ACT Government
Health

4/5/15

Dear TGA,

Re: Submission Re rescheduling of Naloxone

Naloxone is a safe drug. It saves lives and reduces injuries from opioid overdose. It's widely available in many other jurisdictions with positive impact and without negative impact. It is easy to give, and has no side effects.
Family members, friends, peers and other should have access to it. Just like Epi Pens for anaphylaxis.
It reduces delay between overdose and treatment. Prescription is unnecessary, and also creates a barrier to access.

It is a practical step and needed in the context of ever increasing overdose numbers in Australia (approx. one person dies every-day in Australia from opioid overdose. It can be used for injecting drug users, and ANYONE who takes opioid drugs. It should be provided routinely for anyone on opioids.

I recommend Naloxone be rescheduled from Schedule 4 to Schedule 3.

Regards,

[redacted]

ST VINCENT'S HOSPITAL
SYDNEY
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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1st May 2015

Advisory Committee on Medicine Scheduling
Therapeutic Goods Administration
medicines.scheduling@tga.gov.au

Dear Committee members,

Public consultation on the Proposed Amendments to the Poisons Standard (Medicines)

Thank you for the opportunity to provide a submission to the Therapeutic Goods Administration regarding the above.

The Alcohol & Drug Service of St Vincent's Hospital, Sydney agrees with the proposed rescheduling of naloxone and wishes to offer its support to the submission from the Pennington Institute on this matter.

Specifically we agree with the proposal to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

Increasing access to naloxone is an important step to reducing opioid overdose-related deaths and morbidity. We believe rescheduling naloxone will provide much needed access to naloxone in the community.

Yours sincerely

[redacted]

5th May 2015

Submission to the Advisory Committee on Medicines Scheduling for July 2015 Meeting

Response to invitation for public submission on application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Closing date for submission – 7 May 2015

Prepared by [redacted]

[redacted] **- Kirketon Road Centre – South Eastern Sydney Local Health District**

On behalf of [redacted]

Contact details:

[redacted]

General position.

As clinicians working in a primary health care facility involved in the care of people who inject drugs, and in prevention and management of opioid overdoses in this population we strongly support the proposed rescheduling of naloxone pre-filled 400mcg/ml syringes to S3.

Summary.

The Kirketon Road Centre (KRC) is a primary health care facility in Kings Cross involved in the prevention, treatment and care of HIV and other transmissible infections among people who inject drugs, sex workers and “at risk” young people. KRC provides care to over 1000 people who inject drugs each year, and the majority drug class reported over the last few years remains opioids.

KRC has provided opioid overdose prevention and management for many years. More recently we participated in the first pilot naloxone distribution program in New South Wales, successfully training over 100 clients, many of whom have been able to respond in an overdose situation.

We have provided naloxone training to opioid users at our service in Kings Cross, and also at the Sydney Medically Supervised Injecting Centre, and the NSW Users and AIDS Association (NUAA) Needle Syringe program. We have trained NUAA Aboriginal peerlink workers, patients at the Aboriginal medical service in Moree, and have set future training dates at the Mt Druitt Aboriginal medical service and for the NSW Aboriginal Residential Healing and Drug and Alcohol Network.

During detailed follow-up interviews no clients provided with naloxone reported significant adverse reactions to their use of naloxone when used to reverse suspected overdose.

At many of our training sessions clients have been accompanied by family and friends interested in how they can provide support to their loved ones in the event of overdose. The current restrictions of S4 medication status means we cannot provide, and the family member cannot purchase, naloxone despite them being at high likelihood of witnessing an overdose. Particularly for clients in marginalised or Aboriginal populations the difficulty accessing naloxone due to its S4 status is a significant barrier to the roll-out of this WHO recommended intervention. A change to S3 status would allow family and friends to purchase and store naloxone for use in an emergency, and could easily be accompanied by some brief instructions in its use, or direction on how to access training.

Many family members expressed regret that they could not have accessed naloxone due to its S4 status when managing a previous overdose situation with a loved one before the ambulance arrived, unfortunately not always with a successful result.

The primary health care sector is in a unique position to see not only the opioid users themselves, but the wider community of family and friends, and is thus in a unique position to recommend naloxone purchase to those who do not themselves use opioids.

Finally, given naloxone is likely to be used as a public health intervention in some of the most marginalised populations, any change to S3 status must not be undermined by an excessive price for naloxone min-jets, and the capacity to still provide this medication under S4 should remain for so that those who inject opioids can still access this life-saving intervention under the PBS at minimal cost.

Yours sincerely

[redacted]

[redacted]

5 May 2015

Therapeutic Goods Administration
Department of Health
Australian Government

To whom it may concern,

Re: Public consultation on the proposed amendments to the Poisons Standard (Medicines)

The Drug Policy Modelling Program (DPMP) aims to improve Australian alcohol and other drug policy. DPMP is at the cutting edge of international work in alcohol and other drug policy and has received its core funding from the Colonial Foundation Trust, a private Australian philanthropy. DPMP also attracts competitive research grants from the Australian Research Council and the National Health & Medical Research Council, among others. DPMP is part of the National Drug and Alcohol Research Centre (NDARC) at the University of New South Wales which is supported by funding from the Australian Government. DPMP collaborates with a wide range of stakeholders including government departments, drug consumer groups and peak bodies; and conducts commissioned research for governments across Australia.

We welcome the opportunity to contribute to the consultation regarding the proposed amendments to the Poisons Standard. In particular, this submission addresses the proposal to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

DPMP agrees with the proposed rescheduling of naloxone submitted for public consultation, and provides this submission in support of the rescheduling application. This rescheduling is a necessary and practical step to ensure the wider availability of naloxone in the community.

Naloxone is a short-acting opioid antagonist, which temporarily reverses the effects of opioids and respiratory depression. It has been used for over 40 years by medical professionals, particularly in emergency medicine, and has been shown to be safe, reliable and effective [1]. For more than two decades, researchers and drug policy experts have argued that naloxone should be widely available to potential overdose witnesses, particularly people who inject drugs, to help prevent morbidity and mortality associated with opioid overdose [2, 3, 4, 5]. These calls to expand the availability of naloxone have been heeded internationally, and a variety of programs have been successfully implemented and evaluated [see 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18].

A recent US study concluded that distribution of naloxone to potential overdose witnesses would be highly cost-effective and would be expected to reduce mortality even by conservative estimates [20]. The accumulated international evidence

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demonstrates that naloxone distribution is a life-saving harm minimisation strategy, which sits alongside drug treatment and other harm reduction services. It is an intervention highly relevant for people who use drugs both in and out of drug treatment.

Australian experts have stated unequivocally that: "In our view, the international evidence clearly indicates that increased naloxone availability will prevent many cases of fatal overdose, that conducting a trial in Australia is now unnecessary, and that naloxone should be made available without delay to be administered by peers in cases of opioid overdose" [19]. DPMP supports this statement.

In Australia, programs that train potential overdose witnesses to recognise overdose signs, respond appropriately and be provided prescriptions for naloxone are now operating in Victoria, New South Wales, South Australia and Queensland. Initial evaluation results indicate that these programs have been successful, and that lives are being saved as a result (see: http://www.atoda.org.au/wp-content/uploads/Summary-of-Interim-Findings-summary-for-release-2.pdf). However, these programs are still regarded as small scale, and coverage is limited. The current prescription requirement generates a barrier to wider availability of naloxone.

While the prescription programs have been a first step towards making naloxone available for overdose witnesses in Australia, we suggest that naloxone is not currently being used to its full potential as an opioid antagonist in overdose situations due to the scheduling limitations. Scheduling the single-use pre-filled syringe 400µg/1mL as a Pharmacist Only medication, while maintaining it on the PBS, will increase the options available to the community.

Naloxone should be rescheduled to ensure its widespread availability to potential overdose witnesses. A limited rescheduling of naloxone from a Schedule 4 Prescription Only Medicine to a Schedule 3 Pharmacist Only Medicine would assist in providing much needed access to naloxone in the wider community.

Sincerely,

[redacted]

National Drug and Alcohol Research Centre | UNSW Medicine
UNSW AUSTRALIA
SYDNEY NSW AUSTRALIA 2052
[redacted]

References

1. Dietze, P. and Lenton, S. The case for the wider distribution of naloxone in Australia. (2010); Available at: http://www.atoda.org.au/wp-content/uploads/The_heroin_reversal_drug_naloxone_FIN2.pdf [accessed 26 August 2013].
2. Darke, S. and Hall, W., The distribution of naloxone to heroin users. Addiction, 1997. 92(9): 1195-1200.
3. Lenton, S., Dietze, P., Degenhardt, L., Darke, S., and Butler, T., Now is the time to take steps to allow peer access to naloxone for heroin overdose in Australia. Drug and Alcohol Review, 2009. 28(6): 583-585.
4. Strang, J., Darke, S., Hall, W., Farrell, M., and Ali, R., Heroin overdose: The case for take-home naloxone. British Medical Journal, 1996. 312(7044): 1435-1435.
5. Strang, J. and Farrell, M., Harm minimisation for drug misusers. BMJ: British Medical Journal, 1992. 304: 1127-1128.
6. Piper, T.M., Rudenstine, S., Stancliff, S., Sherman, S., Nandi, V., Clear, A., and Galea, S., Overdose prevention for injection drug users: lessons learned from naloxone training and distribution programs in New York City. Harm Reduction Journal, 2007. 4(3): 291-301.
7. Piper, T.M., Stancliff, S., Rudenstine, S., Sherman, S., Nandi, V., Clear, A., and Galea, S., Evaluation of a Naloxone Distribution and Administration Program in New York City. Substance Use & Misuse, 2008. 43(7): 858-870.
8. Maxwell, S., Bigg, D., Stanczykiewicz, K., and Carlberg-Racich, S., Prescribing Naloxone to Actively Injecting Heroin Users. Journal of Addictive Diseases, 2006. 25(3): 89-96.
9. Strang, J., Powis, B., Best, D., Vingoe, L., Griffiths, P., Taylor, C., Welch, S., and Gossop, M., Preventing opiate overdose fatalities with take-home naloxone: pre-launch study of possible impact and acceptability. Addiction, 1999. 94(2): 199-204.
10. Strang, J., Manning, V., Mayet, S., Best, D., Titherington, E., Santana, L., Offor, E., and Semmler, C., Overdose training and take-home naloxone for opiate users: prospective cohort study of impact on knowledge and attitudes and subsequent management of overdoses. Addiction, 2008. 103(10): 1648-1657.
11. Seal, K.H., Thawley, R., Gee, L., Bamberger, J., Kral, A.H., Ciccarone, D., Downing, M., and Edlin, B.R., Naloxone distribution and cardiopulmonary resuscitation training for injection drug users to prevent heroin overdose death: A pilot intervention study. Journal of Urban Health, 2005. 82(2): 303-311.
12. Tobin, K.E., Sherman, S.G., Beilenson, P., Welsh, C., and Latkin, C.A., Evaluation of the Staying Alive programme: Training injection drug users to properly administer naloxone and save lives. International Journal of Drug Policy, 2009. 20(2): 131-136.
13. Enteen, L., Bauer, J., McLean, R., Wheeler, E., Huriaux, E., Kral, A., and Bamberger, J., Overdose Prevention and Naloxone Prescription for Opioid Users in San Francisco. Journal of Urban Health, 2010. 87(6): 931-941.
14. Walley, A.Y., Xuan, Z., Hackman, H.H., Quinn, E., Doe-Simkins, M., Sorensen-Alawad, A., Ruiz, S., and Ozonoff, A., Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. BMJ, 2013. 346.
15. Kim, D., Irwin, K.S., and Khoshnood, K., Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality. American Journal of Public Health, 2009. 99(3): 402-407.
16. McAuley, A., Best, D., Taylor, A., Hunter, C., and Robertson, R., From evidence to policy: The Scottish national naloxone programme. Drugs: Education, Prevention, and Policy, 2012. 19(4): 309-319.

17. Strang, J., Bird, S., and Parmar, M.B., Take-Home Emergency Naloxone to Prevent Heroin Overdose Deaths after Prison Release: Rationale and Practicalities for the N-ALIVE Randomized Trial. Journal of Urban Health, 2013: 1-14.
18. Galea, S., Worthington, N., Piper, T.M., Nandi, V.V., Curtis, M., and Rosenthal, D.M., Provision of naloxone to injection drug users as an overdose prevention strategy: Early evidence from a pilot study in New York City. Addictive Behaviors, 2006. 31(5): 907-912.
19. Lenton, S., Dietze, P., Degenhardt, L., Darke, S., and Butler, T., Naloxone for administration by peers in cases of heroin overdose. Medical Journal of Australia, 2009. 191(8): 469.
20. Coffin, P.O. and Sullivan, S.D., Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal. Annals of Internal Medicine, 2013. 158(1): 1-9.

HepatitisSA

Advisory Committee for Medicines Scheduling
Meeting July 2015

Application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Contact person: [redacted]
Position: [redacted]
Contact details: [redacted]

Hepatitis SA supports the application to the Advisory Committee for Medicines Rescheduling July 2015 Meeting, to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3, provided it remains listed on the Pharmaceutical Benefits Scheme (PBS).

Hepatitis SA is a community-based organisation which operates a secondary Clean Needle Program site and Clean Needle Program Peer Education and Support Services to a further 10 host sites across metropolitan Adelaide, as well as viral hepatitis information, education, support and referral services across South Australia.

It is estimated that opioid overdoses cause approximately one death per day in Australia. In 2009, there were a total of 633 deaths attributed to opioids (compared with 500 in 2008), with many of these deaths being due to multiple drugs taken including prescription opioids.[1] Data projections suggest an increasing trend in opioid deaths in Australia, with South Australia recording a rise in the number of opioid deaths compared to 2008.[2]

Naloxone is an opioid antagonist that reverses the effects of opioids including heroin and pharmaceutical opioids such as methadone and morphine. Naloxone is safe to use, non-addictive and has no active effect other than to reverse opioid overdose. Because there are no psychoactive effects, Naloxone is not a drug that has potential for misuse. Naloxone is carried by ambulance paramedics and administered when there is a known or suspected opioid overdose.

The majority of both fatal and non-fatal opioid overdoses occur at the home of the victim or in the company of others.[3] Naloxone distribution to people who inject opioids for 'peer administration' provides otherwise non-existent opportunities for overdose to be treated immediately, preventing brain injury or death. Naloxone peer distribution and training programs operate effectively in many countries including the United Kingdom, United States of America, Canada, parts of Europe, Russia, Afghanistan, China and Vietnam. In Italy, naloxone has been available over-the-counter since 1995.[4] The World Health Organization supports peer administration of naloxone and launched evidence-based guidelines recommending that people who are likely to witness an opioid overdose (including people who use opioids, and their family and friends) should be given access to naloxone and overdose response training.[5] Analysis of naloxone distribution to people who use heroin, suggests this form of intervention is highly cost effective.[6]

Successful peer administered naloxone pilot programs have been developed in ACT, NSW, SA and WA. Although there is no published material on the SA naloxone trial, the following summary was provided to us by Drug and Alcohol Services South Australia (DASSA).

