effective in providing ongoing support to people who accessed THN, encouraging information updates, refill of used naloxone supplies and links to follow up treatment where required. For example:

I have actually given naloxone. I ran into a guy that just started using. And I gave him a bottle of naloxone and the leaflet and that. And I sat down with him and his girlfriend and explained what to do and how it works and that. Because she doesn't use (NSW, PUIO, Recruited from Community Pharmacy, Interviewed August 2020).

... there's been you know there's been us in the CNPs and peer network programs actually promoting it to their friends and their networks, so that would've all helped (SA, PUIO, Recruited from Community Pharmacy, Interviewed June 2021).

Such networks were also invaluable for promoting the Pilot to people who may not access services providing THN, who may not consider themselves as at risk of overdose, or who may not have considered their potential role as a witness to overdose, and would thus be unaware of the opportunity.

7.2.2.13 Existing infrastructure (policy frameworks, e.g., ORTHN in NSW)

The ability of operations in NSW and WA to build on existing naloxone programs prevented a lag in the operationalising of the Pilot in those areas. Service familiarity, trained staff and

existing policies and procedures all helped prevent delays. Such infrastructure was able to be shared with newly engaged sites, such as policy templates, promotional materials and mentoring of staff new to working with naloxone. Conversely this did provide challenges in some instances where organisations perceived a requirement to “change operations once more to essentially do the same thing”.

Implications

- The Pilot has addressed or partially addressed a number of barriers to THN, through free provision of THN without a prescription available at a number of sites, and these are key elements that should be carried forward in a national model of THN provision.
- A national roll-out of THN should also aim to address the barriers that still exist: stigma aimed at people who use opioids, consumer and community awareness of THN and processes and places to obtain it, awareness of overdose risk, availability of THN at desired locations for access, and barriers to having naloxone on hand in the event of an overdose. Chapter 9 discusses recommendations for further work to address these barriers.
- The design of the national model for THN should leverage off the key facilitators of the Pilot by ensuring continued free access to THN without a prescription, in a range of formulations. Furthermore, cross-sectoral collaboration should be further encouraged, along with supporting the activity of local and state level champions and peer organisations. Chapter 9 further expands on how the strengths of the Pilot can be leveraged in a national rollout of THN.

8. Were there any unintended consequences of increasing access to naloxone?

The TGA Delegate's 2015 decision to down-schedule naloxone to Schedule 3 when used as treatment for opioid overdose, to be implemented in Feb 2016, listed the following potential risks of rescheduling: "an incentive for supply when not necessary, that opioid users may use opioids in a riskier manner knowing that an antidote is available (although there is no evidence that this is the case), that bystanders may be less likely to call an ambulance, and risks of unsafe administration."(49)

These risks were considered in the evaluation of the PBS-Subsidised THN Pilot. We found:

- No evidence of supply when not necessary. There were instances, particularly early in some pharmacies' involvement in the Pilot, where staff recommended naloxone to all clients who received prescribed opioid medicines, resulting in dispensing of large amounts of naloxone. This would not be considered 'unnecessary supply', because these were individuals at potential risk of overdose, although some may not have been deemed at 'high risk'.
- No evidence that people used opioids in a riskier manner knowing that naloxone was available. Our interviews, those of the IDRS, and of previous evaluations (e.g. ORTHN) did not find any increase in use related to naloxone availability (30).
- No evidence that bystanders were less likely to call an ambulance. Our interview data indicates that 65% of participants who witnessed an overdose called an ambulance as part of overdose responses. Findings of the ORTHN trial evaluation were noted no change to calling of ambulance (30).
- No evidence of unsafe administration. Our interview data did not note any adverse situations. The inclusion of the nasal spray formulation in the Pilot and its widespread uptake is likely to have reduced any potential risk associated with administration by injection.

Two stakeholders from NGOs interviewed as part of the roundtables noted there was some initial resistance among staff to the idea of naloxone provision on exit from residential treatment programs, fearing that it "sent the wrong message" to clients, suggesting to them there was an "expectation to fail" (relapse). Failure to engage however would have entailed a significant missed opportunity for the clients, as there is extensive evidence that return to community after periods of abstinence (e.g. leaving treatment, or post-corrections release) is a high risk period, due to increased stress and reduced tolerance (50-52).

However, despite both organisations having a history of abstinence-based approaches to treatment of dependence, governing boards and the majority of staff accepted the THN Pilot as a "natural part of harm reduction". Neither has reported negative feedback to date.

9. What needs to be considered in relation to a national roll-out?

This section discusses how the strengths of the current THN Pilot can be leveraged to inform a national roll-out. Our recommendations draw on the information provided to us by state implementing agencies, consumers and providers of THN, and experts from the health, justice and research sectors, as well as recommendations from national and international literature.

First, we consider the core elements that should exist in a national roll-out of THN, including free access to naloxone through continued subsidisation, access to naloxone without a prescription, permanency of a national roll-out, access to THN from a range of sites, and joint working between the Australian Government and state and territory governments. This is followed by a discussion of the recommendations to support the core elements of a national roll-out of THN.

CORE ELEMENTS OF A NATIONAL ROLL-OUT

ELEMENTS TO SUPPORT A NATIONAL ROLL-OUT

CORE ELEMENTS

1. ENSURE CONTINUITY



Commit to implementing the national roll-out of take-home naloxone on a permanent basis rather than as a Pilot and ensure continuity between the Pilot and national roll-out of THN.

2. ENSURE FREE ACCESS TO THN



Retain the ability for naloxone to be fully subsidised on the PBS.

3. ENSURE ACCESS WITHOUT A PRESCRIPTION



Retain the ability for naloxone to be provided without a prescription and without a PBS co-payment.

4. ENSURE BROAD AVAILABILITY



Retain and further expand the ability to access THN from a range of sites, including community pharmacies, NSPs and other AOD services, on exit from correctional settings, and further settings.

5. ENSURE COORDINATION



Continue and formalise joint working between the Australian Government and state and territory governments.

1. AWARENESS AND PERCEPTIONS OF THN



Build awareness and reduce stigma through public awareness campaigns and targeted promotion.

Build awareness amongst professionals within and beyond AOD sector.

2. ENGAGEMENT AND COMMUNICATION



Identify and engage with professional groups to encourage participation within and beyond the AOD sector.

Identify and support local champions for THN.

Consult across a wide range of sectors and encourage partnerships.

Build further capacity for peer organisations and networks.

3. FUNDING AND RESOURCES



Funding for a national coordinator position.

Establish formal communication mechanism and/or national working group.

Resource implementation at state/territory level.

Develop national resources to guide implementation.

4. TRAINING AND EDUCATION



Standardise training for THN providers, and offer online/on-demand.

Standardise brief education materials for consumers and include information to address consumer concerns around ambulance and police attendance.

Include naloxone in professional competencies/CPD.

5. PROGRAM MONITORING AND DATA COLLECTION



Decide on minimum data for reporting on THN supply.

Leverage existing data collection and funding arrangements to facilitate data collection.

9.1 Core elements of a national roll-out

9.1.1 Ensure continuity: Commit to implementing the national roll-out of take home naloxone on a permanent basis rather than as a Pilot

Removing the time pressure of a short-term Pilot program will allow suitable lead time for considered development of structures, workforce and systems to manage the program: for example, policy/directives, staff authorisation and training, establishing logistics of supply. Ensuring continuity will also prevent jurisdictions being reluctant to engage for fear of the program ending soon, and allow sufficient time for program operations to achieve maturity (we would suggest a five year minimum). It will be important to continue to monitor implementation and outcomes to ensure best practice is embraced and ongoing learning takes place during implementation. This will allow the program to further adapt where needed. To facilitate permanency of THN on a national scale, it will be important for the naloxone program to align with and be part of a strategic national policy framework, rather than operating as a disconnected stand-alone activity.

9.1.1.1 Nest the ongoing THN program in the broader health policy environment

Naloxone should be embedded as part of broader opioid stewardship programs, relevant to the general population and not as a purely AOD issue. International best practice recommends that naloxone provision be nested within a range of strategies to reduce the risk of opioid overdose, including: overdose education and naloxone distribution, effective delivery of medication for opioid use disorder, safer opioid analgesic prescribing and a public health approach to broaden recognition of impact that work *in combination*, rather than as alternatives (53).

Some activity is currently underway in this space; actions could be extended to incorporate THN in many cases.

