



Submission to the TGA consultation on naloxone rescheduling

Authors

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The Centre for Research Excellence into Injecting Drug Use (CREIDU) is funded by the National Health and Medical Research Council to improve the health of people who inject drugs through research that generates new evidence and informs public health policy and practice. CREIDU brings together experts in injecting drug use from across Australia working in research, policy and practice. CREIDU wishes to make this submission on behalf of our members and key stakeholders.

CREIDU also auspices the Naloxone National Reference Group, a working group which include services and communities directly involved in the implementation of the 'take home naloxone' programs described below. CREIDU supports increasing the availability of naloxone in Australia to assist in reversing opioid overdoses which occur in the community.

The Therapeutic Goods Administration (TGA) is seeking submissions in relation to amending "the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3".

Our submission supports amending the scheduling of naloxone from Schedule 4 to Schedule 3.

1. Background

Opioid overdose is one of the key drug related harms in Australia. There were at least 613 accidental opioid-related deaths in 2010. (1) Responses are available, but they are limited in their effectiveness, meaning that new approaches are required to prevent opioid-related deaths (2).

Naloxone is a powerful opioid antagonist that has been used for the purposes of reversing the effects of opioids for over 40 years (3). In this capacity it has a variety of applications, but the most noteworthy is when it is used to reverse opioid overdoses. In Australia, this typically happens when ambulances are called to overdose events and naloxone is administered by paramedics. It is also used by emergency staff when needed in the Emergency Department (ED). Access to naloxone varies by jurisdiction in Australia but it is generally available for use by paramedics and medical practitioners for reversing the effects of opioids (4). Indeed, the drug has been available on prescription in Australia for many years, and was listed on the Pharmaceutical Benefits Scheme in April 2013. The naloxone that is now available in Australia on the Pharmaceutical Benefits Scheme is in the form of a pre-filled syringe, or Minijet[®], manufactured by UCB Pharmaceuticals. Although this formulation requires a needle to be attached to the syringe prior to use, and is suitable for intramuscular administration, there is scope for other routes of administration, such as intranasal, where a needle may not be required in future (5). These Minijets are currently available only in 400 microgram doses, a relatively small dose by international standards, and larger doses than this are often used in reversing opioid overdoses (6).

Naloxone is a drug with no documented abuse potential and no health or life threatening consequences if misused deliberately or used inappropriately (7).

2. Responding to opioid overdose

Research shows that there is considerable scope to intervene at opioid overdoses: most occur a considerable time after the use of the drug, with others present who could intervene effectively if given appropriate education and training on how to respond (7). There is evidence that simple bystander responses can significantly improve outcomes for people experiencing overdose (8). Indeed, both mortality and morbidity can be improved with more timely opioid overdose response; opioid overdose deaths are largely avoidable (2, 3, 7).

3. Take Home naloxone

Programs have been established to make naloxone more widely available so that it can be administered by people other than medical professionals to reverse opioid overdose in community settings (3, 7, 9). Termed 'take-home' naloxone (THN) or 'peer distribution of naloxone', these programs have been established in many countries since the first published reports of programs in the mid 1990s (10). International program guidelines for THN have

now been issued by the World Health Organisation (7). Largely as a result of the Australian heroin 'drought' (11) Australia has been a late adopter, with this country's first THN program only commencing in 2012 in the ACT (12). This was soon followed by similar prescription naloxone programs in New South Wales. Programs have since been established in South Australia, Western Australia and Victoria, with a fledgling program started in Queensland. The basic principle of existing programs is to provide training to potential overdose witnesses and victims on how to prevent and best respond to overdose (typically including airway management, basic life support, calling an ambulance, naloxone administration, and monitoring the victim) and then provide naloxone, or at least a prescription for naloxone, at the end of the training (7, 9, 12). The training models vary, reflecting program variations seen overseas (13, 14), however the primary target group of most THN programs is people who inject drugs (PWID) who use opioids. As THN programs have evolved in Australia, studies of PWID show increased awareness of the programs (15).

Most Australian THN programs have been run by peer-based drug user representative organisations (e.g. Canberra Alliance for Harm Minimisation and Advocacy, Harm Reduction Victoria). To date, we estimate that around 1000 people have been provided THN through their participation in take-home naloxone programs. Importantly, a significant number of reversals have been reported by participants in these programs. For example, at least 60 reversals were reported to the Harm Reduction Victoria program (of 475 trained participants) though to April 2015 (<http://hrvic.org.au/overdose/naloxone-update/>).

4. Risk of overdose

The main target group for take-home naloxone programs has been PWID who use opioids. This is because most opioid related deaths in Australia involve current or past exposure to injecting. PWID are traditionally a disadvantaged population, with poorer health and wellbeing than the general population and poorer outcomes across a range of domains (16). As a consequence, many are in receipt of government benefits with limited capacity to pay for medicines.

Within the broader population of PWID, those most at risk of opioid overdose include marginalised groups such as recently released prisoners, people who use opioids in public settings and people who have overdosed previously (17-19). Furthermore, those at risk of opioid overdose may be reluctant to call ambulances in the case of an overdose for fear of negative repercussions such as police attendance (20). Resourcing these groups with access to life-saving measures, and associated education, assists in both encouraging them to seek emergency medical care from professionals but also to administer life support themselves.

5. Costs and target groups

It is likely that groups other than PWID are now also at risk, such as those presenting with non-cancer chronic pain (21-23). We understand that there will be no cost implications for

the key target group in rescheduling naloxone to Schedule 3. We note that the current cost of naloxone for people on Health Care Cards is low (around \$6 for up to five 400mcg Minijets), and that this cost structure would remain for people obtaining naloxone through the S3 scheduling (i.e. over-the-counter) with a health care card. Cost implications should be a key consideration in any rescheduling, with the potential to even reduce costs for those not on a Health Care Card a possibility that should be factored into the TGA decision.

6. Barriers to THN programs

Most THN programs in Australia have received only limited funding for their activities, which has impacted on the scope and reach of existing programs, despite the potentially life-saving initiative being relatively low cost. Any initiative that has the potential to reduce costs to consumers and program providers and increase the accessibility and availability of naloxone is strongly supported by CREIDU.

7. Clear benefits of re-scheduling

Any strategy which lowers the threshold for disadvantaged and marginalised at risk individuals to access naloxone will be beneficial. Italy has had naloxone available over-the-counter since 1985, with no reported adverse effects. We believe that this shift would be of significant benefit here in Australia. Although there has been considerable success in reaching PWID, the key risk group in Australia, there is an urgent need for scale-up to reach more PWID, particularly those most at risk of overdose such as recently released prisoners (18), and people in other risk groups such as prescription opioid users (21). The ability to access naloxone under an S3 schedule will be an important step in this direction as it may provide extra opportunity for the engagement of pharmacists in the wider distribution of naloxone, particularly those engaged in dispensing as part of opioid substitution therapy (OST). Importantly, it will provide a simple mechanism for individuals who have participated in THN programs to replenish supply after they have used their supply or their supply is unavailable for other reasons (e.g. past expiry date).

8. Additional considerations

Pharmacists and representative bodies will need to develop mechanisms for training and quality assurance to ensure that those who obtain naloxone have the requisite skills to recognise the circumstances when the drug should be administered and subsequently how to administer the drug. Further, consideration will need to be given to appropriate packaging given that the Minijet[®] does not come with a needle supplied. Finally, work will need to be undertaken to raise awareness of the accessibility of naloxone amongst the target groups and pharmacists given the likelihood that individuals will obtain naloxone for use in emergency situations.

9. References

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