---

[1] Australian National Council on Drugs. (2012). *Expanding Naloxone Availability.* ANCD Position Statement. URL: http://www.atoda.org.au/wp-content/uploads/ANCD-Position-Statement-Expanding-Naloxonle-Availibility-September-2012.pdf

[2] Roxburgh A. and Burns, L. (2013). *Accidental drug-induced deaths due to opioids in Australia, 2009*. National Drug and Alcohol Research Centre: Sydney

[3] Kim, D., Irwin, K.S. & Khoshnood, K. (2009). Expanded access to naloxone: options for critical response to the epidemic of opioid overdose mortality. *American Journal of Public Health*,*99*(3), p.402-407

[4] Australian National Council on Drugs. (2012). op. cit

[5] World Health Organization. (2014). *Community management of opioid overdose*. Geneva, Switzerland

[6] Coffin, P.O. & Sullivan, S.D. (2013). Cost-effectiveness of distributing naloxone to heroin users for lay overdose reversal. *Annals of Internal Medicine, 158.* p.1-9

Thirty-one individuals participated in the pilot training program, 29 people who use opioids and two family members as potential overdose witnesses. In the follow up period DASSA received six reports of pilot participants helping someone who overdosed on opioids. The findings of the pilot demonstrated that naloxone can be used appropriately in a non-medical setting by people who use opioids, with participants willing and able to use naloxone in emergency situations, call an ambulance and administer first aid.

The South Australian pilot program contributed to the strong case for wider distribution of naloxone among people who use opioids and their potential overdose witnesses and supports the expansion of community access to overdose response strategies.

In Australia naloxone is currently a Schedule 4 drug, obtainable only by prescription. As a drug that is prescribed only to the person who will be using it, accessing a naloxone prescription requires disclosing opioid use to a GP. Given the stigma and discrimination associated with illicit drug use, approaching a GP for a prescription can present a barrier. Patients may be reluctant to risk disclosing illicit drug to their regular doctor or equally to a GP they have not seen before, and they definitely won't approach their Opioid Maintenance Treatment (OMT) prescriber for a script.

Hepatitis SA believes the most effective way to increase access to naloxone is to change it from Schedule 4 (prescription only) to Schedule 3 (Pharmacist only). Schedule 3 drugs may be accessed over-the -counter at any pharmacy, in conjunction with advice from a pharmacist. Enabling naloxone to be available over the counter will not only increase access for opioid users but will also allow family members and friends of opioid users to access naloxone easily to have on hand in the event of witnessing an overdose. As there are generally higher costs for over-the-counter medicines than those available through prescription on the PBS, ensuring that naloxone remains available through the PBS will reduce the cost barrier for people on low incomes who aren't willing to disclose their illicit drug use to GPs in order to access a naloxone prescription.

Changing the scheduling of naloxone is unlikely to result in larger numbers of opioid users or potential overdose witnesses accessing naloxone merely because it is available over-the-counter at pharmacies. In order to maximise the benefits of a change in the scheduling of naloxone, there will need to be targeted promotion amongst people who use opioid drugs and service providers to inform them of the increased availability. Additionally there will need to be training and education for pharmacists in the use of naloxone, and training for opioid drug users and relevant service providers in overdose response, CPR and use of naloxone.

Submission

Network of Alcohol and other Drugs Agencies
Author: Larry Pierce, Chief Executive Officer
Date: 5 May 2015

Email to: medicines.scheduling@tga.gov.au
Subject: Proposed Amendments to the Poisons Standard (Medicines)
Request: To amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

The Network of Alcohol and other Drug Agencies (NADA) is the peak organisation for the non government alcohol and other drugs sector in NSW. NADA represents over 100 organisational members that provide a broad range of services including drug and alcohol health promotion, early intervention, treatment, and after-care programs. These community based organisations operate throughout NSW.

NADA would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

Naloxone is a safe drug for use by non-medical people with appropriate information and training that has no effect on people with no opioids in their system. It cannot be abused, has no resale value on the illicit drug market, is inexpensive to provide, and is a fast acting and reliable antidote for opioid overdose in dependant and non-dependant people.

Prompt and proper use of naloxone is critical and there is often a significant time lapse between reporting an overdose and waiting for an ambulance with naloxone to arrive which evidence indicates increases the risk of fatality or brain damage. Easy access to naloxone by drug users, their peers, family and carers and the health workforce will significantly decrease this risk. Response times can be shortened and lives can be saved.

In the alcohol and other drugs sector, we know through experience that drug users do not often visit GP's. By being able to access naloxone over the counter at a chemist, it means that drugs users, their peers, family and carers, as well health and welfare workers can access naloxone legally and prevent the risk of harm and fatality. Naloxone is simple to administer by witnesses of an overdose, with limited instruction, therefore all persons should be able to administer the drug with simple instruction from a pharmacist.

Post access to drug treatment is a common time for overdose, as the body's central nervous system is no longer used to the same levels of substances used before withdrawal management and drug treatment. It would be opportunistic and highly appropriate to provide overdose prevention training that incorporates the use of naloxone to the non government alcohol and other drugs sector, as well as other health and welfare sectors to prevent harm.

NADA, on behalf of the non government alcohol and other drugs sector, support the amendment for the scheduling of naloxone and do not suggest any further improvements.

For more information:

[redacted]

north richmond
community health

Department of Health
Therapeutic Goods Administration
Medicines.scheduling@tga.gov.au

30 April 2015

PROPOSED AMENDMENTS TO THE POISONS STANDARD (MEDICINES) – NALOXONE

Dear Sir or Madam,

North Richmond Community Health (NRCH) welcomes the opportunity to comment on the proposed changes to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

North Richmond Community Health (NRCH) is located on the grounds of Victoria's largest public housing estate. NRCH provides a range of services predominantly within inner city Melbourne these include Alcohol and Drug Outreach and a Needle Syringe Program (NSP). The NSP is one of the busiest primary NSPs in metropolitan Melbourne. North Richmond, as a destination, has had a very long history and reputation of a hot spot for public injecting and associated behaviours. NRCH also hosts medical, dental services and other primary health onsite.

Currently NRCH provides a response to people that have overdosed within the immediate surrounds of our building. Overdose response currently involves a range of care providers including Doctors, Nurses and support staff to address the medical emergency. At NRCH, the Doctor administers the Naloxone injection or directs a nurse to do so. As an organisation an overdose response at NRCH is estimated to cost approximately $1180 for one hour of response. For February and March 2015 alone NRCH provided 17 over dose responses, this does not include time associated with overdose monitoring (whereby the client did not require Naloxone). This cost does not cover the impact of not being able to undertake other work and the subsequent impact on service delivery. This cost analysis has not been calculated.

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north richmond
community health

The NRCH Alcohol and Other Drug (AOD) Outreach team provide overdose response within the area of North Richmond. They assess each situation and will frequently provide basic life support until an ambulance arrives. The AOD Outreach team within their scope of practice currently do not administer Naloxone. [redacted]

NRCH AOD team currently support two programs that promote the use of Naloxone. In partnership with Harm Reduction Victoria we have implemented a Naloxone project whereby suitable individuals are trained to administer naloxone in the event [redacted] NRCH pay for the scripts for participants. It is known that [redacted] have administered Naloxone and we have evidence of 16 [redacted] this program.

[redacted] been trained in the Penington Institute's COPE Training [redacted]

[redacted] change to listing Naloxone to Schedule 3 will have a range of impacts and will reduce the reliance upon clients to have to access a medical service for a script. This is particularly important as some Doctors are reluctant to prescribe Naloxone while others have limited opportunity on their lists to include more clients and some clients are reluctant to attend appointments for scripts. The proposed shift of moving the responsibility to Pharmacists will require a considered response. Some Pharmacists are reluctant to deal with people who inject drugs. Clients have reported experiencing stigma and discrimination. Capacity building with Pharmacists and education will need to be undertaken.

Being able to access Naloxone without a prescription, we anticipate will result in more reversals and less deaths caused by opiates. With early intervention the medical costs and burden on the health care system after an overdose will be reduced. We also assume that there will be an increase in people purchasing Naloxone.

It is important to note that these assumptions will only translate into practice if Naloxone remains on the Pharmaceutical Benefits Scheme (PBS). If moving Naloxone to the Schedule 3 results in Naloxone being taken off the PBS and a consequential

north richmond
community health

price rise, this will be detrimental to people that use opiates. Naloxone must remain affordable for this population.

For further information please contact myself or the manager of the [redacted],
[redacted]

Regards

[redacted]

Submission regarding proposed amendments to the poisons standard (medicines):

Naloxone - To amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Prepared by [redacted] on behalf of NDRI

5 May 2015

Key Points:

- NDRI supports the proposed rescheduling of the single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.
- Consistent with international experience and research evidence, the potential benefits of the rescheduling are substantial and the risks negligible.
- Improved access to naloxone for potential opioid overdose witnesses is a key component of strategies for overdose prevention and management.
- Placing naloxone in Schedule 3 is consistent with this approach.
- Not inconsistent with rescheduling is requirement for:
    - Suitable materials and/or training in overdose management including naloxone administration;
    - Ensuring that naloxone continues to be available at a subsidised price under the PBS and through discounted S3 access for Health Care Card holders;
    - Rescheduling of the pre-filled injectable preparations should not be an obstacle to newer intranasal preparations of naloxone being similarly scheduled as they become available.

Table of Contents

About NDRI

The National Drug Research Institute's (NDRI) mission is to conduct and disseminate high quality research that contributes to the primary prevention of harmful drug use and the reduction of drug-related harm in Australia. Since its inception in 1986, the Institute has grown to employ about 30 research staff, making it one of the largest centres of drug research and public health expertise in Australia. It is a designated World Health Organization (WHO) Collaborating Centre for Alcohol and Drug Abuse.

NDRI's Key Result Areas are to i) conduct research that will contribute to the primary prevention of harmful drug use and the reduction of drug related harm, and ii) contribute to national capacity for research and disseminate research findings to key groups. Researchers have completed about 500 research projects, resulting in a range of positive outcomes for policy, practice and the community. For example, NDRI research has significantly informed and contributed to policy and evidence-based practice such as the National Drug Strategy and the National Alcohol Strategy; contributed to Australia's involvement in international strategies, such as WHO Global and Regional Strategy to Reduce Harmful Use of Alcohol; directly contributed to Australian and State government alcohol and illicit drug policy; informed liquor licensing decisions and government debate regarding cannabis policy; significantly contributed to international evidence-based school interventions; influenced NHMRC guidelines to reduce alcohol health risks; and been cited in development of policy documents for Aboriginal Australians.

Relevant expertise

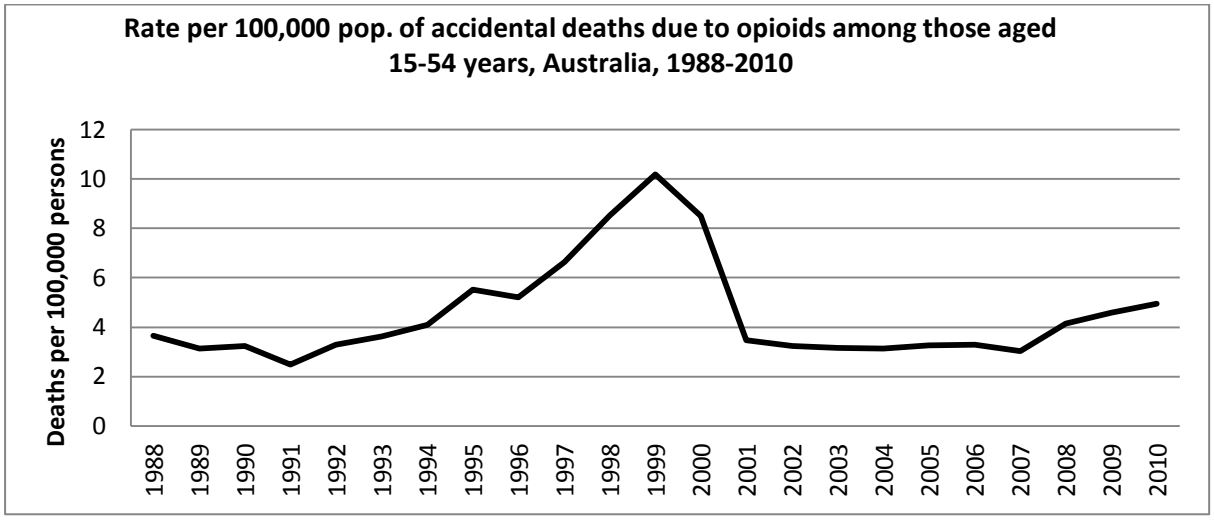
NDRI has an extensive track record of completing and disseminating research on Take Home Naloxone (THN) which is relevant to questions regarding the rescheduling application. A listing of publications NDRI researchers have published on the topic, plus some key projects related to this research area, are listed at Appendix A.

NDRI's Deputy Director, Professor Simon Lenton PhD MPsych(clin), has conducted research and evidence based advocacy for wider availability of naloxone for some 15 years and has co-authored publications on this topic in academic, trade and mass media publications. He has given a number of invited keynote and other presentations at conferences on the topic in Australia and internationally and he is currently a Chief Investigator on evaluations of THN programs in the ACT, NSW and WA. Most recently Professor Lenton contributed to the development of the World Health Organisation's newly published guidelines for the community management of opioid overdose (World Health Organization, 2014) which call for wider access to naloxone for people who are likely to witness and opioid overdose.

Substantive points pertaining application and section 52E of the Therapeutic Goods Act 1989

Background

In this country, deaths from heroin and other opioids among people aged between 15 and 54 years peaked at 1116 deaths in 1999, a rate of 10.19 deaths per 100,000 people. This rapidly declined to 386 deaths in this age range in 2001, a rate of 3.46 per 100,000 persons (Roxburgh & Burns, 2014). Despite this decline, overdoses involving heroin or other opioids continue to account for most illicit drug related deaths in this country (Degenhardt, Day, Gilmour, & Hall, 2006). In 2010, 613 Australians aged between 15 and 54 years died from accidental opioid overdose, a rate of 4.95 deaths per 100,000, up from 4.59 deaths per 100,000 in 2009 (Roxburgh & Burns, 2014). In 2010 most of these deaths (69%) were due to pharmaceutical opioids rather than heroin (Roxburgh & Burns, 2014). Heroin is still the drug of choice among the majority of people surveyed who inject drugs in Australia (Stafford & Burns, 2013).



Adapted from (Roxburgh & Burns, 2014)

In the mid-1990s calls were made to make naloxone available to opioid (typically heroin) users, their peers and family members to prevent overdose deaths, through what has become known as Take Home Naloxone (THN) programs (Darke & Hall, 1997; Strang, Darke, Hall, Farrell, & Ali, 1996). While such programs were implemented internationally particularly in the US which in the early 2000s we experiencing the beginnings of a rapid escalation of deaths associated with pharmaceutical opioid misuse developments towards implementing THN programs in Australia stalled, largely due to the 'heroin shortage' in Australia (Degenhardt, et al., 2006). In response to the evidence of some increase in opioid deaths in this country there were renewed calls take-home naloxone in the Australian academic literature (Lenton, Dietze, Degenhardt, Darke, & Butler, 2009a; S. R. Lenton, Dietze, Degenhardt, Darke, & Butler, 2009b) despite the fact that the increase in deaths was still far below the heroin 'glut' of the late 1990s (Dietze & Fitzgerald, 2002), it was reasoned that it was timely to start to develop take-home naloxone programs in this country, which could subsequently be scaled-up over time if and when overdose mortality continued to increase.