- Restricted pack sizes for immediate-release opioid and renewed guidelines for opioid prescribing are in place: prescriber guidelines could be extended to incorporate co-prescribing/provision of naloxone
- Real time prescription monitoring for opioids has commenced in some states and a national approach is being developed; automatic co-dispensing of naloxone with opioids above a dose threshold could be included in these programs, building on evidence from overseas opt-out programs (22).
- Development of national action plans for chronic pain management could incorporate naloxone provision where opioid therapy is indicated to ensure that effective delivery of analgesia continues but does not increase risks of overdose.
- TGA scheduling of medicines may consider further reassessment of naloxone to overcome barriers to third-party supply.
- The inclusion of THN in opioid dependence treatment programs and withdrawal management strategies currently implemented by some states and territories could be formalised to become national practice.

These activities would benefit substantially from an overarching policy framework to ensure coordination and alignment of policy approaches with frontline delivery of THN programs.

Further down-scheduling of naloxone to S2 for the prevention of opioid overdose has been proposed as a potential mechanism to overcome barriers preventing third-party supply in some settings, such as peer-to-peer supply. Although this may be out of step with similar emergency

medicines such as the EpiPen® for anaphylaxis that remains S3, it would pragmatically remove logistical challenges such as the requirement for pharmacists to provide naloxone direct to the recipient, would anonymise transactions and allow postage to consumers in regional or remote areas. This may also alleviate some challenges in hospital settings (e.g., requirements to relabel). However, this approach would need to be balanced with the need to provide sufficient education and instruction on use to consumers. Other options for the provision of the brief intervention/education would need to be explored if this avenue was pursued.

9.1.2 Ensure free access: Retain the ability for naloxone to be fully subsidised on the PBS schedule

A core element of a national roll-out should be the continued subsidisation of naloxone to ensure that it remains free to consumers. Stakeholders agreed that funding naloxone itself remained critical, and as indicated in the evaluation data, consumers also indicated that they appreciated the free provision of naloxone and this significantly enhanced uptake.

9.1.3 Ensure access without a prescription: Retain the ability for naloxone to be provided without a prescription and without a PBS co-payment

Currently, to ensure that naloxone supply is PBS subsidised, GPs and other prescribers are restricted to prescribing limited quantities (5 ampoules, 1 pre-filled syringe, or 2 nasal sprays) with no repeats. This means that patients must return to their GP to obtain further prescriptions and visit a pharmacy to dispense these prescriptions if further supply through the PBS is needed. In practice, this translates to a combination of time, cost and effort barriers; compared with Pilot provisions which does not impose costs or the need for additional prescriptions, in the event of a refill being required.

9.1.4 Ensure broad availability: Continue and expand availability through a range of access sites

A national roll-out of THN should ensure availability from a range of access site types, including but not limited to community pharmacies, NSPs, AOD treatment services, peer settings, and on exit from correctional service settings. A strength of the national Pilot has been the availability of THN from a range of access sites.

Community pharmacies have been a key site for delivery of THN under the Pilot due to their ubiquity and ability to reach a range of potential THN recipients. As such they should also be a key focus of a national rollout. To this point, only 40% of PBS approved pharmacies across the Pilot states enrolled in the Pilot. Of the 40% who enrolled, only half provided naloxone at least once and 18% provided monthly supplies. To improve the pool of pharmacies for consumers, it is recommended that all 5,822 PBS registered pharmacies in Australia be automatically enrolled in the national THN program, thus normalising naloxone supply. Non-PBS registered pharmacies should be able to register with their state/territory implementing agency. Further effort would then be required to convert registration into active provision.

Primary care is an important setting for provision of THN that the Pilot model did not effectively address. A national rollout should consider how to facilitate direct provision of THN in primary care settings. This is discussed further in section 9.2.2.1

The national rollout should continue to expand provision through AAS. The *Special Arrangement 2019* facilitated this at the Commonwealth level, but states and territories will need to make their own amendments to legislation and/or policy directives to allow trained workers to supply naloxone to people at risk. Victoria has recently (6 August 2021) amended its *Drugs, Poisons and Controlled Substances Act 1981*, enabling NSP workers to provide naloxone.

Such processes could be facilitated by the Commonwealth by facilitating information sharing or through provision of resources and/or guidance on legislative change.

Priority should be given to settings where effective distribution of THN has been demonstrated. Settings show considerable variation in both demand for THN and systems available to facilitate naloxone provision. Prisons and Community Corrections should remain and be expanded as key outlets, acknowledging their place in supporting people in a well-established high-risk situation (50, 51). Australian studies have demonstrated that training and naloxone provision upon release is feasible and more effective than expecting clients to attend a pharmacy (29).

The literature offers indications of the variable effectiveness of other settings. For example, Emergency Departments appear to be a prime opportunity to engage with people experiencing opioid overdoses but ED staff report challenges implementing additional programs in a pressured environment, and recent evaluation in the US of an ED THN program found this did not substantially influence opioid related overdose deaths in the longer term (54). Several UK studies are currently underway and warrant monitoring (43, 55).

First responders such as ambulance services currently carry naloxone in Australia but do not provide THN. It will be important to monitor the success in WA of St John Ambulance's provision of THN to overdose patients who refuse transport. Evaluation of a similar program in Scotland did not show a clear association between THN and reduced ambulance attendance at opioid overdoses in the subsequent four years (56). Overseas police officers' carrying of naloxone has been deemed successful; the upcoming evaluation of WA Police Force's program will prove informative for further such initiatives in Australia.

9.1.5 Ensure coordination: Joint working between the Australian Government and state and territory governments

The Australian Government and state and territory governments should continue to work together to ensure the success of the national roll out of THN. While the Australian Government can provide the policy scaffolding necessary to facilitate the national roll-out (such as subsidy through the PBS, amendments to Commonwealth legislation, and the provision of national guidance on criteria for the program), state and territory governments have crucial roles to play in implementation. For jurisdictions involved in the national roll out, consideration should be given to whether implementation should be led by a central government agency (State or Territory Department of Health), a Commission (e.g., in WA, the Mental Health Commission), or a consortium including government and non-government representatives. In all cases, broad health sector representation would be imperative, with commitments formalised in Terms of Reference and memoranda of understanding.

9.1.5.1 Establish broad ongoing consultation across states and sectors

To extend current collaboration into an operational working consortium, mechanisms and terms of reference should be formalised to facilitate steering of the program, sharing of learnings, implementation strategies and resources. The National Naloxone Reference Group hosted by the Burnet Institute fulfils some of these functions, but membership is currently limited to the AOD sector and would need to expand to other health sectors to ensure THN programs reach all intended target populations.

Funding for a national coordinator position may assist with this and allow direct connection into Commonwealth policy frameworks and activity. The crucial roles played to date by state-based champions of the THN Pilot should be reflected in ongoing commitment by participating jurisdictions to resourcing such roles as additional members of a joint working group, rather than activity being dependent on specific committed individuals (21).

This consultative body could facilitate collaborative systems development to support a long-term naloxone program, encourage partnerships and ensure cross-sectoral communication. Such a body may also act as a centralised repository for consistent resources such as guidelines for systems development and implementation of THN, policy templates, staff training and materials to support engaging with clients.

9.2 Elements to support a national roll-out

9.2.1 Awareness and perceptions of THN

The AOD sector is already aware and appreciative of the value of naloxone to prevent overdose deaths, which facilitated uptake of the THN Pilot in this sector. Benefit would still be achieved through further promotion to encourage demand for THN, particularly among family and carer networks who may witness overdoses.

Expansion of the THN program beyond the AOD sector will require normalisation of naloxone provision to reduce stigma. There are important sectors, such as the pain sector, that need further awareness building.

9.2.1.1 Build awareness amongst the community

Building general community awareness of opioid overdose risks, especially beyond risks due to use of illicit drugs, is critical to drive demand for naloxone. Community preventative health programs typically include both universal awareness raising and targeted promotion or intervention for groups perceived as being at highest risk; both strategies would be useful in this case.

The Overdose Lifesavers program is one example of a targeted approach, where the stories of overdose focus on people who use illicit opioids but represent a wide range of community members and contribute to destigmatising the overdose situations (<https://overdoselifesavers.org/>) (57). Existing events such as International Overdose Awareness Day provide annual opportunities to highlight the need for broad overdose responses, spotlight the role of family and friends, and showcase programs such as THN.