Risks and benefits of the use of a naloxone

Naloxone is a very low risk medicine. It does not produce intoxication and has a very low abuse potential, has no impact on people who do not have opioids in their system, and has a well-

documented four decade history of use in emergency medicine and anaesthesia (Brunton, Chabner, & Knollmann, 2011). As such, we have previously called for its rescheduling from S4 to S3 (Lenton, et al., 2009a; Lenton, et al., 2009b) as is proposed in the rescheduling application before the TGA.

The recent WHO Guidelines document addresses many of the points of interest to the current rescheduling application and should be reviewed by the TGA as part of the rescheduling application. For brevity they are not produced in detail here beyond the following quote which goes to the issue of relative risks and benefits of making naloxone available for take-home use.

> *"The GDG [Guideline Development Group] judged the risk-benefit profile to be strongly in favour of naloxone distribution, due to its clear potential for saving lives and apparent low risk of significant adverse effects. While training was considered an important and intrinsic component of increased naloxone availability, the GDG cautioned against making it compulsory or institutionalizing it as there were concerns that lack of certified training may be used as a barrier to provision of naloxone. The panel noted that while minor adverse events from naloxone administration (such as vomiting and opioid withdrawal) were not uncommon, serious adverse events were extremely rare".*
> (World Health Organization, 2014, p. 8)

<u>Risks of wider availability of Naloxone and responses to these.</u>

Lenton and Hargreaves (2000) summarised the evidence for distributing the opioid antagonist naloxone for administration by peers to prevent deaths from heroin overdose and reviewed a number of concerns regarding more widespread none of which were considered a major impediment to conducting a trial of THN. However, a trial did not proceed in Australia at that time, largely due to the 'heroin shortage' in Australia (Degenhardt, et al., 2006). Overseas research and evidence of program implementation has subsequently found that these concerns have either been addressed, or have not proved to be an issue in the field. Specifically:

(1) There has been no evidence greater availability of naloxone leading to more risky drug use. Indeed the opposite appears true, with those engaged in naloxone programs reporting having reduced their drug use (Maxwell, 2010; Maxwell, Bigg, Stanczykiewicz, & Carlberg-Racich, 2006; Seal, et al., 2005).

(2) There is concern that because Naloxone has a shorter half-life than heroin & many prescription opioids there is a risk that people fall into overdose again after administered naloxone wears off. In practice, this is a very rare event occurring in less than 0.2% of cases (Rudolph, et al., 2011), if at all (Maxwell, et al., 2006; Vilke, Sloane, Smith, & Chan, 2003; Wampler, Molina, McManus, Laws, & Manifold, 2011). Nevertheless the potential for re-intoxication is real and is addressed in training and materials provided through Australian THN programs.

(3) There were concerns about the shelf life of naloxone, which is documented as 18 months to 2 yrs, depending on the preparation. However, whilst noting this and the need for replacement doses within this specified period, controlled studies have shown it to be a very robust drug which is temperature resistant from − 20°C to +70°C (Küpper, et al., 2006) and remains viable up to a mean of 77 months when stored under recommended conditions (Lyon, Taylor, Porter, Prasanna, & Hussain, 2006).

(4) There was concern that because many opioid overdoses involve poly drug use, notably other CNS depressants such as benzodiazepines and alcohol, however it seems that using naloxone to take the opioid component out of the overdose, combined with careful monitoring of the person, substantially contributes to reducing the risk of death.

(5) Another concern was whether drug intoxicated persons could safely administer naloxone. Evidence suggests that naloxone is a very easy drug to administer, and is probably less complicated than many other interventions for overdose (monitoring airway, administering rescue breathing, calling an ambulance, etc.), particularly when a pre-filled syringe is used. The evidence is that active drug users are capable of safely administering naloxone as part of overdose management and this contributing to saving lives (Kim, Irwin, & Khoshnood, 2009).

(6) There were concerns that availability of naloxone for peer administration may contribute to delays in calling an ambulance. However rates of ambulance calling by participants on peer naloxone programs witnessing overdoses are at around 50-60% (Stancliff, Mathews, & Rath, 2010; Wagner, et al., 2010) and are almost identical to rates of calling ambulance in earlier studies of overdose witnesses prior to the implementation of THN programs (Darke, Ross, & Hall, 1996). Reasons why people chose not to call an ambulance, may be varied include: concern of police involvement if an ambulance is called; the victim recovering after naloxone administration and refusing ambulance attendance; concern from those present about consequences for them if their drug use is known to other departments such as child welfare services; and concern about the cost of ambulance transport which may be around $900 per trip in some Australian states.

(7) Concerns about precipitated withdrawal leading to aggression on the part of the victims seemed largely dependent on dose and route of administration, often based on the experience of ambulance staff who in the past had experience of administering large doses (2mg to5mg) intravenously. In contrast, the experience of administration of one 400mcg of naloxone intramuscularly, with only a subsequent dose being used if the person is not roused has been associated with far fewer observer reports of aggressive behaviour by those receiving such doses. Anecdotal reports from participants in current Australian peer naloxone reports include many accounts where the victim, having been administered such a dose, often gently roused and was unaware that naloxone had been administered. It is also noted that in recent times ambulance protocols have changed with smaller doses being used by IM route which makes the patient easier to manage during transport.

<u>Benefits of wider availability of naloxone</u>

International experience of THN program implementation confirms that naloxone is a very safe drug and injecting drug using peers, family members and outreach workers can successfully administer naloxone to reverse heroin overdose — with few, if any, adverse effects (e.g. Bennett & Holloway, 2012; Doe-Simkins, Walley, Epstein, & Moyer, 2009; Enteen, et al., 2010; Green, Heimer, & Grau, 2008; Kim, et al., 2009; Markham Piper, et al., 2008; Maxwell, et al., 2006; McAuley, Best, Taylor, Hunter, & Robertson, 2012; McAuley, Lindsay, Woods, & Louttit, 2009; Piper, et al., 2007; Rowe, et al., 2015; Tobin, Sherman, Beilenson, Welsh, & Latkin, 2009) . In the US alone, as of 2010, there had been over 53,000 kits containing naloxone distributed through 188 programs across 16 US states with 10,171 reported overdose reversals incorporating naloxone administration (Wheeler, Davidson, Jones, & Irwin, 2012).

Many of the THN programs internationally and in Australia involve training provided in a range of settings locations (street, treatment agency, training room, etc.) and durations (ranging from 5 minutes to well over an hour) (Clark, Wilder, & Winstanley, 2014) and there are many protocols, materials videos available online. Typical training components include some or all of: review of the causes and how to prevent overdose; assessment of an overdose; necessity of calling an ambulance; airway support and management; basic life support; information about naloxone and its administration; post

naloxone monitoring and support; communication with ambulance and police services; procedures for returns, new naloxone and reporting back; often pre-post evaluation.

However recent work has suggested only minimal training may be required for successful naloxone administration. One study found less than 10 minutes of training in naloxone administration is sufficient (Behar, Santos, Wheeler, Rowe, & Coffin, 2015) and another found no statistically significant differences in help-seeking, rescue breathing, staying with the victim, or successful naloxone administration, between trained and untrained rescuers (Doe-Simkins, et al., 2014).

Importance of access and timely administration

Timely naloxone administration is crucial in preventing morbidity and mortality associated with opioid overdose (World Health Organization, 2014). Wider distribution of naloxone to laypersons who are likely to be potential overdose witnesses has the potential to reduce these harms, particularly during when awaiting ambulance arrival or when there are distance or other barriers to timely ambulance attendance. The six THN current projects which have been commenced in Australian since 2012 (operating in ACT, NSW, Vic, SA, WA, Qld) are, with the exception of Victoria's, largely small scale (less than 200 participants). Given this limited coverage they are unlikely to have a significant impact on population rates of overdose, although they have been important as demonstration projects and identifying scale-up issues (Lenton, et al., 2014) in anticipation of further potential increases in opioid related overdoses in this country increasingly associated with pharmaceutical opioid misuse. Clearly if naloxone were available as an S3 medication in this country there would be great potential for wider coverage and earlier intervention in opioid overdoses.

Impact of THN programs on population rates of overdose mortality

The evidence has been growing that THN programs can increase the skills and knowledge of participants and naloxone can be safely administered by participants in these programs to save lives However, until recently most of the evidence regarding the impact of THN programs on impacts of rates of overdose at a *population level* have been based on observational studies (Maxwell, et al., 2006; Schmitz & Kane-Willis, 2010; Stancliff, et al., 2010), New York (Paone, Heller, Olson, & Kerker, 2010) and San Francisco (Evans, et al., 2012), which could not control for potential confounders. However, an interrupted time series analysis of 19 geographically distinct cities and towns in Massachusetts found lower opioid related overdose death rates in locations where programs of Overdose Education incorporating THN had been implemented with more than program 100 enrolments per 100,000 population (OR =0.54), compared to control communities where no such programs existed, despite controlling for a number of factors previously associated with overdose rates, including availability of opioid substitution treatment (Walley, Xuan, et al., 2013). A recent cost effectiveness study concluded that naloxone administration by trained lay persons is likely to reduce overdose death rates, and is highly cost-effective even under very conservative assumptions (Coffin & Sullivan, 2013). It has been long known that in the first weeks after prison release is high risk for overdose due to reduced tolerance due to incarceration (Binswanger, Blatchford, Mueller, & Stern, 2013). The most recent data from the Scottish National Naloxone program reports a fall on overdose death rates during the first 4 weeks post prison release from 9.8% at baseline steadily decreasing to 4.7% in 2013, coinciding with introduction of provision of THN kits to at risk prisoners upon release from incarceration (National Health Services Scotland, 2014).

Purposes for which naloxone is to be used and the extent of use

Naloxone is an opioid antagonist drug that reverses the effects of heroin and other opioid drugs. It does not cause intoxication. It has been used for over 40 years in emergency medicine and anaesthesia (Brunton, et al., 2011).

In the mid-1990s calls were made to make naloxone available to opioid (typically heroin) users, their peers and family members to prevent overdose deaths, through THN programs (S. Darke & Hall, 1997; Strang, et al., 1996). Such programs have now been implemented in many countries including the U.K., the U.S., Canada, Germany, Georgia, Russia, Spain, Norway, Afghanistan, China, Kazakhstan, Tajikistan and Vietnam (Curtis & Guterman, 2009; Eurasian Harm Reduction Network, 2010). Naloxone has been available across the counter in Italy since 1995 without reported adverse consequences (Kim, et al., 2009). In November 2010 Scotland became the first country internationally to roll out a national Take-home Naloxone program, which was funded for 5 million pounds over 2 years (McAuley, et al., 2012).

Toxicity of naloxone

Naloxone has negligible toxicity. Small numbers of people may have an allergy to Naloxone. However, we will not comment further here as they are already available in the product information previously approved by the TGA.

Dosage, formulation, labelling, packaging and presentation of a substance

Currently naloxone is available in Australia in a 400mcg pre-filled syringe (minijet®) produced by UCB pharmaceuticals. While a single dose of this size is appropriate for reversing most opioid overdoses which have been dealt with in the Australian THN programs, most programs offer more than one minijet ® (2-5) to enable re-dosing if the initial dose is insufficient or the person falls into overdose again once the initial dose has worn off. Having more than one minijet® is also helpful where the rescuer has to manage situations more than one person has overdosed simultaneously. Whilst the minijet® is ideal for lay administration as it is easier to operate that using ampoules and a syringe, an issue is that in its current packaging, the minijet® is really packaged and presented for use in a medical setting does not come with the required needle or appropriate instructions for layperson use.

Existing THN programs in Australia have been providing the naloxone as part of kits, based on international practice and typically including 1x 23gauge needle suitable for intramuscular (IM) injection per minijet®, along with brief instruction materials designed for lay administration, alcohol wipes, faceshields (for CPR), disposable gloves and a sharps disposal container. Whilst it may not be feasible to include all such materials for naloxone made available through S3, IM needles and appropriately designed brief instruction materials will be essential. Importantly the instruction information materials in these kits have been produced by and for current drug users which is considered crucial in terms of communication best practice. It should be possible for companies bringing THN formulations to the market for S3 to engage with Australian drug user groups involved in current THN naloxone programs to put together appropriate supporting materials for this setting.

It is noted that internationally naloxone is available in other forms. Multi-dose 10mL vials while providing a lower cost per dose, are not suitable in Australia due to valid concerns about the potential for Blood-Borne Virus transmission. Single dose glass vials were available for use in Australia prior to the availability of the pre-filled syringes, but they were more difficult to use and we had some reports of loss due to breakage and cuts from use. Naloxone is available in a higher concentration

(2mg/2ml) for intranasal (IN) administration with the application of a mucosal atomiser device (MAD) unit on the end of the minijet®. Although this form is currently off-label for IN use in the U.S., pending FDA approval. A currently approved naloxone auto-injector device by EVIZIO has not has pricing determined (Thomas, 2015), but it is said to be likely many times greater than the available forms (Kroll, 2014). It is anticipated that a cost-effective IN preparation of naloxone ideally suited to layperson use may be put before the TGA for approval in the next 12 months, but this should not be a barrier to the TGA approval of the current application as for S3 scheduling of the mini-jet formulation for IM administration.

Potential for abuse of naloxone

Naloxone has negligible potential for abuse. It does not produce intoxication, has no dependence potential and no action in persons who do not have opioids in their system. There are no known reports of abuse of naloxone in the literature of THN programs.

Other matters necessary to protect public health.

Italy is the only country which has thus far allowed naloxone to be available across the counter in pharmacies (Advisory Council on the Misuse of Drugs, 2012; Simini, 1998), and although there have been no reported adverse consequences (Kim, et al., 2009) previous reviews have failed to find any report of the effects of the Italian naloxone provision arrangements (e.g. Baca & Grant, 2005). We don't believe this is any reason to oppose the current rescheduling, but rather is something worth noting. Rescheduling naloxone in this way is, as already mentioned, likely to have a number of advantages in terms of reducing opioid overdose mortality and morbidity. Should the current scheduling application be approved, it will no doubt be noted and celebrated internationally and it will be important that its impacts, unlike those of the Italian example, are monitored and evaluated. The existing work on Naloxone availability in Australia means this country is well-positioned to do that.

Potential overdose witnesses due to their employment

As this submission has already noted, the proposed application has the capacity to greatly improve access of naloxone to potential overdose witnesses and be more likely to have an impact on population-level rates of opioid overdose mortality and morbidity in a way that the small demonstration programs currently in place in Australia are unlikely to.

One group for which the rescheduling is likely to have a great impact is those who are likely to witness overdoses as part of their employment. As we have previously described (Lenton, et al., 2014), these include, but are not limited to, peer outreach workers, needle exchange staff, drug treatment workers, staff at shelters and other emergency accommodation services, and indeed, police and other emergency services workers who may attend overdose scenes. In Australia, such staff are requesting and attending naloxone training through the existing THN programs, but they cannot be provided naloxone under the current prescription model. Particularly now that IM injection practice associated with the use of an adrenaline auto-injector (Australian Society for Clinical Immunology and Allergy Inc., 2012) has been adopted as part of First Aid training courses in this country, the rescheduling will provide a mechanism for much needed access for workers to have access to naloxone. It is anticipated that the Good Samaritan laws in place in most jurisdictions would cover workers administering naloxone in this situation.

Training and instructions

There is no question that having naloxone available as an S3 medicine should be supported. Nevertheless there is also a recognition that the administration of naloxone is but one component of a comprehensive response to prevention and management of opioid overdose. As described above the current Australian and international training packages associated with THN programs address a range of important issues including airway management, resuscitation, naloxone administration, post naloxone care, and the need for replacement of naloxone deemed expired as it is beyond its use-by-date. Thought will have to be given as to how the most essential elements of these packages can be delivered to members of the community who access naloxone over the counter through pharmacies. This will likely be through a combination of appropriately designed information materials within the naloxone package, combined perhaps with other brief materials, perhaps pointers to on-line training videos and likely some brief advice or instruction by the pharmacy staff. There is at least one internationally call for pharmacists to take on this role (Thomas, 2015) and there are similar models applied in other settings such as drug treatment settings (Walley, Doe-Simkins, et al., 2013) where there may be more time for instruction, and provision of an 'overdose management kit', allowing that individuals might be required to access the naloxone for that kit across the counter from a pharmacy. Whilst ideally it would be best for the naloxone and the instruction to be provided concurrently, the general point is that this issue will need to be addressed and there may be a range of possible solutions across different settings. The existing materials and training protocols which have been developed in Australian since 2012, and are based in international best-practice, provide a useful starting point for such deliberations. Rescheduling to S3 potentially will allow a range of new and innovative ways of doing this to maximise the benefits of wider naloxone availability on preventing morbidity and mortality.

Simplifying Good Samaritan protection

Australian THN programs currently provide naloxone under prescription with the intention that it will be administered to the person whose name is on the prescription. Should the medication be administered to a third person in an emergency situation, this can be covered under Good Samaritan laws that exist across Australian jurisdictions, although coverage is not perfect. For example, in both ACT and NSW (Australian Capital Territory Parliamentary Counsel, 2013; Parliament of New South Wales, 2013) such laws exclude persons under the influence of a drug. Although legal advice has been received that it would be extremely unlikely that legal action would be pursued against someone trying to save a life with naloxone, another potential benefit of the rescheduling of naloxone to S3 is that it would simplify, if not remove this potential barrier to appropriate use of naloxone in an emergency overdose situation.

Price and access

If the naloxone minijet® is re-scheduled to S3 to make it available across the counter, it would be important that the PBS listing is not adversely affected. The cost of naloxone is currently listed (exclusive of dispensing fee) as $16.64 per 400 microgram minijet®. It is our understanding that those on a Health Care Card would pay approximately $6 for two minijet® supply should they access the drug across the counter. Cost is likely to be central factor in the up-take of naloxone particularly for members of disadvantaged communities.

REFERENCES

Advisory Council on the Misuse of Drugs. (2012). *Consideration of naloxone*. London: ACMD, Available at: https://www.gov.uk/government/publications/naloxone-a-review (Accessed 23/1/2014)

Australian Capital Territory Parliamentary Counsel. (2013). Australian Capital Territory Civil Law (Wrongs) Act 2002 A2002-40 Republication No 51. Available at: http://www.legislation.act.gov.au/a/2002-40/current/pdf/2002-40.pdf (Accessed 6/12/2013). In (Vol. A2002-40). Australia: Australian Capital Territory Parliamentary Counsel,.

Australian Society for Clinical Immunology and Allergy Inc. (2012). *First aid treatment for anaphylaxis*: ASCIA. Available at: http://www.allergy.org.au/health-professionals/anaphylaxis-resources/first-aid-for-anaphylaxis (Accessed 19/2/2014)

Baca, C. T., & Grant, K. J. (2005). Take-home naloxone to reduce heroin death. *Addiction, 100*, 1823-1831.

Behar, E., Santos, G.-M., Wheeler, E., Rowe, C., & Coffin, P. O. (2015). Brief overdose education is sufficient for naloxone distribution to opioid users. *Drug and Alcohol Dependence, 148*, 209-212.

Bennett, T., & Holloway, K. (2012). The impact of take-home naloxone distribution and training on opiate overdose knowledge and response: An evaluation of the THN Project in Wales. *Drugs: education, prevention and policy, 19*, 320-328.

Binswanger, I. A., Blatchford, P. J., Mueller, S. R., & Stern, M. F. (2013). Mortality after prison release: Opioid overdose and other causes of death, risk factors, and time trends from 1999 to 2009. *Annals of Internal Medicine, 159*, 592-600.

Brunton, L. L., Chabner, B. A., & Knollmann, B. C. (2011). *Goodman & Gilman's pharmacological basis of therapeutics, Twelfth Edition* (12th ed.). China: McGraw-Hill.

Clark, A. K., Wilder, C. M., & Winstanley, E. L. (2014). A systematic review of community opioid overdose prevention and naloxone distribution programs. *J Addict Med, 8*, 153-163.

Coffin, P. O., & Sullivan, S. D. (2013). Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal. *Annals of Internal Medicine, 158*, 1-9.

Curtis, M., & Guterman, L. (2009). *Overdose prevention and Response: A guide for people who use drugs and harm reduction staff in Eastern Europe and Central Asia*. New York: Open Society Institute

Darke, S., & Hall, W. (1997). The distribution of naloxone to heroin users. *Addiction, 92*, 1195-1199.

Darke, S., Ross, J., & Hall, W. (1996). Overdose among heroin users in Sydney, Australia: II. Responses to overdose. *Addiction, 91*, 413-417.

Degenhardt, L., Day, C., Gilmour, S., & Hall, W. (2006). The "lessons" of the Australian "heroin shortage". *Substance Abuse Treatment, Prevention, and Policy, 1*, 11.

Dietze, P., & Fitzgerald, J. (2002). Interpreting changes in heroin supply in Melbourne: droughts, gluts or cycles? *Drug and Alcohol Review, 21*, 295 - 303.

Doe-Simkins, M., Quinn, E., Xuan, Z., Sorensen-Alawad, A., Hackman, H., Ozonoff, A., & Walley, A. Y. (2014). Overdose rescues by trained and untrained participants and change in opioid use among substance-using participants in overdose education and naloxone distribution programs: A retrospective cohort study. *BMC Public Health, 14*.

Doe-Simkins, M., Walley, A. Y., Epstein, A., & Moyer, P. (2009). Saved by the Nose: Bystander-Administered Intranasal Naloxone Hydrochloride for Opioid Overdose. *American Journal of Public Health, 99*, 778-791.

Enteen, L., Bauer, J., McLean, R., Wheeler, E., Huriaux, E., Kral, A., & Bamberger, J. (2010). Overdose Prevention and Naloxone Prescription for Opioid Users in San Francisco. *Journal of Urban Health*, 1-11.

Eurasian Harm Reduction Network. (2010). *Saving lives with naloxone: Global update on overdose programming*. Available at: http://www.harm-reduction.org/images/stories/library/overdose_awareness_day_update.pdf: EHRN

Evans, J. L., Tsui, J. I., Hahn, J. A., Davidson, P. J., Lum, P. J., & Page, K. (2012). Mortality Among Young Injection Drug Users in San Francisco: A 10-Year Follow-up of the UFO Study. *American Journal of Epidemiology, 175*, 302-308.

Green, T. C., Heimer, R., & Grau, L. E. (2008). Distinguishing signs of opioid overdose and indication for naloxone: an evaluation of six overdose training and naloxone distribution programs in the United States. *Addiction, 103*, 979-989.

Kim, D., Irwin, K. S., & Khoshnood, K. (2009). Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality. *American Journal of Public Health, 99*, 402-407.

Kroll, D. (2014). FDA Rapidly approvesnaloxone auto-injector for heroin and prescription opioid overdose. In *Forbes Magazine (published 03/04/2014)*.

Küpper, T. E. A. H., Bettina, S., Burkhard, R., Hemmerling, A. V., Volker, S., & Juergen, S. (2006). Drugs and drug administration in extreme environments. *Journal of Travel Medicine, 13*, 35-47.

Lenton, S., Dietze, P., Olsen, A., Wiggins, N., McDonald, D., & Fowlie, C. (2014). Working together: Expanding the availability of naloxone for peer administration to prevent opioid overdose deaths in the Australian Capital Territory and beyond. *Drug and Alcohol Review*, DOI: 10.1111/dar.12198.

Lenton, S., & Hargreaves, K. (2000). Should we trial the provision of naloxone to heroin users for peer administration to prevent fatal overdose? *Medical Journal of Australia, 173*, 260-263.

Lenton, S. R., Dietze, P. M., Degenhardt, L., Darke, S., & Butler, T. (2009a). Naloxone for administration by peers in cases of heroin overdose. *Medical Journal of Australia, 189*, 469.

Lenton, S. R., Dietze, P. M., Degenhardt, L., Darke, S., & Butler, T. G. (2009b). Now is the time to take steps to allow peer access to naloxone for heroin overdose in Australia. *Drug and Alcohol Review, 28*, 583-585.

Lyon, R. C., Taylor, J. S., Porter, D. A., Prasanna, H. R., & Hussain, A. S. (2006). Stability profiles of drug products extended beyond labeled expiration dates. *Journal of Pharmaceutical Sciences, 95*, 1549-1560.

Markham Piper, T., Stancliff, S., Rudenstine, S., Sherman, S., Nandi, V., Clear, A., & Galea, S. (2008). Evaluation of a Naloxone Distribution and Administration Program in New York City. *Substance Use and Misuse, 43*, 858-870.

Maxwell, S. (2010). Distributing Naloxone...because dead addicts NEVER recover. In *The Australian Drug Conference: Public Health and Harm Reduction*. Melbourne Australia, 25-26 October.

Maxwell, S., Bigg, D., Stanczykiewicz, K., & Carlberg-Racich, S. (2006). Prescribing Naloxone to Actively Injecting Heroin Users: A Program to Reduce Heroin Overdose Deaths. *Journal of Addictive Diseases, 25*, 89-96.

McAuley, A., Best, D., Taylor, A., Hunter, C., & Robertson, R. (2012). From evidence to policy: The Scottish national naloxone programme. *Drugs: Education, Prevention, and Policy, 19*, 309-319.

McAuley, A., Lindsay, G., Woods, M., & Louttit, D. (2009). Responsible management and use of a personal take-home naloxone supply: A pilot project. *Drugs: education, prevention and policy*.

National Health Services Scotland. (2014). *National Naloxone Programme Scotland – naloxone kits issued in 2013/14 and trends in opioid-related deaths Publication date – 28 October 2014.* Scottish Drugs Forum. Available at: https://www.google.com.au/search?q=https://isdscotland.scot.nhs.+uk/Health-Topics/Drugs-and-Alcohol-Misuse/Publications/2014-10+28/2014-10-28-Naloxone-Report.pdf%3F2581423522&ie=utf-8&oe=utf-8&gws_rd=cr&ei=VAo_VZHgA4rdoATeyYCwBg#. (accessed 26.11.2014)

Paone, D., Heller, D., Olson, C., & Kerker, B. (2010). Illicit Drug Use in New York City. *NYC Vital Signs, 9*, 1-4.

Parliament of New South Wales. (2013). New South Wales Civil Liability Act 2002 No 22, Part 8. Available at: http://www.legislation.nsw.gov.au/fragview/inforce/act+22+2002+pt.8+0+N (Accessed 6/12/2013). In.

Piper, T., Rudenstine, S., Stancliff, S., Sherman, S., Nandi, V., Clear, A., & Galea, S. (2007). Overdose prevention for injection drug users: Lessons learned from naloxone training and distribution programs in New York City. *Harm Reduction Journal, 4*, 3.

Rowe, C., Santos, G.-M., Vittinghoff, E., Wheeler, E., Davidson, P., & Coffin, P. O. (2015). Predictors of participant engagement and naloxone utilization in a community-based naloxone distribution program. *Addiction*, n/a-n/a.

Roxburgh, A., & Burns, L. (2014). *Accidental drug-induced deaths due to opioids in Australia, 2010.* Sydney: National Drug and Alcohol research Centre.

Rudolph, S. S., Jehu, G., Nielsen, S. L., Nielsen, K., Siersma, V., & Rasmussen, L. S. (2011). Prehospital treatment of opioid overdose in Copenhagen-Is it safe to discharge on-scene? *Resuscitation, 82*, 1410-1413.

Schmitz, S., & Kane-Willis, K. (2010). *Heroin Use in Illinois: A Ten-Year Multiple Indicator Analysis, 1998 to 2008*. Chicago: The Illinois Consortium on Drug Policy, Roosevelt University.

Seal, K., Thawley, R., Gee, L., Bamberger, J., Kral, A., Ciccarone, D., Downing, M., & Edlin, B. (2005). Naloxone distribution and cardiopulmonary resuscitation training for injection drug users to prevent heroin overdose death: A pilot intervention study. *Journal of Urban Health: Bulletin of the New York Academy of Medicine, 82*, 303-311.

Simini, B. (1998). bologna Naloxone supplied to Italian heroin addicts. *The Lancet, 352*, 967.

Stafford, J., & Burns, L. (2013). *Australian Drug Trends 2012: Findings from the Illicit Drug Reporting System (IDRS)*. Sydney: NDARC.

Stancliff, S., Mathews, B., & Rath, C. (2010). Building Capacity in Overdose Prevention. In *Symposium: Increasing community access to naloxone to prevent opioid overdose deaths: lessons for Australia held at the National Conference of the Australasian Professional Society on Alcohol and other Drugs (APSAD) 2010*. Canberra, 28 November -1 December.

Strang, J., Darke, S., Hall, W., Farrell, M., & Ali, R. (1996). Heroin overdose: the case for take-home naloxone. *BMJ, 312*, 1435-1436.

Thomas, S. A. (2015). Opioid overdose rescue kits. *U.S. Pharmacist, 40*, HS2-HS6.

Tobin, K. E., Sherman, S. G., Beilenson, P., Welsh, C., & Latkin, C. A. (2009). Evaluation of the Staying Alive programme: Training injection drug users to properly administer naloxone and save lives. *International Journal of Drug Policy, 20*, 131-136.

Vilke, G. M., Sloane, C., Smith, A. M., & Chan, T. C. (2003). Assessment for Deaths in Out-of-hospital Heroin Overdose Patients Treated with Naloxone Who Refuse Transport. *Academic Emergency Medicine, 10*, 893-896.

Wagner, K. D., Valente, T. W., Casanova, M., Partovi, S. M., Mendenhall, B. M., Hundley, J. H., Gonzalez, M., & Unger, J. B. (2010). Evaluation of an overdose prevention and response training programme for injection drug users in the Skid Row area of Los Angeles, CA. *International Journal of Drug Policy, 21*, 186-193.