Ongoing campaigns such as the UK's Involved and Informed: Good Community Medicines Support (<https://www.rpharms.com/resources/pharmacy-guides/medicines-optimisation-hub/managing-medicines-in-the-community>) take a broader-audience awareness raising approach, encouraging active involvement of physicians, patients and families/carers in safe management of medicines in general. Naloxone could form part of such a program adapted for Australia. Culturally appropriate materials will be critical for any community awareness campaigns.

9.2.1.2 Build awareness for professionals using multiple avenues

It will be important to embed THN provision as part of clinical practice and standard service for all access sites, particularly services which regularly engage with a range of consumers. Opt-out programs, such as those in Canada which remove the need for practitioners to undertake a risk or suitability assessment before offering naloxone, encourage the normalisation of naloxone and facilitate incorporation into usual practice (22). Peak organisations, councils, email lists, social media, conferences and other professional events can facilitate access to a range of professions to encourage such practices. Contact through professional peak bodies may also assist with the necessary 'authority' required to encourage uptake in the different sectors.

9.2.2 Engagement and communication

Engagement and communication with key stakeholders are important components to support a national roll-out of THN.

9.2.2.1 Engage with specific professional groups to encourage participation

To facilitate availability of THN through a range of access sites, professional groups from a range of different access settings should be engaged.

Inclusion of a broader range of sectors beyond the AOD sector may benefit from a re-mapping of stakeholders, particularly to ensure inclusion of stakeholders in other jurisdictions for a national roll out. Subsequent wide-ranging consultation, and the encouragement of partnerships between and across sectors will be critical in developing a cohesive national program. A key part of this will also involve identifying and supporting local champions for THN in the AOD sector, as well as beyond the AOD sector. This re-mapping of stakeholders and consultation process should not delay the beginning of the national roll-out, but should be an ongoing process.

Linking with a range of champions/authoritative organisations (such as the Pharmacy Guild of Australia, the PSA, the Royal Australian College of General Practitioners, and primary health networks) will help raise awareness of naloxone and assist with embedding of naloxone provision in standard professional guidelines and core practice. Specific training to address stigma in the workforces that may be involved with naloxone, such as that developed by NSW Users and AIDS Association (NUAA), is an example of such capacity building, with continuing professional development points attached to encourage GPs to participate. Such capacity building should extend into carer organisations, who often engage with family and significant others of people who use prescribed and illicit opioids (i.e., potential witnesses).

Connections should also be made with Aboriginal Controlled Community Health Organisations (ACCHOs), rural community health services and remote health workers, including the Royal Flying Doctor Service, as targets to reach remote areas. Links with telehealth services and My Emergency Doctor may provide referral points and opportunities for follow up care after provision of naloxone.

9.2.2.2 Engage with the primary care sector

As highlighted in Chapter 7, GPs also present an area of opportunity for the provision of THN as one of the most commonly accessed health services. However, the most effective processes for engaging GPs in direct provision of THN would need careful consideration in a national model.

The most appropriate method may be through Prescriber Bag provision, however this would require reconsideration of Prescriber Bag allowances and formulations approved, so that Nyxoid® is also included in Prescriber Bag provisions, to increase acceptability of naloxone among patients unfamiliar with injecting.

Enlisting nurse practitioners within primary care facilities, potentially through programs supported by PHNs, may prove an alternative avenue for providing THN and brief education on overdose to potential recipients in universally familiar community health services.

9.2.2.3 Continue to engage with pharmacies

Community pharmacies will remain a core part of THN programs, as they form a constant and accessible hub for a broad range of potential THN consumers. Although some pharmacies were active in providing naloxone, particularly those already engaged in harm reduction programs such as OAT, others were less confident or motivated to provide naloxone, as found in earlier studies (58).

Large-scale pharmacy chains are an important mechanism for program engagement and supply of THN, however it will be important to encourage more-than-nominal participation as observed during the Pilot, where a head office registered, but without a plan for implementation, with the result that staff of local pharmacies were unaware of “their” business’ participation. The national rollout will also need to consider how best to ensure that staff from large scale pharmacy chains are trained and aware of THN. Targeted consultation with representatives from chain pharmacies may assist with this. Engagement with stakeholders connected with pharmacy registration (such as the Pharmacy Board of Australia and state/territory-based registration bodies) may also assist with this.

In this context it is also important to further develop strategies to convert registered organisations into actively participating sites. It must be acknowledged that different pharmacies will have different client characteristics that impact on the demand for naloxone, but monitoring and follow up where a pharmacy has registered but not supplied (as attempted via the PPA portal) will support improved access to this life saving drug (10).

9.2.2.4 Peer organisations and networks

Building capacity among professional peer networks will assist an ongoing THN program to become more sustainable. A number of AOD-based peer networks are currently involved in naloxone distribution in the ACT and Victoria as well as in Pilot states. These provide the advantages of familiar, sympathetic and credible information sources and a non-judgemental approach to harm reduction for people who use illicit drugs. Numerous evaluations have shown these networks to be effective for take home naloxone programs (28, 30). Leveraging existing peer distribution programs (such as those for needle and syringe provision) would allow swift introduction of naloxone provision among this at-risk group.

A similar strategy could be used to encourage naloxone provision among potential witnesses of overdose. National organisations such as Family Drug Support may facilitate access to those who assist people with problematic substance use, but parallel organisations providing support for families of people with mental health or chronic pain problems offer scope to extend THN programs into non-AOD support systems.

9.2.3 Funding and resources

While funding of naloxone itself is vital to the national roll-out, funding should also be made available to assist with program implementation to ensure consistency and sustainability of effort. Details of the resourcing required for the ACT’s THN program show clearly that implementation costs are significant; workforce and training costs accounted for a large proportion of the program budget (28). This is particularly relevant when systems and training development are required, even if existing human, social and other capital in participating organisations are being leveraged.

The responsibility for this funding may be shared between the Commonwealth and participating state and territories. A national coordination role as discussed in section 9.1.5 would ideally be supported by Commonwealth funding. Dedicated state/territory-based implementation staff with ongoing responsibilities for naloxone programs would be best supported by jurisdictional funding. The provision of such funding may be a lever by which organisational participation in cross-sectoral coordination activities, monitoring and reporting could be encouraged.

9.2.3.1 Supply chain sustainability

Existing supply chain mechanisms for pharmacies appear to be working well in the current Pilot, and future reimbursement activities could potentially be migrated to the Services Australia system to align with other PBS programs. Some form of prior authority approval would however

need to be incorporated into the current system to permit PBS-subsidised supply without a prescription.

Based on reports from WA and NSW, supply chain mechanisms for AAS could benefit from streamlining. In WA, the single bulk supply arrangement is appreciated by services but may result in delayed delivery if stock forecasting is not accurate. The NSW distribution arrangement for AAS incurs larger costs due to small-volume ordering by individual sites; a coordinated system may be able to leverage higher levels of activity to reduce these costs.

Alternatively, if smaller AAS were able to negotiate 'bulk supply' through a local entity (such as a pharmacy or bulk AAS, potentially connected to a local hospital/health service), this may obviate the need for independent supply chain/distribution mechanisms. Claiming could then be undertaken by the bulk supplier through an adjusted Services Australia arrangement.

Measures to ensure demand for naloxone can be met may be useful. One round table suggestion was for all pharmacies to be provided with two units of naloxone as a 'starter kit' to encourage stocking, but the cost of this may prove prohibitive. It may also provide a limited return prior to demand being established, with a risk of stock going out of date ahead of provision. One US state has mandated that all community pharmacies maintain a sufficient supply of naloxone for dispensing; such a strategy places the onus for ordering (and then provision to ensure that purchase cost is reimbursed) on the site rather than the program sponsor (59).

9.2.4 Training and education

Although the existing skills of pharmacists in dispensing and advising on medicine safety are acknowledged, naloxone-specific training and advice were broadly appreciated by interview participants. Similarly, staff at many AOD-specific AAS had pre-existing harm reduction knowledge and skills in harm reduction, but recognised the value of training specific to educating others about overdose prevention and naloxone. Upskilling for more generalist services to provide naloxone will continue to be necessary. As a result, training and education will be an ongoing requirement for a national program.

9.2.4.1.1 Professional education

For community pharmacy staff, the inclusion of naloxone education and training in the pharmacy degree program would ensure all new professionals acquire the specific knowledge but may be challenging to achieve across multiple educational providers. Inclusion of overdose awareness training as a 'performance outcome standard' through the Australian Pharmacy Council would ensure that all new pharmacy graduates achieve these standards during either their degree program or the subsequent internship. Training for pharmacy assistants should be developed in consultation with the pharmacy sector.