Walley, A. Y., Doe-Simkins, M., Quinn, E., Pierce, C., Xuan, Z., & Ozonoff, A. (2013). Opioid overdose prevention with intranasal naloxone among people who take methadone. *Journal of Substance Abuse Treatment*, 241-247.

Walley, A. Y., Xuan, Z., Hackman, H., Quinn, E., Doe-Simkins, M., Sorenson-Alawad, A., Ruiz, S., & Ozonoff, A. (2013). Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. *BMJ, 346*.

Wampler, D. A., Molina, D. K., McManus, J., Laws, P., & Manifold, C. A. (2011). No deaths associated with patient refusal of transport after naloxone-reversed opioid overdose. *Prehospital Emergency Care, 15*, 320-324.

Wheeler, E., Davidson, P. J., Stephen Jones, T., & Irwin, K. S. (2012). Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010. *Morbidity and Mortality Weekly Report, 61*, 101-105.

World Health Organization. (2014). *Community management of opioid overdose*. Geneva: WHO

APPENDIX A – NDRI NALOXONE-RELATED PUBLICATIONS AND PROJECTS

Publications *(in chronological order, most recent first)*

Dietze, P., Cogger, S., Malandkar, D., Olsen, A. and Lenton, S. (2015). *Knowledge of naloxone and take-home naloxone programs among a sample of people who inject drugs in Australia*. National Drug and Alcohol Research Centre, University of NSW, Sydney. Available at: https://ndarc.med.unsw.edu.au/resource/knowledge-naloxone-and-take-home-naloxone-programs-among-sample-people-who-inject-drugs.

Tait, R.J. and Lenton, S. (2014). Commentary on Williams et al. (2014): Family matters: new resources for managing opioid overdose with take-home naloxone. *Addiction*, *109*, (2), pp. 260-261.

Lenton, S., Dietze, P., Olsen, A., Wiggins, N., McDonald, D. and Fowlie, C. (2014). Working together: making naloxone available for peer administration to prevent opioid overdose deaths in Australian Capital Territory and beyond. *Drug and Alcohol Review*. DOI: http://dx.doi.org/10.1111/dar.12198

Lenton, S., Dietze, P., Degenhardt, L., Darke, S. and Butler, T. (2009). Naloxone for administration by peers in cases of heroin overdose. *Medical Journal of Australia*, *198*, (8), pp. 469.

Lenton, S., Dietze, P., Degenhardt, L., Darke, S. and Butler, T. (2009). Now is the time to take steps to allow peer access to naloxone for heroin overdose in Australia. *Drug and Alcohol Review*, *28*, pp. 583-585.

Lenton, S. (2008). Commentary: Case for peer naloxone further strengthened. *Addiction*, *103*, pp. 1658-9.

Hargreaves, K.M. and Lenton, S. (2003). *Naloxone for overdose: Consideration of a trial of naloxone provision for peer or worker administration in Victoria*. National Drug Research Institute, Curtin University of Technology, Perth. ISBN: 1 74067 299 2

Hargreaves, K.M. (2001). *Is it time to reconsider a trial of the naloxone provision to heroin users as an aid in the prevention of fatal heroin-related overdose? A Submission to the WA Community Drug Summit*. National Drug Research Institute, Curtin University of Technology, Perth.

Hargreaves, K.M. and Lenton, S. (2001). *The Naloxone Feasibility Study*. National Drug Research Institute, Curtin University of Technology, Perth, Western Australian.

Lenton, S. and Hargreaves, K.M. (2000). Editorial: A trial of naloxone for peer administration has merit, but will the lawyers let it happen? *Drug and Alcohol Review*, *19*, (4), pp. 365-369.

Lenton, S. and Hargreaves, K.M. (2000). Should we conduct a trial of distributing naloxone to heroin users for peer administration to prevent fatal overdose? *Medical Journal of Australia*, *173*, (4), pp. 260-263.

***Projects** (in chronological order, most recent first)*

Evaluation of the Western Australian Peer Naloxone Program
Chief Investigators: [redacted]
Funding: ACT Health ($25,993).
This project is an evaluation of The Naloxone Peer Education project being conducted by the West Australian Substance Users Association (WASUA) throughout 2012-2014. The evaluation consists of a pre and post education session questionnaire, collecting quantitative data; followed by a three to six month follow up interview, collecting qualitative and quantitative data on the retention of information from the education session and any subsequent responses to overdoses including the use of naloxone. Around 150 opioid users and potential overdose witnesses will be recruited to the program and will be trained in overdose prevention and management, including naloxone administration. As at April 2014 over 120 participants have been trained and 60 follow-up interviews have been conducted.

Evaluation of the Sydney Overdose Prevention Education and Narcan® (OPEN) Project
Chief investigators: [redacted]
Unfunded.
In July 2012 a pilot opioid overdose prevention and management intervention OPEN was implemented for the first time in NSW in two clinical settings in central Sydney: the Kirketon Road Centre - a low threshold primary health care service targeting PWID, and the Langton Centre - a drug treatment clinic. This incorporates a clinician delivered overdose management training session for PWID and the prescription of take home 'naloxone packs'. A comprehensive evaluation of this intervention was undertaken to assess its feasibility and acceptability in these different clinical settings. As part of this evaluation key informant semi-structured questionnaires and interviews were conducted at the commencement of the intervention and following six months of operation. Clients' attitudes regarding overdose management and naloxone administration were assessed pre- and post-training and at six months follow up. As at April 2014 the project report and a journal article were under submission.

Independent evaluation of the 'Expanded Naloxone Availability in the ACT (ENAACT)' Program, 2011-2013
Chief Investigators: [redacted]
Funding: ACT Health $100,000
Naloxone is a schedule 4 drug in the ACT that is routinely used by health personnel to reverse opioid overdoses. Consistent with developments internationally, the Alcohol and Other Drug sector in the ACT has designed a public health program to expand naloxone availability in the ACT with the aim of reducing opioid overdose morbidity and mortality. The program commenced in April 2012 to train and dispense naloxone to 200 potential overdose witnesses over two years. It involves comprehensive overdose management training and the supply on prescription of take-home naloxone to eligible participants who are not health professionals. People prescribed take-home naloxone are administered it by a trained peer (usually a friend or family member) in the event of an opioid (primarily heroin) overdose. The evaluation used a mixed methods strategy, assessing implementation fidelity and participants' experiences of the program. It involved pre- and post-training knowledge assessment and follow-up at 3-6 months post training and when naloxone is administered. It will contribute significantly to new knowledge about the implementation of expanded naloxone availability in the ACT context. As at April 2014 the project report was being finalised.

Naloxone Trial - a proposal to scope the need and circumstances for a Naloxone trial in Victoria.
Investigators: [redacted].
Funding: 2000 Human Services, Victoria via Turning Point Alcohol and Drug Centre Inc. ($15,000).
The main purpose of the project was to undertake a 'scoping exercise' to determine the need and circumstances for a naloxone trial to be undertaken in Victoria. This included: a review of the national and international literature; determining the current state of naloxone use in Victoria; investigating the

potential to increase access to naloxone; determining whether a naloxone trial should take place, its design and costs. Interviews were held with stakeholders from research, the emergency medical field (both hospital and ambulance), drug and alcohol services, the Health Department and user groups were interviewed as key informants. These individuals provided assistance with the identification and clarification of the key issues relating to Victoria, potential problems that might result and possible solutions to these problems. The report was released as an NDRI Technical report in November 2003 (Hargreaves & Lenton, 2003).

Feasibility into the provision of naloxone to heroin users for peer administration to prevent fatal heroin-related overdose.

Chief Investigator: [redacted].

Funding: 1998 Health Department of WA ($33, 850).

Heroin overdose is a major cause of death among heroin users and non-fatal heroin overdoses are common. Most deaths attributed to heroin overdose occur some time after last injection, in the company of others, mostly other users. Yet despite the opportunity for intervention, witnesses to fatal overdose rarely call an ambulance or seek help, often because of concern about police being involved. Naloxone hydrochloride (Narcan®) is an injectable narcotic antagonist which reverses the effects of opioid overdose. It has been suggested that it be provided to heroin users for administration by their peers in an overdose situation. The project aimed to determine the feasibility of conducting a trial of the provision of naloxone to heroin users for peer administration and to design such a trial. The project included a literature review, establishment of an expert key informant group, data collection with heroin users, addressing medico-legal and supply issues, developing and piloting a protocol for administration, and trial design. This study generated a report (Hargreaves & Lenton, 2001) and two refereed journal publications (Lenton & Hargreaves, 2000a, 2000b) including one in the Medical Journal of Australia, which has been extensively cited. The study formed the basis of a submission to the WA Drug Summit which led to the establishment of a working group within the WA Department of Health to consider the issue. As a result of this project we were commissioned by the Department of Human Services Victoria to do a further project on Naloxone provision (see above).

3rd May 2015

[redacted]

[redacted], NSW 2010

[redacted]

Submission to the Advisory Committee on Medicines Scheduling for July 2015 Meeting

Response to invitation for public submission on application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Dear Sir/Madam,

Thank you for the opportunity to make a submission to the Committee. I am in favour of the proposed rescheduling to S3, as this should make naloxone more widely available and accessible in the community, especially to carers and family members of individuals at risk of opioid overdose.

Background.

Opioid overdoses continue to occur in Australia, and in recent years there has been an increasing trend towards overdose with prescription opioids (e.g. oxycodone, fentanyl, morphine), rather than illicit heroin. Most of these overdoses occur in a context of polydrug use with other sedative drugs, notably benzodiazepines and alcohol. Many of these are unintended overdoses (not suicide).

One strategy to reduce fatal overdoses is the increased availability of the opioid antagonist, naloxone, to opioid users and their family/friends or carers to have available in the event of an overdose. The use of, and evaluation of 'take-home' naloxone for overdose prevention has recently been summarised by the World Health Organisation Guidelines regarding the Community management of opioid overdose[1]. The guidelines recommend countries expand naloxone access to people likely to witness an overdose in their community, such as friends, family members, partners of people who use drugs, and social workers.

Providing 'take-home' naloxone for overdose prevention

Whilst 'take-home' naloxone programs are now widespread practice in many parts of the world, such programs are relatively new in Australia – commencing in several jurisdictions since 2011. I have been involved in the establishment of programs in NSW, which have now expanded to include

[1] World Health Organisation (2014) Community management of opioid overdose. Geneva. ISBN 978924 1548816

a number of services in inner-city Sydney, including services based in South East Sydney LHD, the Medically Supervised Injecting Centre, and St. Vincent's Hospital D&A Services. Between these services we estimate that 'take home' naloxone has been provided to about 200-300 patients on prescription. The prescriptions are accompanied with

(a) an education intervention delivered by a health professional – addressing how individuals can identify a suspected overdose, immediate responses to an overdose, and how to use naloxone to reverse opioid overdose; and

(b) an Overdose Prevention Kit that includes 2 x Minijet naloxone pre-filled syringes, needles, a 'sharps' container, gloves, swabs and printed information regarding responding to an overdose.

However, the need to have naloxone prescribed by a medical practitioner to a patient (S4 conditions) is a potential barrier to the more widespread dissemination and availability of naloxone for overdose prevention programs. S4 conditions require that a medical practitioner prescribe the medication to the individual for whom it will be used (ie the opioid user) and cannot be prescribed to the patient's family or carer. The proposed rescheduling to S3

1. will enable concerned family and friends to access and store naloxone at home without the need of the particular patient to acquire a prescription from a medical practitioner.
2. may increase the willingness of opioid users or concerned carers to store naloxone at home without the stigma of approaching a medical practitioner and disclose their opioid use or risk of overdose.

The safety of naloxone (there are no relevant side effects or potential for misuse) suggest that the medication can safely be provided as an S3 medication.

There are however some concerns regarding the rescheduling to S3 that can be addressed to enhance naloxone availability. These include (a) cost of the medications and (b) education of patients and carers.

(a) Cost of naloxone Minijets under S3

The cost of naloxone Minijets may be prohibitive to many patients if not subsidised under PBAC conditions. Wholesale price of naloxone Minijet is approximately $15-20 per Minijet, such that a box of 5 will cost $75-100 to the patient as an S3. In contrast, a health care card benefit holder currently now only pays $6.20 per box of 5 Minijets. Hence, even if Minijets are available as an S3 medication, the widespread affordability of the medication may require for it to be continue to be available as an S4 medication subsidised by PBAC. A similar approach has been used for the Epipen® – enabling both over-the-counter and prescription systems.

(b) Education of patients and carers

The second concern with an S3 rescheduling is the extent to which patients, families and carers will receive adequate information and education regarding avoiding overdoses, responding to suspected overdoses and on the use of naloxone in the event of an overdose. Whilst some pharmacists currently have adequate information to educate customers, it is safe to assume that the vast majority of pharmacists have never been trained to provide such overdose prevention education, nor have the willingness or time to do so. In our take-home naloxone programs, education of patients routinely takes 5-10 minutes with a health worker (e.g. nurse, pharmacist, doctor, D&A worker) to address the necessary issues regarding naloxone for OD prevention. It is unclear if community pharmacists will feel comfortable or have the resources to provide such a service.

However, this is not dissimilar to other over-the counter medications where pharmacists admit to not always feeling comfortable or skilled in delivering appropriate education to customers, particularly on such sensitive issues. Rather than this being seen as a barrier to naloxone's rescheduling as an S3 medication, we should recognise that there are now effective strategies for providing consumer education - such as the internet, and we encourage the development and dissemination of accurate information and education programs regarding overdose prevention and the use of naloxone that can be targeted to opioid users (both illicit and prescription opioids) and their families or carers. Pharmacists can fulfil their professional obligations by directing consumers and carers to relevant education materials.

In conclusion, the rescheduling of naloxone to S3 medication is strongly supported, although there should be mechanisms to ensure adequate consumer and carer education, and to ensure the affordability of naloxone to the target population. I would be happy to provide further information on request.

Yours sincerely

The Lyndon Community
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Advisory Committee for Medicines

Scheduling Meeting July 2015

Response by The Lyndon Community to invitation for public submission on application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Authors: Joshua Snowdon, Megan Gray, Julaine Allan

Closing date for submission – 7 May 2015

Contact:

[redacted]

Contents

1. **The Lyndon Community**

The Lyndon Community is a non-government organisation providing alcohol and other drug treatment in residential and non-residential programs. The organisation provides residential services in Orange and Canowindra and non-residential programs to much of rural and remote NSW, including in Central West, the Murdi Paaki Region (from Brewarrina to Dareton), and on the Far South Coast. Services include withdrawal, rehabilitation, education programs, women's groups, mental health and drug use groups, family support and parenting programs; and one to one counselling. Lyndon Community has a strong commitment to conducting practice-based research that informs work across the sector. Lyndon has been providing drug and alcohol treatment for over 30 years and is accredited through The Australian Council on Healthcare Standards.

2. **Purpose of Submission**

The Lyndon Community refers to the invitation for public comment on the application made to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3. **The Lyndon Community supports proposed rescheduling**, for reasons outlined in the following sections of this submission.

3. **Background**

Opioid overdose is a significant cause of morbidity and mortality in Australia. Between 2007 and 2011 there were 4,102 recorded fatal opioid overdoses in Australia, of which, around 75% were deemed unintentional (NCIS 2014). Indigenous Australians and people in rural and regional areas are at greater risk of drug related harms, including overdose (Pennington Institute 2014; NIDAC 2014). Access to quality services and evidence based treatment options is paramount in reducing drug related harms in these populations (Allan 2014).

Traditionally, overdose has been associated with heroin; however in Australia today, more fatal overdoses occur due to prescription opioids. Morphine, oxycodone, methadone and codeine are amongst the most commonly identified contributing opioids in cases of overdose in Australia (NCIS 2014). Increasingly, fentanyl is also being misused, particularly in rural and regional areas of NSW (Allan, Herridge, Campbell & Fisher 2015).

Naloxone is an opioid antagonist which can be used safely and effectively by laypeople to prevent both fatal opioid overdose and morbidity related to non-fatal opioid overdose (UK Government 2012). It is the Lyndon Community's experience that in Australia the number of injecting opioid users, their families and friends with access to naloxone preparations is currently very low. In the context of an ever increasing death toll from opioid overdose, harm reducing measures such as the rescheduling of naloxone injections are of increasing importance.

4. Benefits and risks of the proposed rescheduling

- Naloxone is a safe drug that has no effects on a person that has not recently used an opioid drug (UK Government 2012).

- The risk profile for naloxone is well known, as previously outlined by the TGA (2012).

- Naloxone is effective in treating opioid overdose, and preventing opioid related death and morbidity in the community setting (Wheeler, Davidson, Jones & Irwin 2012)

- Naloxone injections have been shown to be effective both in the Australian setting and abroad when administered by a properly trained layperson, such as friends, family or any other person likely to witness an overdose (Wheeler et al 2012; ATODA 2014).

- The rescheduling of naloxone injections will reduce barriers to access of this lifesaving treatment. People in rural and remote areas, with poor access to medical services, will no longer need a prescription before accessing this treatment.

- There is no evidence to suggest that access to naloxone promotes high risk behaviours, such as using larger doses of opioids (UK Government 2012).

- Naloxone no has potential for abuse (UK Government 2012).

5. Case study: Implementing naloxone training with people who use drugs – Our experience

Staff from Lyndon Community wanted to develop our own group for clients on overdose first aid because we heard stories from clients about how they had witnessed overdoses and deaths of friends and family and were unable to help them We organised training from the Sydney Medically Supervised Injecting Centre in late 2014. With our new found knowledge we embarked on educating our clients at the Lyndon Withdrawal Unit in Orange, NSW and Lyndon House Rehabilitation Centre in Canowindra, NSW.

As the overdose first aid group was developed it became clear that we needed to include as much information as possible about Naloxone. It became very clear within minutes of doing an internet search, that Harm Reduction Victoria were leading the way in Australia when it came to Naloxone training. So who else better to contact for advice? We were even more excited when we heard of all reported overdose reversals by drug users following their Naloxone training.

This only spurred us on and our group took shape very quickly, we have been running the group for five months now at both the withdrawal unit and rehab and the feedback has been very encouraging. Clients reported that their overall knowledge of what an overdose looks like and how to safely respond in an emergency has increased a great deal. More importantly large numbers of clients who never knew about Naloxone are now armed with the information they so badly need to help save lives. We hope that in turn they can return to their communities and spread the word.

Of course everything comes with a catch and that was getting GP's on board to prescribe. Our next step was to try and educate local doctors so they could feel confident in prescribing Naloxone to drug users in their communities but if the changes are supported this extra step in making naloxone available won't be needed, one less hoop to jump through.

We understand that if the proposed changes are approved larger cities like Sydney and Melbourne will be better equipped to educate larger numbers of the public in regards to safe administration of naloxone. However, our growing concern is for rural and remote communities who at present are not being educated and as a result are also losing friends and families on a daily basis because of a very much preventable problem.

If Naloxone becomes a Schedule 3 drug this will most definitely help save lives all over Australia. Making Naloxone available from pharmacists will in turn have a positive impact on our rural and remote communities because they too will be able to access this safe, inexpensive, fast acting and reliable antidote for opioid overdoses. Lives will be saved.

Megan Gray RN, Mental Health Specialist, Lyndon Community

6. Conclusion

The Lyndon Community supports the proposed rescheduling of naloxone injections as a harm reduction strategy. The potential benefit of this change has been demonstrated both abroad, and in limited settings in Australia, while the risks have proven to be minimal. The Lyndon Community believes that in the same way that family and friends of anaphylactic people carry Epi-Pens to protect their loved ones, family and friends of opioid users should have access to naloxone injections. This is one of the essential steps in curbing the upward trend in opioid related deaths, especially in vulnerable populations such as those in rural and remote areas, and Indigenous Australian.

7. References

Alcohol Tobacco and Other Drug Association ACT [ATODA] (2014), *Key Interim Findings – Independent evaluation of the 'Implementing Expanding Naloxone Availability in the ACT (I-ENAACT)' Program, 2011-2013*, Retrieved May 2015 from http://www.atoda.org.au/wp-content/uploads/Summary-of-Interim-Findings-summary-for-release-2.pdf

Allan, J (2015). Prescription opioids and treatment in rural Australia: a failure of policy for Indigenous Australians. *Substance Abuse.*36(2):3 DOI:10.1080/08897077.2014.990132 http://www.tandfonline.com/doi/full/10.1080/08897077.2014.990132#.VUf5F5MXVKo

Allan, J., Herridge, N., Campbell, M., Fisher, A (2015). Illicit fentanyl use in rural areas – an exploratory study, *J Alcohol Drug Depend 2015, 3:2* http://dx.doi.org/10.4172/2329-6488.1000196

National Indigenous Drug and Alcohol Committee [NIDAC] (2014). *Alcohol and other drug treatment for Aboriginal and Torres Strait Islander peoples.* Retrieved July 2014 from http://www.nidac.org.au/images/PDFs/NIDACpublications/AOD-Treatment-report.pdf

National Coronial Information System [NCIS] (2014). *Opioid related deaths in Australia (2007-2011)* Retrieved May 2015 fromhttp://www.ncis.org.au/wp-content/uploads/2014/08/NCIS-Fact-sheet_Opioid-Related-Deaths-in-Australia-2007-2011.pdf

Therapeutic Goods Administration [TGA] (2012), *Product and Consumer Medicine Information – naloxone*, Retrieved May 2015, from https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=naloxone

UK Government (2012). The Advisory Council on the Misuse of Drugs, *Consideration of naloxone*, Retrieved May 2014 from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/119120/consideration-of-naloxone.pdf

Wheeler, E., Davidson, .P.J, Jones, T.S. and Irwin, K.S. Community-Based Opioid Overdose Prevention Programs Providing Naloxone (2012) *MMWR. Morbidity and Mortality Weekly Report,* 61(6), 101–105

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone . Further to the amendment I recommend that the pricing for Naloxone over the counter remain the same price as on the PBS otherwise it becomes prohibitively expensive for those that need to access it the most
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
• Working in the Alcohol and Drugs sector, I know many people who are at risk of a fatal Overdose. Easy access to naloxone will significantly decrease this risk. • Prompt use of naloxone is critical and there is often a significant time lapse between reporting an overdose and waiting for an ambulance with naloxone to arrive which increases the risk of fatality or brain damage. Response times can be shortened and lives can be saved. • There is often someone else present during an overdose so it makes sense for them to have naloxone • People do not want to access naloxone from GP as they will have to disclose their drug use and fear discrimination • Sometimes it can be hard to organise an appt to the Doctors to ask for a prescription of Naloxone. By being able to get it over the counter at a chemist, it means you are much more likely to obtain initial and refill packs in a timely manner • Naloxone is a safe drug and has no effect on someone with no opioids in their system. You can't abuse it, it has no resale value, it is inexpensive to provide, fast acting and a reliable antidote for opioid overdoses. • Naloxone is simple to administer by witnesses of an overdose, with limited instruction therefore all persons should be able to administer it with simple instruction from a pharmacist

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
- keep naloxone on PBS while allowing it to be purchased over the counter.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
- I support the rescheduling of Naloxone to an S3 over the counter medication.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
• It will allow me to save lives as I work amongst the people who inject drugs community. • It will allow peer education to take place and equip peer educators with the medicine needed to reverse overdose.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
No other suggested improvement.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
As a health professional who works with people with complex trauma, AOD use is very common with people I provide services to. Opiates such as heroin and prescription opiates are a common drug of choice, as it seems to help people manage the effects of complex PTSD. Allowing people to access naloxone will save lives, as many/most people do not have access to safe and supervised consumption facilities. Over the last year, I have witnessed the loss of 10 lives, nearly half of them to preventable death from opiate OD. Having access to over the counter naloxone will allow people to stay alive and to eventually move to increased well-being and fulfilment in life.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I fully support the amendment for the scheduling of Naloxone & do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I Support the amendment
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
• To make sure it remains on the PBS. • The prompt use of Naloxone is critical! There can be significant time lapse between reporting an overdose & waiting on an ambulance with Naloxone to arrive. The risk of brain damage & fatality then increases. • Some people do not have access to GPs.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the ammendment for the scheduling of naloxone and do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the ammendment for the scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Naloxone is a safe drug and has no effect on someone with no opioids in their system. You cannot abuse it, it has no resale value, it is inexpensive to provide, fast acting and a reliable antidote for opioid overdoses.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone and do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of Naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
I work with people who inject drugs and almost everyday hear their stories about someone from their past & present overdosing and losing life because they didn't have Naloxone to save their lives. I think it is extremely important to make this medication easily accessible - that is the least we can do for people who inject drugs in our community and represent one of the most vulnerable groups in our society.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Greater availability of naloxone will decrease the incidence of preventable death by overdose amongst clients I'm working with without any discernable risk.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I agree strongly with the amendments.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Making naloxone a Schedule 3 drug will allow greater access to this lifesaving medication for people who come into contact with those who take opiates, including people who inject drugs (PWID) and those prescribed opiates. All these people are at risk of overdose and their deaths can be prevented by the timely administration of naloxone. Ambulances can take time to reach a person who has overdosed but if their friend or family member or even a passer by has naloxone on them it may save their life. Cost savings to the health system can also be made by providing better access to naloxone as if overdose is treated quickly and efficiently, the person will likely spend less time, if any in hospital. Cumulative brain damage from overdose occurs in many PWID. Early administration of naloxone can prevent greater brain injury which in the long term means savings for the healthcare system who ends up paying to support those with brain injury.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone and do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Naloxone is a safe drug and has no effect on someone with no opioids in their system. You can't abuse it, it has no resale value, it is inexpensive to provide, fast acting and a reliable antidote for opioid overdoses. Naloxone is simple to administer by witnesses of an overdose, with limited instruction therefore all persons should be able to administer it with simple instruction from a pharmacist.

[redacted]

I am writing to give my support to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

I would suggest an improvement to the proposition, that is, making it available as at Schedule 2 rather than S3.

Assessment of how it affects me, costs and benefits including actual costs.

1. A Safe and effective antidote for opioid overdose

Naloxone is a safe medication and has no effect on someone with no opioids in their system.

It has no abuse potential or resale value and is inexpensive to provide.

It is a reliable antidote for opioid overdoses, especially now with the advent of fentanyl (100 times stronger than morphine) being responsible for numerous overdoses.

Naloxone is a short-acting medication and is active for about 30 – 90 minutes, which is usually long enough to prevent death, because opioid levels have decreased by the time the naloxone has worn off.

2. Why easy access to general members of the community is important

Making naloxone available as an S3 will make it easier for drug users and their family and friends to access.

Naloxone is currently available on a script and evidence shows that users are not accessing it this way.

The nature of many drug users' lives means that a visit to the doctor hard at the best of times, so they are not likely to make a specific trip to their GP for a naloxone script.

Some users will not want to ask their GP about a script as they might not have disclosed their drug use and fear discrimination.

Another drug user is the most likely person to be present at a drug overdose so it makes sense for them to carry naloxone

Naloxone should also be accessible to other groups e.g. the friends and families of people who use drugs and staff who work closely with drug users.

3. Why a fast response is important

Prompt use of naloxone is critical and there is often a significant time lapse between reporting an overdose and waiting for an ambulance with naloxone to arrive which increases the risk of fatality or brain damage. Making naloxone S3 or S2 means that more people can access it more easily, and people are more likely to carry it and response times to opioid overdoses can be shortened and lives can be saved.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone and do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

As part of my work I have witnessed and assisted to manage a number of opiate related overdoses, many of which would have been fatal if it weren't for the administration of naloxone.

The quicker that an opiate related overdose can be managed the less time the individual is receiving sub-optimal levels of oxygen which causes permanent brain damage. The cost of supporting those with brain injury in the community is immense and there are not enough services providing this support as it is. Research has shown a high level of cognitive impairment among substance users and that this in turn results in less people taking up treatment or dropping out of treatment early. It is likely that long term opiate users develop cognitive impairments due to having many non fatal overdoses (hypoxia) throughout their time using. The use of naloxone could reduce this brain damage and resulting cognitive impairment.

Working in a forensic environment it is clear to see and has also been shown in research that aquired brain injury (linked to substance use and overdose) is prevelant in the prison system. In Australia it costs on average $106,580 per year to keep a prisoner in jail. If we can reduce the amount of cognitive impairment due to hypoxia perhaps there will also be a decrease in the number of offences comitted and individuals incarcerated, saving the government hundreds of thousands of dollars per year.

As users age they are more likely to experience an opiate related overdose and research has also shown that the older the individual is (40+) the longer they take to recover, resulting in more time in hospital causing bed block which is very costly. If the overdose was prevented or managed quickly with the use of peer administered naloxone, the individual would not

necessarily be required to go to hospital at all and not require the use of an abulance (average cost $349), which is another huge cost.

People report they will often not call an ambulance when they are with someone who overdoses and would rather leave the scene for fear that the Police will also come. If they had naloxone available and could use it on their friend, they wouldn't necessarily need to call an ambulance.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support naloxone being available over the counter without prescription.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendments.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
[redacted] and so I see first-hand the benefits of naloxone administration to people experiencing opiate related overdose. Since the Sydney MSIC started operation, ambulance call outs to Kings Cross in response to drug overdose has decreased by 80%. MSIC has managed over 5,000 drug overdoses without a single fatality. Naloxone is one of the tools we use to save lives, it is a crucial component – the statistics speak for themselves. Whilst [redacted] access our service to inject opiates, they can be assured of their safety whilst onsite. Unfortunately some of [redacted] over the years have died of overdose when they inject in other locations – at home, in a park, inside a public toilet, etc. MSIC has been making efforts to train interested clients in how to administer naloxone and provide them with naloxone ampules to take home or keep on their person. A barrier to this is client concern about the implications of naloxone being on a prescription in their name; that is, they are worried that their anonymity might be compromised. Drug users fear discrimination and often do not want to disclose to others, like their doctors, that they sometimes take illicit substances, or inject opiates. Naloxone available over-the-counter and without prescription would go a long way in breaking down drug-user suspicion and to ensure that naloxone enters the drug using "scene", becomes part of the culture, and thus saving more lives from opiate related overdose.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is:

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support amendment for scheduling of naloxone
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
clients would be supported to get training so they could buy OTC → Anyone could therefore carry it & be able to save

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the rescheduling amendment for Naloxone to an over the counter product.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support this
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
freely available naloxone would aid in street OD, the more people who carry it the better management of overdose, and less pressure on ambulance or medical services. its easy to administer and cant do any real harm, but its earlier availability would mean it could do more good.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone and do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the rescheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
As a [redacted] who works with injecting drug users, I see a huge benefit to IVDUs being able to readily access naloxone to improve the outcomes of overdoses in the community. If the people around the drug user, peers/friends/family, were able to use naloxone to reverse an opioid overdose without having to wait for an ambulance it would decrease the mortality and morbidity of overdoses, particularly in more remote areas. Naloxone is simple to administer, with simple instruction from a pharmacist. It has few adverse effects, cannot be abused and has no re-sale value.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone + do not suggest any further improvements.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the ammendment for the scheduling of Naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
I strongly feel that if Naloxone was made easier to obtain + more freely available it would benefit the whole community. There would be less overdoses + overdose related deaths. It would make people more accountable + able to assist friends + family. In case of an emergency. I personally know of one death that could have been avoided if someone had been not waiting to obtain another script for Naloxone. In this time his friend overdosed + died. Thank You.