Completion of overdose/naloxone training could be made mandatory for pharmacies wishing to register as OAT providers, but may restrict the potential pool of access sites to those intending to address AOD issues, and the pool of recipients to people engaged in this treatment.

Incorporating naloxone and overdose into professional guidelines and standard competencies would be similarly helpful for other professionals, as would attaching CPD points to training. Liaison with peak bodies will facilitate these.

Continual inclusion of overdose awareness and naloxone training in CPD allocations for a range of professionals GPs, nurse practitioners, allied health professionals, and pharmacists will encourage uptake.

9.2.4.1.2 Access site staff

Training and education on THN for access site staff should continue, be standardised, and recognise existing staff skills to reduce any redundant credentialing requirements. Online interactive models should be incorporated to remove barriers of time and geographic access. and recognise existing staff skills to reduce redundant credentialing requirements.

Consultation should be undertaken with pharmacy sector about how to facilitate training of all pharmacy assistants.

Inclusion of overdose response skills and knowledge in standard First Aid training may help promote broad community-level awareness in addition to being helpful for a range of access site staff.

9.2.4.1.3 For consumers

Brief intervention/education for consumers needs to address negative perceptions of naloxone, as well as encouraging best practice in administering THN to reverse an overdose. Addressing the myths of legal consequences and reassurance about attendance of law enforcement at an overdose will be helpful (24), and reinforcing the importance of ambulance support for overdose response is essential. Mystery shopping visits showed that ambulance attendance was not consistently mentioned in all settings.

The education should also help people to manage potential reactions (for example, how to respond to potential anger or aggression on the part of the recipient) so as not to discourage naloxone administration.

9.2.5 Program monitoring and data collection

Ongoing monitoring is essential to ensure effective and appropriate implementation of a national THN program. It will be critical to feed regular and timely data back to access sites and organisations to help them monitor performance and activity levels, and to plan forward for resourcing. This will also assist sponsors to predict stock requirements.

Entry of data into the PPA portal was considered an efficient and effective process for staff in community pharmacy settings who were familiar with such systems.

However, the requirement to enter data into the PPA portal resulted in problems in tertiary healthcare where responsibilities lay across multiple staff, and in AAS settings with less experience of such systems. We recommend that the Department and/or state implementing agencies consult widely and across sectors to determine the most appropriate systems, and what is critical in terms of data collection for ongoing monitoring of THN provision.

There are difficulties in the current data collection and reporting systems for identifying stock movement, due to overlap between individual supply and bulk supply records. The national rollout needs to consider the best method for addressing this issue to ensure that all THN stock is effectively accounted for, and that there is a means of monitoring whether naloxone is reaching the intended recipients. This may be feasible within the Services Australia system but will need examination and monitoring to ensure that data capture is fit for purpose.

Current methods of accounting for Prescriber Bag naloxone may also need to be considered, to ensure that any provision by doctors for individual patient use (i.e., using Prescriber Bag supplies as *de facto* THN) is captured in data collection.

9.2.5.1 Leverage existing funding arrangements to facilitate data collection

It will be important for the Commonwealth to continue collaborating with current service delivery partners to encourage Pilot uptake and recording of activities as the Pilot matures further in its

current iteration, and then evolves into an ongoing national program. NGOs currently funded by the Australian Government (such as AOD services) are already required to provide data for National Minimum Data Sets as part of current operations. If a field was added to existing systems to record naloxone provision, this would capture engagement and provision within familiar recording mechanisms. Many such organisations also support families and significant others (i.e., potential witnesses), and this approach could be extended to include social and disability support and home nursing/supportive care services. Such a system may then be able to capture information on the full range of intended naloxone recipients.

9.3 Limitations

The data collected for this Evaluation and our subsequent analyses must be viewed in light of a number of limitations.

Of the naloxone provision recorded during the Pilot, only 48% of supplies recorded evaluation data. Mystery shopping visits confirmed that not all sites requested consent from naloxone recipients. Regression analyses indicate, however, that this response rate was relatively consistent across the Pilot period. Supply events in AAS were more likely to record evaluation data than those in pharmacies, and events in WA were more likely to record evaluation data than those in NSW and SA.

Pilot participants self-identified regarding their use of opioids. People who identified as using prescription opioids included people on opioid agonist therapy (OAT), some who also reported consuming illicit opioids, and may have included people using prescribed opioids extra-medically. People who identified as likely to witness an overdose (rather than experience an overdose) also included some people whose opioid use placed them at risk of experiencing overdose.

The balance of people who provided evaluation data and participated in interviews may not fully reflect the profile of people who accessed naloxone during the Pilot. People who identified as using prescription opioids were under-represented in interview data, comprising 25% (n=80) of the interviews, compared to 54% of recorded supply events for which we have evaluation data. This may reflect their reluctance to participate in interviews, or may suggest that people using illicit opioids (50% of interviews) were more likely to participate when recruited through AOD services with which they were familiar than they were to identify as such in a public setting like a pharmacy (24% of recorded supplies). The categories of opioid use (prescribed opioids, non-use, and “other” or illicit use) were not necessarily stringently exclusive, in that some people who identified as using prescription opioids also disclosed use of illicit opioids. As such we have not been able to identify a significant group of “chronic pain” participants within the sample.

Data from our interviews of consumers about their health circumstances and use of naloxone are self-reported, and so may be subject to recall or social desirability biases. These and other interview data cannot be regarded as a representative sample and so may not be generalised to all persons who received naloxone through the Pilot. However, we sought participants from a range of settings, locations and circumstances to provide a range of perspectives and experiences.

Similarly, interviews of access site staff did not seek a representative sample from all THN provision settings, but were chosen to describe a range of settings and to complement the findings of earlier Australian naloxone program evaluations. There may also have been some self-selection bias in staff participation.

The slow uptake of the Pilot in its earliest phase (January-March 2020), COVID-19 restrictions and resulting methodology changes and ethics re-approvals, delayed enlisting of sites for interview recruitment. As a result, the number of people with at least two interviews (n=82; 38%) is lower than planned, and our ability to monitor change at individual level across the Pilot was curtailed.

We were not permitted to link the PBS data on dispensing of prescribed opioids and of naloxone with data from the PPA Portal on pharmacy provision of take home naloxone through the Pilot; this precluded direct comparisons between these data sets. It is possible that some pharmacies provided naloxone via the Pilot and via the PBS.

Finally, data on hospitalisations and deaths as a result of opioid overdose for the period of the Pilot will not be available for analysis until mid-late 2022 (as anticipated), and will be subject to revision until at least 2025. This restricted our ability to measure changes in these overdose outcomes that could be attributed to the Pilot. These data will be worthy of examination once available

10. Conclusions

In summary, most of the key THN Pilot activities were implemented as planned. The Pilot improved access to take home naloxone among a large number of people, who represented each of the intended target populations. The evaluation recorded 27,955 occasions of naloxone supply over 18 months of the Pilot, compared to 3,579 supplies through the PBS in the previous 2 years. Removal of cost and prescription barriers, availability through a broad range of access site types of different naloxone formulations were key to the Pilot's success. Naloxone was successfully used to resuscitate people in opioid overdose situations. The pilot enabled at least 1,649 overdose reversals, saving an estimated three lives each day over the duration of the Pilot to date.

In some areas, the Pilot did not fully achieve all its original intentions, due in part to the challenges of rapidly scaling up existing operations with limited resources, and an initial focus solely on the alcohol and other drug sector. There were also significant challenges in attempting to implement a major new health initiative in the competing environment of the COVID-19 pandemic.

It is very strongly recommended that Take Home Naloxone be expanded and extended into an ongoing national program that forms an integral part of opioid safety stewardship. There is an established need to address the significant and ongoing risks of opioid overdose, opportunity to include an evidence based effective intervention, and strong impetus among the health sector to implement such a program.

The significant learnings from this Pilot should be taken forward, and the opportunity to continue learning from program operations ensured.