1

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment without improvements.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendments.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
I believe this change will create a more informed and prepared group of clients who can assist in preventing unnecessary deaths. This will be positive for [redacted] in promoting health safety and harm reduction. Also ensuring [redacted] are able to support each other in an emergency.

SYDNEY MSIC
UnitingCare
NSW.ACT

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7th May 2015

Dear Sir/Madam

Re: Submissions for proposed amendments to the Poisons Standard (medicines) Meeting July 2015

I attach thirty-eight Naloxone consultation submissions for the July 2015 meetings from individuals that attend the Sydney Medically Supervised Injecting Centre (MSIC).

The MSIC is a harm reduction health service aimed at reducing the mortality of drug overdose and morbidity of injecting drug use, reducing the transmission of blood borne virus', and providing a gateway to drug treatment, health and social welfare services. The service is staffed by experienced clinicians including registered nurses and drug and alcohol counsellors. Further information can be found on our website www.sydneymsic.com

The MSIC has supported people to make submissions regarding the proposed rescheduling of Naloxone. Many of the individuals who have made submissions are either street homeless (and therefore have no permanent address) and/or do not have phone numbers and email addresses to provide on the cover sheet. Therefore they have used the MSIC details to provide c/o contacts. Sydney MSIC is committed to linking you with any individual if follow up is required.

If you have any further questions, please do not hesitate to contact me.

Yours Sincerely

[redacted]

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I greatley support Naloxone scheduling
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Ive Reen AT A Few O/Dosos over The years Noloxone MUST Be Readiley Availble As IT Will SAVE MANEY LIVES People FROM All WAIKS OF life Should Be Able To Purchas over The counter Noloxone To Have ON HAND. IF EVER It is Needed Noloxone will save Lives It Will ALSO SAVE THE PUPLIC PURSE Eg. AMbulances Doctors Hospital [redacted]

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
I would ~~BE ABLE~~ BEABLE To SAVE SOMEONE Life

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements

freely available over the counter.

Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.

I support the amendment for the scheduling of naloxone.

An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

people in my social circle are at risk of death. it would be good to have it freely available.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I Support the amendment of naloxone + and I don't Suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I Support the Scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
I think Anything that helps Stop or Slow down the amount of overdoses is a great thing.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements I support the ~~feasth~~ Rescheduling of naloxone [redacted] and also in ~~nea~~ nasal perp.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
If I can get it over the counter. I can save friends live's.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
It would save a life quicker, great idea being able to access Naloxone over the counter.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
YES I SUPPORT THE AMENDMENTS ✓
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
WOULD LIKE TO HELP IMPROVE MY DIABETIC HEALTH.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
—
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
Yes I am in support of the amendments.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Easy Access at all hours without seeing a doctor 1st. Ability to save lives if I had access 24hrs/7 to this medicine.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
Yes support amendments
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
More people are ~~let~~ able to access the naloxone thus preventing overdoses that otherwise may occur.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
yes I support the ammendments.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
less stress in creating availability in supporting a safer environment for drug users & people associated in that lifestyle.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
—
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendments.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Greatly. I've had to ring ambulances wher friends have overdosed, so if I had naloxone from over the counter I could administer it whilst waiting for ambulance, which would decrease my anxiety. My [redacted] is an [redacted] + I constantly worry that she is going to overdose, so if naxolone was easily available to me or others, it would greatly reduce my worry.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling and do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
I have been present at many overdoses. Some bystanders are scared to call the ambulance through fear of police attending and have therefore left people overdosing on the side of the road. If it were available at pharmacies this would make a difference in the time it takes to administer to the patient. It would make it a lot easier if it were available as parents of drug addicted people could keep some in their cupboards for an emergency as ~~there~~ it is easy to administer & could save a life.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment and do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for scheduling of naloxone.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
I would be more likely to carry naloxone and store it at home if i could obtain it from a pharmacy without having to get a perscription first. Which makes it much easier to save somebody who is overdosing

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
None
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support ammendment.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
It will be easier to save lives by making it easier to get, through a chemist rather than a doctor. I know people at risk of overdose so would be handy to have it on me.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
With no need for training this would open the door for much easier administration, and potential for saving lives!

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the AMENDMENT for the Scheduling of NALOXONE AND ANY improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the AMENDMENT for the Scheduling of NALOXONE
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
It's important to keep the cost of NALOXONE to a miniman. If I can get my hands NALOXONE I could SAVE Not only family but strangers to.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support this Idea Fully
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
MAKES it more accessible for the genral public Advertises the exsistance of NARCAN and encourage more people to look into it.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I Support the Amendment for the Scheduling of NALOXONE. And Any further improvements.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the AMENDment for the scheduling of Naloxone.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
it is important to keep the costs down on Naloxone as it is important so we can save lives. if We can get our hands on Naloxone easily for my friends, Loved ones and myself.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
To be accessable to drug users
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
Full support.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
I have lost alot of friends due to drug over doses & to have naloxone readily available it will save alot of lives - cost is not important although most drug users do not have much financial sensibility so if it could be sold on P.B.S. it would benefit all! ANYONE WHO HAS LOST A LOVED ONE WILL AGREE! Much thanks

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
none
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support it
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Three times last December alone I needed to do CPR on mates while waiting for an ambulance to arrive. I also spend a lot of time in remote locations where an ambulance could be well over an hour away where we do use drugs alot...

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
none.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support it
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
It should be available, it will save a lot of lives. Everything is real secret in the bush + country towns. People don't call an ambulance because they don't want the Police to come or for the community or family to find out which they will in a small town.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment and do not have any further suggestions or improvements to add.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I do support the amendments for the scheduling of Naloxone.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
* There are benefits to buying naloxone over the counter, such as keeping the user anonymous, there's no problems with having police attend a scene with the ambulance which puts some people off and causes delays in treatment. As I [redacted], the time saved having naloxone on hand could be the difference between life + death. Having naloxone at home may save an ambulance time in having to attend a scene because once given the naloxone the patient may come around + be coherent, then the patient can see a G.P. or go to hospital as they see fit. But it can save the ambulance from coming altogether.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment to the scheduling of naloxone and do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
If it is more accessible less people would die from overdoses and there would be less drama. You can't hurt someone by giving it to them. If it was around in the 90's not so many people would have died. It was nothing to see a dead person on the street, dead from an overdose.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
creation of a 'purchase register' similar to SUDAFED. SAFE STORAGE CHILDREN - ETC.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of NALOXONE.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Assisting in possible "long term" destigmatisation of "ADDICTION" ACCESS for carers / families etc — life saving.

[redacted]

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
MAKE IT SCHEDULE 2
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I SUPPORT AMENDMENT
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
CAN ADMINISTER IT TO MY NEIGHBOURS WHO HAVE OD'ED, ESPECIALLY IF IT IS EASIER TO GET THROUGH A CHEMIST WITHOUT A SCRIPT.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone and do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I Suppo
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
My [redacted] overdosed from Heroin, I don't know How many people drop and die everyday from Threats or Heroin. (Per etc IT is a lifetime vendetta of Mine to stop The surge of O.D.'s from Heroin and I Think if people can self administer Narcane (I love you to death) I Think Brain damage and overdoses (ODs) will be reduced (love is The key to survival & Narcane will prove to be Sick in The reductions of overdoses. I Think it is very important to feel love and to express it!! Narcane can help Please make it readily accessible to The General public. The more available it is The less death due to overdoses etc "I love you to death!" Thank you for Helping The world survive and love again

Changes or Blocks

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
Made readily available
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
Support H
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
As long as it is at a reasonable price

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment to the scheduling of naloxone and do not support any further implementation
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment to the scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
IF A COUPLE ARE USING. AND THE MALE CAN HANDLE MORE OPIATES THAN THE FEMALE AND SHE WAS TO DROP HER BOYFRIEND. COULD SAVE HER LIFE. THANK YOU.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I SUPPORT THE AMENDMENT FOR THE SCHEDULING OF NALOXONE AND DO NOT SUGGEST ANY OTHER AMENDMENTS
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I SUPPORT THE AMENDMENT FOR THE SCHEDULING OF NALOXONE
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
NEED TO SUPPLY NALOXONE To be able to help SOMEONE THAT HAS OVERDOSED FOR FREE most people wont have money to get it so people wont die on overdose

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
No improvement
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support it totally
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Safer to bring people back and sometimes doing CPR you can and I have broken someones Ribs [redacted]

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements	I SUPPORT AMENDMENT
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.	
I SUPPORT AMENDMENT	
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.	
FRIENDS OF MINE IN THE PAST HAVE DIED OF HEROIN OVERDOSE, IF I COULD ADMINISTER NARCAN MYSELF THIS COULD BE PREVENTED	

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
Support the effort/amendment for re-scheduling of Naloxone to allow patients over-the-counter access.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
To reduce overdose risk for anyone with opiate/opioid dependency. Without direct/immediate access to Naloxone risk of overdose is extremely high.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I SUPPORT THE AMENDMENT FOR THE SCHEDULING OF NALOXONE FULLY
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I SUPPORT THE AMENDMENT FOR THE SCHEDULING OF NALOXONE
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
IT SAVES LIVES I WAS THE FIRST ONE TO GET LICENSE TO ADMINISTER + TREAT OD VICTIMS I HAVE SEEN FIRST HAND HOW IT SAVES LIVES IT SHOULD BE READY AVAILABLE AT (PBS) SO EVERY ONE CAN GET IT. IT WILL BENEFIT THE COMMUNITY [redacted]

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I Support the amendent
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I Support the amendent
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Available to more people if over the counter, rather than by prescription, + so will save more people's lives

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
None
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I Support the amendment
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Easy access of this life-saving drug is vital. Peace of mind knowing you have narcan easy to hand to administer in an overdose. I have seen people overdose before and if I had Narcan I could have used it to reverse the overdose.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
N/A
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
The need for easier access would save a lot more lives, especially in my local community. I have lost too many friends because the access to narcan was not readily available and time was lost trying to find a doctor who was not out to lunch.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is:

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you. YES I SUPPORT THE AMENDMENT
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
NARCAN IS EASY FOR ANOTHER ADDICT TO ADMINISTER. BEING AN ADDICT MYSELF I AM MORE LIKELY TO HAVE OCCASIONS WHERE OTHER ADDICTS WHO USE, DO SOMETIMES OVERDOSE. GIVING BACK TO THE COMMUNITY BY HELPING TO SAVE A LIFE. ASSISTING AMBULANCE PEOPLE BEFORE THEY ARRIVE AND SAVE LIVES. ASSISTING THE AVAILABILITY OF NARCAN IS THE OBVIOUS NEXT STEP, HELPING PROVIDE MORE EDUCATION.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
over the counter maybe some sensitivity training for people dispensing
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
also removing the sodium valle from S3 to S2 would help the stigma discrimination.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
I am around people who use all the time and I worry about the time it takes for an ambulance to arrive. Also there are times away where I may not be near a phone or have reception.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is:

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the Amendment for the scheduling of naloxone. I also support changing the classification from S3 to S2 for easier access
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you. S3 to S2
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
I have been present at an overdose where an ambulance was more than 20 minutes away. All efforts to revive were made to no avail. I believe strongly in having Naloxone as in My case the person who overdosed would more than recovered if naloxone had been avaible. As for cost, well, what price human life? Only Making it at least an S2 rather than S3 Would Make it available readily and out of business closing times.

CONSULTATION SUBMISSION

PROPOSAL TO RESCHEDULE NALOXONE PRE-FILLED SYRINGES

INTRODUCTION

The Advisory Committee on Medicines Scheduling (ACMS) has invited public comment on the proposed amendments to the Poisons Standard (Medicines), submitted to the committee and included on the agenda of the July 2015 meeting. The agenda items include an amendment to the existing scheduling of naloxone.

Currently naloxone is listed as a schedule 4 medicine on the Standard for the Uniform Scheduling of Medicines and Poisons number 6, February 2015.

The proposal, for which advice of ACMS is sought, is:

> *'To amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in schedule 3.'*

While we endorse the broad intention of this amendment, we do not support the proposed text as currently suggested, as it restricts schedule 3 listing to a single dose form.

We would like to submit an alternative wording which does not unnecessarily limit wider access to naloxone to the pre-filled syringe presentation, is more consistent with established listing text and which we believe would further enhance the overall public health benefits intended by the proposal.

OUR SUGGESTED IMPROVEMENT

It is our view that the intent of the proposed amendment can be enhanced by rewording the text so that it can accommodate future availability of naloxone preparations administered by routes other than the parenteral option, and to ensure consistency with listings for other medicines used in acute medical emergencies, which also appear in more than one schedule.

We propose that the following amendment be considered as an alternative to that currently proposed:

> *'To amend the scheduling of naloxone to include single doses containing 2mg or less and a recommended total dose of 10mg or less in schedule 3'*

The wording of the suggested amendment is consistent with the approved dose of naloxone in the Australian Product Information[1], continues to support the public health benefit of wider availability of naloxone and has the necessary flexibility to accommodate possible future introduction of alternative dose forms other than parenteral administered presentations.

It is also consistent with the established practice of basing the wording of the listing text on medicine unit dose and/or method of administration rather than by individual delivery system.

We therefore believe that the cost benefit of making naloxone more readily available to persons at risk of opioid overdose, and their close associates, would be further enhanced by not restricting access to one particular dose form.

BACKGROUND[1]

Naloxone is an essentially pure opioid antagonist. In the absence of opioid agonists it exhibits no pharmacological activity. Single doses up to 280mg have produced few toxic effects.

It is metabolized in the liver primarily by glucuronide conjugation and excreted in the urine. Caution should be observed when administering to patients with renal failure or liver disease, although the impact on safety and efficacy is not well known.

Naloxone is currently available in Australia as an injection ampoule containing 400micrograms/mL of naloxone HCl (Narcan® AUST R 57306 and DBL Naloxone HCl AUST R 16282), as pre-loaded syringes, named Min-I-Jet, containing 400mcg/mL (AUST R 29051), 800mcg/2ml (AUST R 48534) and 2mg/5mL (AUST R 48535) of naloxone HCl or as oral tablets in combination with buprenorphine (Suboxone®) or oxycodone (Targin®).

The approved indication for the injectable products is for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural or synthetic opioids. They are also indicated for the diagnosis of suspected acute opioid overdosage. Both products are scheduled as prescription only products (S4). The products may be administered by IV, IM or subcutaneous routes, however IV administration is recommended in emergency situations.

The oral combination products include naloxone to discourage misuse or reduce adverse events associated with the opioid agonist component. Suboxone is indicated for the treatment of opioid dependence, while Targin is indicated for moderate to severe pain unresponsive to non-narcotic analgesics. The naloxone content in Targin is considered helpful in treating or preventing opioid induced constipation. Both products are controlled drugs (S8).

The initial dose of naloxone in opioid overdose is 400mcg to 2mg IV, which may be repeated every 2 to 3 minutes if desired response is not observed. If no response is observed after total dose of 10mg, the diagnosis of opioid induced toxicity should be questioned. IM or SC administration may be necessary if IV route is not available.

Naloxone is widely used to reverse accidental or intentional overdose with opioid analgesics or illicit narcotic agents.

RATIONALE FOR OUR SUGGESTED IMPROVEMENTS

Public Health Implications

Australian snapshot of opioid overdose

Although it is difficult to accurately estimate the number of injecting drug users of any age, there may be as many as 30,000 regular opioid users in Australia aged 40 years and over and up to 80,000 infrequent or non-dependent opioid users[2].

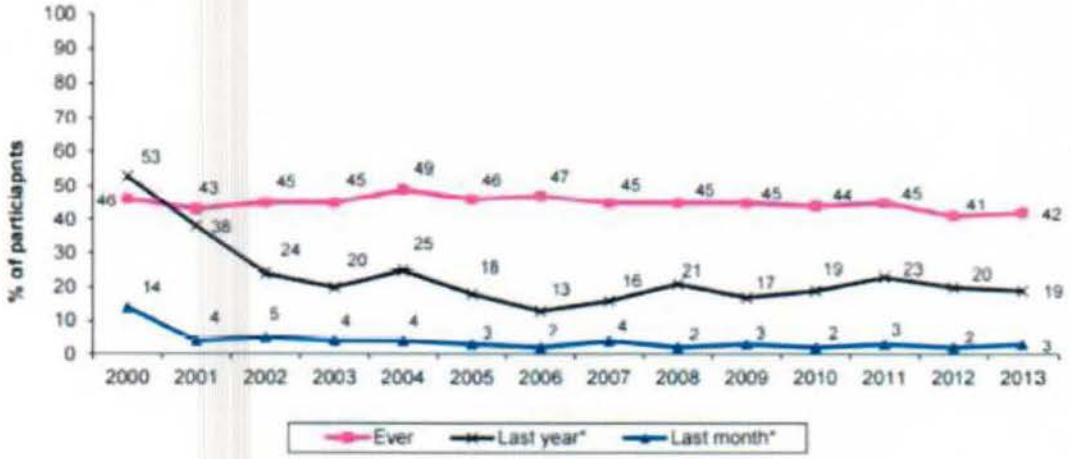
Nearly four Australians die every day from overdose. Overdoses out-numbered road fatalities in Australia in 2012. According to the Australian Bureau of Statistics overdose deaths totalled 1,427 in 2012, while road deaths, which have been steadily declining, ended the year at 1,338. (Data provided to the Penington Institute by Australian Bureau of Statistics, 2014).

Removal of pethidine from the PBS – because of norpethidine neurotoxicity, misuse liability and self-administration by health practitioners – has limited drug-seeking for this drug. However, misuse of other pharmaceutical opioids is increasing in parallel with their increasing availability. The number of PBS-subsidised opioids is increasing and the current wave of prescription opioid abuse involves primarily oxycodone, codeine, morphine, tramadol and methadone. The presentation and management of poisoning with these opioids is similar to that for heroin, although the patient demographic is variable.

There are a much larger number of non-fatal opioid overdoses each year, a proportion of which are currently treated with naloxone. Estimating that number accurately relies on summarising the data from hospital admissions for opioid overdoses (State based), data of attendances on overdose patients by first responders, typically paramedics within the ambulance services (also State based) and self-reported overdoses. Given the large number of data sources, this data is difficult to access, evaluate and compare.

According to the IDRS Project 5, an indicative estimate of overdose for heroin users confirms over 40% of all users have overdosed at least once in their lifetime, and 19% of those have overdosed in the last 12 months [3].

Figure 2: The prevalence of heroin overdose among participants, 2000-2013



Source: IDRS participant interviews
*Among those who had 'ever' overdosed on heroin
Note: Data may differ to previous national and jurisdictional reports due to the method of data analysis

Participants were asked about the treatment they received at the time of a recent heroin overdose (in the past year; N=68). Twenty-four percent of those who overdosed on heroin in the last year reported not receiving any treatment, while 52% reported receiving Narcan®. (Narcan is the brand of naloxone provided in many States by ambulance officers and paramedics in attendance for a suspected opioid overdose).

Participants were also asked about the treatment they received at the time of a recent heroin overdose (in the past year; N=68). Of those who overdosed on heroin in the last year:

- 24% reported not receiving any treatment
- 52% reported receiving Narcan®,
- 41% had an ambulance attend,
- 21% reported receiving cardiopulmonary resuscitation (CPR) from a friend/partner,
- 16% attended the hospital emergency department,
- 15% received oxygen and
- 7% received CPR from a health professional.

There is clearly a strong public health imperative to make naloxone more easily accessible to those at risk of opioid overdose, their close associates, and even in public spaces where the likelihood of an overdose situation may be reasonably high, as well as to health professionals and paramedics.

How naloxone is currently used, and will use change in the near future?

Naloxone is indicated in opioid overdose and should be titrated to respiratory rate and effort, rather than the level of consciousness. Naloxone may be administered through various routes, including intramuscular (IM), intranasal (IN) and intravenous (IV). Doses in adults range from 100–400 µg IV, and 2 mg IM or IN.

Careful and timely administration of naloxone is recommended, as it may precipitate acute opioid withdrawal in opioid dependent patients. Withdrawal is characterised by agitation, diaphoresis and tachycardia.

Naloxone is used by medical personnel to reverse the effects of opioid overdose in and out of hospital settings (such as ambulance attendances) or in acute settings, that is, hospitals. Each year, hundreds of lives are saved and severe brain injuries prevented by Australian paramedics who carry and use naloxone for people who have an opioid overdose[4].

Currently naloxone is generally administered by injection either intravenously by medical personal in hospital settings, or intramuscularly by paramedics if in pre-hospital settings.

Increasingly, government and non government public health agencies as well as individuals with a strong interest in enhancing the prevention and management of medicine misuse are considering new harm minimisation strategies in the treatment of opioid overdose[5].

For example, administration of naloxone by nasal spray has been trialled by paramedics in Victoria where it was found to be effective and safe[6]. However this is not common practice in Australia. Nasal administration has been shown to be as effective as intravenous administration in a retrospective study of paramedics conducted in the United States[7]. The Boston, Massachusetts, program uses nasal administration rather than injection[8].

Another strategy has been to provide education and training on opioid overdose recognition and emergency treatment that can be used by opioid users and close daily contacts in overdose situations, including the administration of naloxone[9].

A study in Massachusetts in 2009 demonstrated that non-HCP 'bystanders' can successfully recognize an opioid overdose and use intranasal naloxone to reverse the effects of overdose[9]. Over the 15 month study period, the program provided training to 385 participants who reported 74 successful overdose reversals. Problems with the intranasal administration of naloxone were uncommon. The authors concluded that overdose prevention education with distribution of intranasal naloxone is a feasible public health initiative.

Because of the risks associated with the administration of naloxone using a conventional needle due to the high incidence of hepatitis C and HIV infection in the opioid misuse community, increased attention is now being directed to naloxone administration by needleless systems including transdermal and intranasal methods[8, 10, 11]. For instance, the Denver and San Francisco emergency systems use an intranasal administration technique as the standard of care to prevent needle stick injury. In these jurisdictions this was achieved using an injectable formulation of naloxone 1mg/ml, with 1mL of the solution administered to each nostril via a marketed nasal atomizer/nebulizer.

Furthermore, investigators such as Panchagnula and co-workers have shown that other non-injectable delivery systems, such as a transdermal formulation of naloxone may also have a role in opioid overdose[10]. Panchagnula have developed a transdermal patch containing 10, 20mg and 30mg of naloxone per gram of gel in a transdermal reservoir and shown that it can provide steady state plasma concentrations of naloxone from between 4 and 48 hours, compared to the 1.5 hour maximum following intravenous administration.

In pre-clinical studies the transdermal gel formulation and prototype patch were shown to be efficacious, safe, stable and non irritant to the skin. The transdermal route may be particularly useful in managing overdose with opioids with long plasma half lives such as methadone.

Ashton and Hassan conducted a systematic review of the published literature in order to establish whether there was sufficient evidence to support the effectiveness of intranasal (IN) naloxone in suspected opioid overdose. Seven clinical studies were identified, 3 of which compared intranasal naloxone to either IV or IM doses. IN administration provided slightly slower response than IV administration, but similar or better rates of response compared to IM naloxone.

The authors also summarised a pharmacokinetic study in rats, which found IN naloxone to be 100% bioavailable compared to the IV formulation, with a C_{max} of 3 minutes.

The authors concluded that it is likely that intranasal naloxone is a safe and effective first line prehospital intervention in reversing the effects of an opioid overdose and has the additional advantage of helping to reduce the risk of needle stick injury. They considered that a large, well designed trial would be considered to test this hypothesis.

While neither a registered intranasal or transdermal formulation of naloxone is currently available in Australia, as the evidence supporting the safe and efficacious use of these products continues to be published in the medical literature, and emergency services continue to include non-injectable routes of administration in overdose protocols, it is likely that in the near future purpose designed non-injectable delivery systems will become generally available.

Consistency of wording of schedules for similar emergency use medicines

We also believe our suggested improvement to the amendment wording of the naloxone schedule is more consistent with the established practice of basing the text on medicine unit dose and/or method of administration rather than by individual delivery system.

Both adrenaline and atropine are used parenterally as emergency treatments for anaphylaxis and as neurotoxin antidote respectively. They are also indicated for other indications, which are scheduled differently to these "emergency" indications.

For all the indications however, appropriate scheduling enables access to the medicine according to knowledge and skill needed to recognize and manage these conditions.

In the case of adrenaline (as an autoinjector) it is scheduled as S3 allowing the parent or care giver ready access through pharmacy for a life threatening indication, considered to be readily diagnosed and managed by lay persons. Atropine injection is restricted to S4 as careful diagnosis and administration is required when used as an antidote.

Both medicines are also indicated for other indications. When used orally, atropine may be used to manage less critical minor gastrointestinal conditions, and is therefore scheduled as an S2 medicine, allowing self medication by the public.

When used as an ampoule for preparation of intravenous infusions as an ionotropic agent or in severe asthma attacks, requiring specialist medical diagnosis and management, adrenaline is scheduled as an S4 medicine.

The schedule text for two other emergency use medicines is provided below:

ADRENALINE (S4) **except**

a) When included in schedule 3; or
b) In preparations containing 0.02 per cent or less of adrenaline unless packed and labeled for injection.

ADRENALINE (S3) in preparations containing 1 per cent or less of adrenaline except in preparations containing 0.02 per cent of adrenaline unless packed and labeled for injection.

ATROPINE (S4) **except** when included in schedule 2

ATROPINE (S2) for oral use;

a) In undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labeled with a dose of 0.3mg or less of... and a recommended daily dose of 1.2mg or less of...
b) In divided preparations containing 0.3mg of less of total solanaceous alkaloids per dosage unit, when labeled with a recommended daily dose of 1.2mg or less of...

If our suggested improvements are adopted, the NALOXONE text would read:

NALOXONE (S4) **except** when included in schedule 3

NALOXONE (S3) in single doses containing 2mg or less with a recommended total dose of 10mg or less.

This wording is consistent with the approved dosage and administration advice provided in the parenteral naloxone Product information. The amended wording will continue to permit conveniently packaged naloxone preparations to be purchased and administered by persons at risk of opioid overdose, or their close associates.

It will not restrict access to only one particularly preparation, allowing similar access to future IN, transdermal or other non-injectable preparations.

POTENTIAL COST BENEFIT OF SUGGESTED IMPROVEMENT

Adopting the alternative wording of the proposed S3 listing of naloxone will have the following additional cost benefits to the community, by permitting additional non-parenteral dose forms of naloxone to be scheduled as pharmacist only medicines if they become available in Australia.

- Lower storage and transportation costs due to a lower risk of breakage of glass pre-filled syringe barrels
- Potentially longer shelf life and consequently less frequent replacement. Naloxone pre-filled syringes have a 30 month shelf life below 25°C
- Easier and more convenient to use. For example, transdermal patch which can be applied directly to skin or a spray applied to both nostrils, rather than by IV or IM injection
- No risks of needle stick injuries and accidental viral infections

It has been estimated that over $79 million is spent each year in diagnosis and treatment of hepatitis C[12]. In 2012-13 Australian Government expenditure for antiretroviral medication was estimated as $218 million[13].

REFERENCES

1. Product Information Narcan Injection. Date of first inclusion in ARTG 2 October 1997.
2. http://www.aivl.org.au/wp_content/uploads/Double_Jeopadry_Older_Injecting_Opioid_Users_in_Australia.pdf.
3. http://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/National_IDRS-2013.pdf.
4. Kerr D, Dietze P, Kelly AM, Jolley D. Improved response by peers after witnessed heroin overdose in Melbourne. Drug and Alcohol Review 2009; 28: 327-330.
5. Wermeling DP. A response to the opioid overdose epidemic: Naloxone nasal spray. Drug Delivery and Translation Research 2013; 3; 63-74.
6. Kerr D, Kelly AM, Dietze P et al. Randomised controlled trial comparing the effectiveness and safety of intranasal and intramuscular naloxone for the treatment of suspected heroin overdose. Addiction 2009; 104: 2067-2074.
7. Merlin MA, Soybolt M, Altar S et al. Intranasal naloxone delivery is an alternative to intravenous naloxone for opioid overdose. American Journal of Emergency Medicine 2010; 28: 296-303.
8. Wheeler E, Davidson PJ, Jones S, Irwin KS. Community-based opioid overdose prevention programs providing naloxone – United States, 2010. Morbidity and Mortality Weekly Reports (Centers for Disease Control) 2012, February 17, 2012 101-105.
9. Doe-Simkins m, Walley AY, Epstein A, Moyer P. Saved by the nose: Bystander-administered intranasal naloxone hydrochloride for opioid overdose. American Journal of Public Health 2009; 99: 788-791.
10. Panchagnula R, Bokalial R, Sharma P, Khandavilli S. Transdermal delivery of naloxone: skin permeation, pharmacokinetic, irritancy and stability studies. International Journal of Pharmaceutics 2005; 293: 213-223.
11. Hillard M. Theconversation.com/eliminating-hepatitis-c-an-ambitious-but-achievable-goal-24485.
12. www.livingpositivevictoria.org.au