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12. Appendices

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Appendix A: International Naloxone Programs evaluated prior to 2021

Jurisdiction	Funding timeline	Project name/description	Target population	Access sites	Results
Canada	Each province and territory funds its own THN program. British Columbia (BC) first to publicly fund in 2012. All publicly funded in 2017 (CRISM, 2019).	Varies from province or territory (e.g. BC's THN program, Alberta's THN program) (CRISM, 2019).	PUPO/PUIO (prescription and illicit), HR* and community organisation clients.	HR* sites, community organisations, community pharmacies, provincial correction facilities, post-secondary institutions, opioid dependency treatment facilities, First Nations communities with FNIHB nurse, urgent care centres (Freeman et al., 2017; Tsuyuki et al., 2020).	BC – Low-barrier access to free THN significantly reduced opioid-related deaths at time of increased fentanyl-related toxicities. Inclusion of community pharmacies as access sites has several benefits: addresses stigma, increases access, screens patients for naloxone and provides education. Ontario – Although large population is prescribed opioids and availability of kits, naloxone dispensing by pharmacies highly variable (only 55.6% dispensed in 2017). Only approx. 7% of patients receiving high-dose opioid prescriptions received THN in 2017. (Tsuyuki et al., 2020). Alberta – enacting an emergency response due to opioid crisis (particularly fentanyl related) allowed for rapid mobilisation and coordinated response. From Dec 2015-16, 9572 kits dispensed through 953 registered sites, 759 of them community pharmacies (Freeman et al., 2017).
Italy	Available from 1991 through Addiction Services (SerDs) and doctors. Classified as OTC*** drug in 1996. Publicly funded in 2016 when HR services added to LEA**, guaranteeing services to all citizens (Ronconi et al., 2017).	The Italian Take Home Naloxone (THN) model (Ronconi et al., 2017).	People using illicit opioids, HR site clients, SerDs clients, general population (through pharmacy stock).	HR sites (NSPs, drop-in centres, outreach work), SerDs, pharmacies. 57 HR sites account for 98% of national THN system. Pharmacies obliged to stock due to life-saving status (Ronconi et al., 2017).	Deaths from opioid OD declining from 470 deaths in 1999 to 101 in 2015. This statistic specifically measures heroin OD, not all opioids. 55 HR services provided data in 2015 – these 55 services distributed 14,999 vials, averaging 272 per site per year. HR services can reach PUIO not in treatment, provide THN education, educate community to become allies (Ronconi et al., 2017).
Northern Ireland	Publicly funded in 2012 by PHA**** with support from Health and Social Care Board (PHA, 2020).	Take Home Naloxone programme (PHA, 2020).	PUIO community outreach and addictions treatment clients, prisoners service clients, potential witnesses.	Community Addictions Team within each Health and Social Care Trust, prison service, community drug treatment services (PHA, 2020).	Number of times naloxone supplied has been steadily increasing since 2012 (except for 1% decrease in 2019-20) – 1,321 pack in 2019-20, 807 in 2017-18, 247 in 2015-16, 139 in 2012-13. Reported uses of naloxone to reverse OD increase overtime (except for decrease in 2019-20) – 180 in 2019-20, 240 in 2018-19, 127 in 2017-18, 34 in 2015-16, <5 in 2012-13 (PHA, 2020).

Scotland	2011 – First country in the world to introduce a national program (Bird et al., 2016).	National Naloxone Programme (Public Health Scotland, 2020).	PUIO, community outlet clients, prisoner upon release, potential witnesses.	Community outlets (usually specialist drug treatment services), prisons at prisoner release, community pharmacies via prescription (Public Health Scotland, 2020).	<p>Programme associated with 36% reduction in opioid-related deaths which occurred within 4 weeks following an individual's release from prison (Bird et al., 2016). 1:1 training viewed as more effective compared to group training. Supplying naloxone is most effective when dispersed in close proximity to training. Peer training is effective, but demand on peer trainers is high which can contribute to high drop-off rate (Watt et al., 2014). 12,135 THN kits issued in 2018/19, a 42% increase from the previous year (8,555). 58,377 kits supplied between 2011/2012 and 2018/19. Majority issued from community outlets (10,609 in 2018/19), compared in 844 in prisons upon releases and 682 via community prescription (Public Health Scotland, 2020).</p>
Wales	<p>THN demonstration project launched in 2009 (Bennett & Holloway, 2011).</p> <p>Publicly funded in 2011 (Bennett & Holloway, 2012).</p>	National Take Home Naloxone Programme (Public Health Wales, 2020).	PUIO, substance misuse service clients, offenders and prisoners, homeless population, potential witnesses.	Substance misuse services, offender services, prisons, approved homelessness services/hostels (Public Health Wales, 2020).	<p>Since April 2013, THN has been used in 2855 opioid drug poisoning events, with a fatal opioid poisoning only reported in 1.3 per cent of case where THN was administered. (Public Health Wales, 2020). 2011 evaluation showed that survival rates across THN and non-THN sites were similar, with almost all deaths occurring when user was alone. This demonstrates the importance of witnesses being present and being able to take effective action (Bennett & Holloway, 2011). Training increased confidence and willingness to use take action, as well as improvements in knowledge and skills (Bennett & Holloway, 2011; 2012).</p>

HR – Harm Reduction; **LEA – Essential Levels of Assistance; *OTC – Over the counter; ****PHA – Public Health Agency*

Appendix B: Australian Naloxone Programs other than PBS Subsidised THN Pilot

State	Project title	Lead Organisation *	Target audience **	Training duration	Commenced	Active July 2021
ACT	Implementing Expanded Naloxone Availability in the ACT (IENAACT)	CAHMA	PUIO, family members/friends	2 hours, brief intervention also offered	Dec 2011	Yes
NSW	The Kirketon Road Centre Take-home Naloxone Program	SESLHD/KRC	PUIO, family members, friends, health workers	15-20 minutes	July 2012	Yes/THNP#
	The Langton Centre Naloxone Program	SESLHD/St George DOA	Overdose prevention & education programs	Client: 20 mins Services: 2 sessions	Oct 2014	Yes/THNP#
	MSIC Naloxone program	Sydney MSIC	MSIC clients , PUIO, potential witnesses	10-15 minutes	Jan 2015	Yes/THNP#
	Overdose Response with Take Home Naloxone (ORTHN) Trial	SESLHD/MSIC/NUAA, NSW Ministry of Health	PWID, people with opioid use disorders	10-30 minutes	2016	Yes/THNP#
NT	Naloxone Access Program	NTAHC	NSP clients	Information not available	2016	Yes
	AOD Opioid Pharmacotherapy Program	Royal Darwin Hospital	OAT clients		Unknown	Yes
	Free Nyxoid® Program	ADSCA	AOD clients		Unknown	Yes
QLD	Pilot Take Home Naloxone Program – script needed	Metro North HHS/BCHCC	PUIO, opioid treatment, withdrawal and NSP clients	10 minutes 15 minutes 15 minutes 15 minutes	Jan 2014 March 2020 Unknown Unknown	Yes Yes Yes Yes
	Harm Reduction Take Home Naloxone Program – no script, free supply	QuIHN	PUIO, opioid treatment; withdrawal, NSP clients, potential witnesses			
	Pilot Take Home Naloxone Program – script needed	Melaleuca Opioid Treatment Clinic	OAT clients only			
	Pilot Take Home Naloxone Program – script needed	Cairns Sexual Health Clinic	Sexual health and NSP clients			
SA	Peer Administration of Naloxone Trial	SA Health	PUIO, family members/friends	Information not available	Nov 2012	No/THNP#
TAS	Take Home Naloxone	TAS Health	Clients of NSPs & AOD services	Information not available	July 2020	No

VIC	The Drug Overdose Prevention and Education (DOPE)	Harm Reduction VIC Penington Institute VIC Gov Justice Health	PUIO, potential witnesses	1-3 hours or brief 15-20 minutes	Aug 2013	Yes
	Community Overdose Prevention and Education (COPE)		Primary health and community organisation staff	1 hour	Aug 2014	Yes
	Naloxone Subsidy Initiative		NSP clients in 6 'OD hotspots' in Melbourne	Information not available	Feb 2017	Yes
	Naloxone Pilot Program		Prisoners on-release	Information not available	May 2020	Yes
WA	The Western Australian Peer Naloxone Education Project	WA Mental Health Commission + Peer Based Harm Reduction WA	PUIO, agency workers, family member, overdose witnesses	2 hours	Jan 2013	Yes/THNP#

* *SESLHD – South Eastern Sydney Local Health District; HHS = Hospital Health Service, BCHCC = Biala Community Health Centre Clinic; CAHMA = Canberra Alliance for Harm Minimisation and Advocacy; KRC = Kirketon Road; MSIC = Medically Supervised Injecting Centre; NTAHC = Northern Territory AIDS and Hepatitis Council; ADSCA = Alcohol and other Drugs Services Central Australia; QuIHN = Queensland Injectors Health Network*

***PUIO = people who use illicit opioids; PWID = people who inject drugs; NSP = Needle and Syringe Program; OAT = opioid agonist therapy; AOD = alcohol and other drugs; OD = overdose*

Activities rolled into PBS-Subsidised THN Pilot

Appendix C: Indicator Matrix for Evaluation of the PBS-Subsidised THN Pilot

Program Logic	Components	Indicators	Methods	Data Source
Impact	Reduction of opioid overdose deaths	Rate of deaths due to unintentional opioid overdose	<ul style="list-style-type: none"> Administrative data^{kk} 	<ul style="list-style-type: none"> National Hospital Morbidity Database Jurisdictional Ambulance Data Australian Bureau of Statistics (ABS) Cause of Death Data
Impact	Change in patterns of opioid use	Prevalence of prescribed opioid use over time	<ul style="list-style-type: none"> Administrative data 	<ul style="list-style-type: none"> Pharmaceutical Benefit Scheme (PBS) Data
Impact	Change in patterns of opioid use	Patterns of illicit opioid use over time	<ul style="list-style-type: none"> Existing survey data 	<ul style="list-style-type: none"> Illicit Drug Reporting System (IDRS) Survey
Intermediate Outcome	Consumers/witnesses are fairly treated at access sites & feel comfortable acquiring/refilling THN	Consumers report feeling they were treated fairly at the access sites	<ul style="list-style-type: none"> Semi-structured Interview with consumers 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Intermediate Outcome	Community attitude to THN/opioid overdose treatment is less stigmatizing	Staff from access point are comfortable providing THN across types of users	<ul style="list-style-type: none"> Semi-structured Interview Round tables with stakeholders 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Intermediate Outcome	Community attitude to THN/opioid overdose treatment is less stigmatizing	Consumers and witnesses reported less stigmatizing experience when accessing THN from access points	<ul style="list-style-type: none"> Semi-structured Interview with consumers Mystery shopping 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Intermediate Outcome	Community attitude to THN/opioid overdose treatment is less stigmatizing	# of people who use illicit opioids reported less stigmatizing experience when accessing THN from access points	<ul style="list-style-type: none"> Existing survey data 	<ul style="list-style-type: none"> IDRS Survey
Intermediate Outcome	Access sites assist consumers/witnesses to make safety plan for THN use	people who use prescribed opioids discuss their feelings around their use of opioid medication (feeling in control of their use)	<ul style="list-style-type: none"> Semi-structured Interview with consumers 	<ul style="list-style-type: none"> THN Pilot Evaluation Data

^{kk} Note that these data were not yet available during the course of the evaluation for the period of the Pilot, but will need to be assessed once available

Program Logic	Components	Indicators	Methods	Data Source
Intermediate Outcome	Access sites assist consumers/witnesses to make safety plan for THN use	people who use illicit opioids report their feelings around their use of opioid (feeling in control of their use)	<ul style="list-style-type: none"> Semi-structured Interview with consumers 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Intermediate Outcome	Access sites assist consumers/witnesses to make safety plan for THN use	# of consumers/witnesses who were given resources upon THN access	<ul style="list-style-type: none"> Administrative data 	<ul style="list-style-type: none"> Pilot Program Administrator (PPA) Data Portal
Intermediate Outcome	Consumers/witnesses are more confident using THN to counteract overdose	Witnesses expressed increased confidence in using THN on others	<ul style="list-style-type: none"> Semi-structured Interview with witnesses 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Intermediate Outcome	Consumers/witnesses are more confident using THN to counteract overdose	Consumers express confidence possessing THN for others to administer during an overdose	<ul style="list-style-type: none"> Semi-structured Interview with consumers 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Intermediate Outcome	THN is used in a range of settings to prevent unintentional opioid overdose deaths	# of consumers and witnesses who used THN provided by credentialed access sites to resuscitate a consumer for the second time	<ul style="list-style-type: none"> Semi-structured Interview with consumers and witnesses 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Intermediate Outcome	THN is used in a range of settings to prevent unintentional opioid overdose deaths	# of consumers who experienced subsequent resuscitation with THN refilled by credentialed access sites	<ul style="list-style-type: none"> Semi-structured Interview with consumers and witnesses 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Intermediate Outcome	THN is used in a range of settings to prevent unintentional opioid overdose deaths	# of consumers and witnesses who refilled THN at credentialed access sites	<ul style="list-style-type: none"> Semi-structured Interview with consumers and witnesses Administrative data 	<ul style="list-style-type: none"> THN Pilot Evaluation Data PPA Data Portal
Intermediate Outcome	THN is used in a range of settings to prevent unintentional opioid overdose deaths	# of people who use illicit opioids who used THN to resuscitate at least twice	<ul style="list-style-type: none"> Existing survey data 	<ul style="list-style-type: none"> IDRS Survey
Intermediate Outcome	THN is used in a range of settings to prevent unintentional opioid overdose deaths	# of THN refills dispensed	<ul style="list-style-type: none"> Administrative data 	<ul style="list-style-type: none"> PPA Data Portal
Immediate Outcome	THN is used in a range of settings to prevent unintentional opioid overdose deaths	# of consumers and witnesses who used THN provided by credentialed access sites (includes both first time and repeated users) to resuscitate a consumer	<ul style="list-style-type: none"> Semi-structured Interview with consumers and witnesses 	<ul style="list-style-type: none"> THN Pilot Evaluation Data

Program Logic	Components	Indicators	Methods	Data Source
Immediate Outcome	THN is used in a range of settings to prevent unintentional opioid overdose deaths	# of consumers who were resuscitated with THN provided by credentialed access sites (includes first time and repeat users)	<ul style="list-style-type: none"> Semi-structured Interview with consumers and witnesses 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	THN is used in a range of settings to prevent unintentional opioid overdose deaths	# of people who use illicit opioids who were resuscitated by a witness using THN	<ul style="list-style-type: none"> Existing survey data 	<ul style="list-style-type: none"> IDRS Survey
Immediate Outcome	THN is used in a range of settings to prevent unintentional opioid overdose deaths	# of people who use illicit opioids who resuscitated someone else using THN	<ul style="list-style-type: none"> Existing survey data 	<ul style="list-style-type: none"> IDRS Survey
Immediate Outcome	Between-state and within-state coordination of THN pilot	Timely delivery of THN to credentialed access sites	<ul style="list-style-type: none"> Round Table Discussions 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Between-state and within-state coordination of THN pilot	Network across credentialed access sites established	<ul style="list-style-type: none"> Round Table Discussions 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Between-state and within-state coordination of THN pilot	Network with other support agencies within the state established	<ul style="list-style-type: none"> Round Table Discussions 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Between-state and within-state coordination of THN pilot	Credentialed access sites able to provide feedback to suppliers and/or state coordinators	<ul style="list-style-type: none"> Semi-structured interview 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Between-state and within-state coordination of THN pilot	Credentialed access sites felt supported in the supply process	<ul style="list-style-type: none"> Semi-structured interview 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Between-state and within-state coordination of THN pilot	State coordinators felt supported by the Department	<ul style="list-style-type: none"> Round Table Discussions 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Between-state and within-state coordination of THN pilot	Good relationship across state coordinators	<ul style="list-style-type: none"> Round Table Discussions 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Between-state and within-state coordination of THN pilot	The Department are well-informed about THN implementation in each state	<ul style="list-style-type: none"> Semi-structured interview 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Increased community awareness of THN: health providers, prescription/non-prescription consumers, witnesses	# of consumers and witnesses who are aware of the THN Pilot	<ul style="list-style-type: none"> Semi-structured Interview with consumers and witnesses 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Increased community awareness of THN: health providers,	# of consumers and witnesses who are knowledgeable on how to administer Naloxone	<ul style="list-style-type: none"> Semi-structured Interview with 	<ul style="list-style-type: none"> THN Pilot Evaluation Data

Program Logic	Components	Indicators	Methods	Data Source
	prescription/non-prescription consumers, witnesses		consumers and witnesses	
Immediate Outcome	Increased community awareness of THN: health providers, prescription/non-prescription consumers, witnesses	# of people who use illicit opioids who have heard of THN Pilot	<ul style="list-style-type: none"> Existing survey data 	<ul style="list-style-type: none"> IDRS Survey
Immediate Outcome	Increased community awareness of THN: health providers, prescription/non-prescription consumers, witnesses	Staff (health providers) are aware of the policies and procedures of the Pilot and THN distribution	<ul style="list-style-type: none"> Semi-structured interview 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	More access sites are credentialed to supply THN	# of credentialed access sites	<ul style="list-style-type: none"> Administrative data 	<ul style="list-style-type: none"> Records from the Department and States
Immediate Outcome	Consistent delivery of Brief intervention/advice to consumers/witnesses	# of consumers/witnesses who received brief intervention at credentialed access site	<ul style="list-style-type: none"> Administrative data 	<ul style="list-style-type: none"> PPA Data Portal
Immediate Outcome	Consistent delivery of Brief Intervention/advice to consumers/witnesses	Brief intervention/advice/education given to all consumers/witnesses who were given THN	<ul style="list-style-type: none"> Semi-structured Interview with consumers and witnesses Mystery shopping 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Good practice in THN provision across access sites	Mystery shopping report the standard of service across access sites*	<ul style="list-style-type: none"> Mystery shopping 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Good practice in THN provision across access sites	Consumers and witnesses report the treatment they experienced at the access sites	<ul style="list-style-type: none"> Semi-structured Interview with consumers and witnesses 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Continuous/sufficient supply of THN to access sites is maintained	# of credentialed access sites without any backorders	<ul style="list-style-type: none"> Semi-structured Interview 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Continuous/sufficient supply of THN to access sites is maintained	Access sites report the status of THN supply in their facility	<ul style="list-style-type: none"> Semi-structured interview 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Immediate Outcome	Consumers and witnesses possess Naloxone	# of consumers and witnesses who accessed THN provided by credentialed access sites (includes both first time and repeated users)	<ul style="list-style-type: none"> Semi-structured Interview with consumers and witnesses -Administrative data 	<ul style="list-style-type: none"> THN Pilot Evaluation Data -PPA Data Portal

Program Logic	Components	Indicators	Methods	Data Source
Immediate Outcome	Consumers and witnesses possess Naloxone	Consumer home postcode is adjacent/near access site postcode	<ul style="list-style-type: none"> Semi-structured Interview with consumers and witnesses Administrative data 	<ul style="list-style-type: none"> THN Pilot Evaluation Data -PPA Data Portal
Output	Implementation meetings	# of stakeholder meetings conducted at national level	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> Records from the Department and States
Output	Implementation meetings	# of stakeholder meetings conducted at state level	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> Records from the Department and States
Output	Leveraging of existing programs	Stakeholders identified aspects of the current THN program that were based on existing programs	<ul style="list-style-type: none"> Round Table Discussions (national level stakeholders and local stakeholders) 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	Leveraging of existing programs	Current program protocol extends on existing programs	<ul style="list-style-type: none"> Document review 	<ul style="list-style-type: none"> Records from the Department and States
Output	Reporting to Department of Health	# of progress reports received by the Department from States and/or access sites	<ul style="list-style-type: none"> Document review 	<ul style="list-style-type: none"> Records from the Department
Output	Promotion of THN Pilot to consumers and community	The Department identifies the different promotion activities conducted targeting potential access sites	<ul style="list-style-type: none"> Round Table Discussions 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	Promotion of THN Pilot to consumers and community	Access sites bring awareness to consumers and witnesses	<ul style="list-style-type: none"> Semi-structured Interview (with access sites, consumers and witnesses) 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	Promotion of THN Pilot to consumers and community	# of promotion and engagement activities conducted	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> Records from the Department and States
Output	Promotion of THN Pilot to consumers and community	# of potential access sites identified	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> Records from the Department and States
Output	Stakeholders, partner and peak bodies recruited	# of engagement meetings conducted with stakeholders and peak bodies	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> Records from the Department and States
Output	Credentiailling process undertaken	# of potential access sites confirmed to undertake training	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> Records from the Department and States
Output	Credentiailling process undertaken	# of existing access sites engaged	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> Records from the Department and States

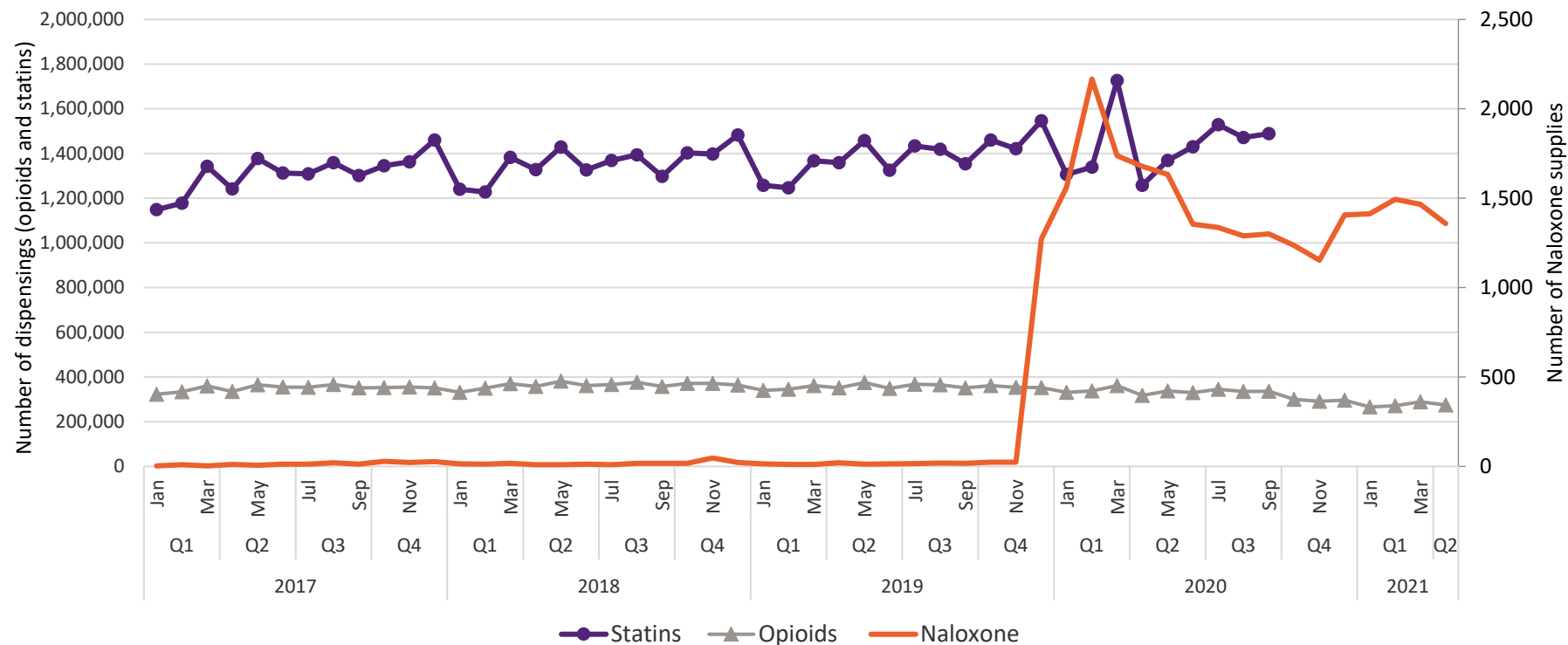
Program Logic	Components	Indicators	Methods	Data Source
Output	Communication processes in place	Stakeholders identified communication mechanisms within and across states	<ul style="list-style-type: none"> Round Table Discussions (national level stakeholders and local stakeholders) 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	Communication processes in place	Communication protocols agreed by stakeholders	<ul style="list-style-type: none"> Round Table Discussions (national level stakeholders and local stakeholders) 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	Training provided for access sites	# of training sessions conducted	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> Records from the Department and States
Output	Training provided for access sites	# of potential access sites trained	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> Records from the Department and States
Output	System level support at access sites	Support mechanisms established across access sites at state-level	<ul style="list-style-type: none"> Round Table Discussions (national level stakeholders and local stakeholders) 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	System level support at access sites	Support mechanisms established across states	<ul style="list-style-type: none"> Round Table Discussions (national level stakeholders and local stakeholders) 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	System level support at access sites	Policies/agreements are made to involve other agencies to support the implementation	<ul style="list-style-type: none"> Round Table Discussions (national level stakeholders and local stakeholders) 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	Database of supply chain established	Working database of supply chain in use	<ul style="list-style-type: none"> Round Table Discussions (national level stakeholders and local stakeholders) 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	Appropriate supply chain logistics	Distributors have functional equipment to facilitate proper handling	<ul style="list-style-type: none"> Semi-structured Interview 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	Appropriate supply chain logistics	Naloxone delivered in good condition (i.e. refrigerated, packaged well)	<ul style="list-style-type: none"> Semi-structured Interview 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	Supplying and monitoring THN distribution	# of Naloxone packs distributed to/received by access sites	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> PPA Data Portal Records from the Department and States

Program Logic	Components	Indicators	Methods	Data Source
Output	Supplying and monitoring THN distribution	Appropriate amount for each access site (Supply-Demand Offset)	<ul style="list-style-type: none"> Semi-structured Interview (access sites) 	<ul style="list-style-type: none"> THN Pilot Evaluation Data
Output	Supplying and monitoring THN distribution	# of regular supply status reports received by States	<ul style="list-style-type: none"> Document review 	<ul style="list-style-type: none"> Records from the Department and States
Output	Supplying and monitoring THN distribution	# of claims submitted through the PPA System	<ul style="list-style-type: none"> Administrative Data 	<ul style="list-style-type: none"> PPA Data portal

Appendix D: Comparative provision of medicines prior to and during the Pilot

Figure 22. Trends in dispensing of naloxone, opioids and statins, NSW, SA and WA, 2017-2021

Source: PBS data, PPA portal data



Dual axis is used to improve visibility of trends; naloxone supplies include PBS dispensing and Pilot provision

This graph shows that the sharp increase in naloxone supply (right axis) that coincides with commencement of the Pilot in December 2019 is not reflected in either opioid dispensing patterns (left axis), or the patterns for a widely-used but unrelated (statin) medication (left axis), but is specific to naloxone. A spike followed by a sudden drop in statin dispensings during the initial phase of the pandemic (Q1 2020) was also observed in naloxone. This was not seen in opioid dispensings.

Appendix E: Stories from consumers about the use of THN for overdose reversals

More than 60 individual stories of opioid overdose reversal were collected across the three waves of Evaluation data collection. Below, some of the stories of participants are recounted.

We've had one OD in the neighbourhood where the bloke died, but we've had two others, where thank f- if it wasn't for the Naloxone, you know, those guys would've probably been, you know, 50/50 you know, probably would've been two out of the three. You know, instead of only one out of three. But yeah, it's lifesaving stuff and needs to be around. (SA, PUJO, Recruited from Community Pharmacy, Interviewed August 2020).

You actually don't need to be a heroin user. You only have to be somebody who could be around people that might overdose. And where I live, there are a few people I know in this block of units that use heroin, so I've made it known that I've always got naloxone in the house, if it need be. (WA, PUJO, Recruited from NSP, Interviewed September 2020)

We tried to wake him, tried to wake him and he didn't wake up. We jabbed him on the upper thigh and you know, injected it and within 5-10 seconds, I don't even know, he was awake. And yeah, he survived thanks to naloxone so yeah it saved his life. (WA, PUJO, Recruited from NSP, Interviewed September 2020)

So I came across a guy lying in the park on his back. It was in the sun so he could have been just resting. But he looked blue. He wasn't moving. Something was not right. And I carry gloves and intra-nasal naloxone in my back-pack. So I immediately turned him on his side and didn't get a response. And put my phone on the ground and dialled 000. And started administering naloxone whilst I was talking to the operator on 000. (NSW, Witness, Recruited from NSP, Interviewed October 2020)

They shared with me the most incredible story... I have to tell you all. In the last two weeks, they resuscitated two of their friends using the Naloxone nasal spray. They told me that one of their friends was in such a critical condition, if they didn't have the Naloxone, he wouldn't have made it in time for the ambulance to arrive. They said it was one of the scariest and most petrifying experiences they have ever had, but they knew how to act quickly because they had been trained on how to use Naloxone.

They extended the biggest appreciation to me ... for interviewing them about THN and spreading awareness about its use and access. They told me that because I was so open to talking about Naloxone and promoting the efficacy of the nasal spray, it's made them more comfortable accessing it regularly from their pharmacist (who they say is fantastic) and because of this it has saved TWO LIVES. (Email from an interviewer in SA)

We had the naloxone in our fridge, and we had both sorts, and within a week of all this knowledge coming into us from you guys, we saved two people's lives (SA, PUJO, Recruited from Community Pharmacy, Interviewed August 2020).

She had an overdose and her partner, that is a non-user, gave her naloxone... it's a positive thing, to have it in your place and be comfortable giving it (WA, PUIO, Recruited from NSP, Interviewed September 2020)

Interviewer: You mentioned that you were resuscitated BY someone, can you tell me more about that?

Participant: Earlier on that day we had a shot, I hadn't had any for quite a while, well no, maybe a week or more or maybe two, so the tolerance level was low. So I had a shot then next thing I know I wake up to him saying stay where you are, he just said basically I dropped or I sat, I was going blue, and I explained it to him, this guy 50 years he's been a heroin addict, so I told him about this stuff, I had the pen or the thing whatever it is the syringe, told him where it was, so he bolted in and just did what I told him to. So he was on the phone to the ambulance at the same time and they said they were listening and they were talking to him as he was doing it, giving him some instructions. After I came around, he said 'ah ok he's come around, just cancel the ambulance'... basically laughed you don't really need the ambulance after that in a sense, so they cancelled the ambulance, he hung up and it was that side of the story, the very same day. (NSW, PUIO, Recruited from AOD Service, Interviewed February 2021).

Interviewer: You mentioned that you have recently used naloxone TO resuscitate someone else since the last time you were interviewed, can you tell me more about that?

Participant: Since the last interview, twice I've had to use that nasal thing and the first time was I knew I was gonna use, so I took the one from the kitchen and took it with me just to be safe and he was having the dose with me and he overdosed and I used it on him. The second time again I took one from home, and my friend Oded but that was not enough. But lucky there was a chemist just around the corner, about 100m or so, then I had to send a friend running to grab it while I kept him in the sideways position and cleared his airway and all of that and waited for an ambulance. Now I always have a stock where I keep the glasses and all that, in the top draw cupboard in the kitchen where all the glasses are. (NSW, PUIO, Recruited from an NSP, Interviewed March 2021).

Yep, a friend, we got the gear, heroin, and a friend she went in the bathroom and had it and didn't respond. My daughter went in there and I remembered that we had it we didn't know how to use it but. I was reading how to use it through the door to my the daughter cause only one of us could fit in through the bathroom to the friend. Not long after she gave her the spray she came around, cause she was blue. Then not long after that the ambulance came. (NSW, PUPO, Recruited from AOD Service, Interviewed February 2021).

So yeah, I gave him one dose of naloxone in the nose and within 10 minutes he started to improve so it like, it didn't really need to go any further. I was pretty confident with you know, how he was going to react, I've used it before, so, I didn't have the same noise as I did the first time. (SA, PUPO, Recruited from Community Pharmacy, Interviewed January 2021).

So it was when alcohol was also involved and um, somebody that did not, who sort of irregularly used opioids, and she had a very small amount and misjudged and then we realised, she wasn't responding, um and sort of was snoring in a way that was strange, and we couldn't get a response, and so then yeah just using the naloxone, sort of put in the first I think...I think it was 2 and waited a minute, and then nothing, and then put in another one, and then she came back (SA, Witness, Recruited from Community Pharmacy, Interviewed June 2021).

Yes, well, we said he was going down pretty quick...instead of worrying about, you know, putting him under water and the rest of it, we went straight to the naloxone spray. You know, no mucking around. And then, you know, yeah, he was fine, within about four minutes, I'd say, he was cursing me [laughs] (SA, PUPO, Recruited from Community Pharmacy, Interviewed January 2021).

Participant: After that, when the ambulance came, they actually then did come to, so the person decided not to go with the ambulance, because they were still awake enough and, yeah, we just made sure that he was OK.

Interviewer: And how did you feel?

Participant: Um, I was actually well...how did I feel about saving his life? Relieved. (WA, Witness, Recruited from NSP, Interviewed May 2021).



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OF QUEENSLAND
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Contact details

Dr Caroline Salom

T +61 7 3346 7695

E c.salom@uq.edu.au

W issr.uq.edu.au

CRICOS Provider Number 00025B