



Lifesavers:

a position paper on access to Naloxone
Hydrochloride for potential opioid overdose witnesses.

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Anex is a leading national voice in the public health sector. Since our inception as independent, non-profit organisation in the 1990s, we have worked to increase understanding and improve responses to the problems arising from the use of illicit drugs and the misuse of pharmaceuticals and alcohol.

Anex does not condone drug use, but strives to protect people from drug-related harm when at their most vulnerable.

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Policy Statement on use of Naloxone for potential opioid overdose

Naloxone Hydrochloride has no other action than to reduce the effect of heroin and other opioids. It does not result in intoxication. It has been used to safely reverse the effects of opioid intoxication in hospital and pre-hospital emergency situations for decades. Although Naloxone is currently only available on prescription in Australia, international experience demonstrates that non-medical personnel can be trained to safely administer Naloxone Hydrochloride to reverse the effects of opioid overdose and prevent death and disability.

Regulatory barriers in Australia need to be removed in order to allow non-medical personnel, including families of opiate users, access to Naloxone so that they may have access to this effective intervention to better respond to an overdose immediately and before paramedics arrive. After more than a decade of debate in Australia, steps should immediately be taken to have Naloxone rescheduled to make it available across the counter in pharmacies. Legal protection should be provided to non-medical personnel who administer it.

However, availability of take-home Naloxone should not be postponed until after these legal steps have been completed. Needle and syringe program (NSP) personnel should be immediately trained so they may educate their participants and, in partnership with physicians who are willing to help, begin distributing Naloxone to opiate addicts and other potential overdose witnesses. Naloxone should be made available to such non-medical personnel free of charge through controlled programmes.

Background

Opium derivatives (opiates) such as heroin, and synthetic pharmaceutical drugs of a similar action, are called 'opioids'. They are Central Nervous System depressants, which, in an overdose, cause gradual suppression of respiration. If no intervention is made an opioid overdose can lead to permanent brain injury or death. It has been estimated that 10 per cent of heroin overdoses are fatal in Australia (1). During Australia's 'heroin glut' (2), more than 1100 fatal opioid overdoses were reported in 1999 (3). Although in recent years the numbers of deaths have significantly reduced, it is estimated that one person per day experiences a fatal opioid overdose, usually involving heroin injection (4).

Naloxone Hydrochloride is a drug that is more commonly known by the trade name of Narcan® (5). Naloxone is a pure opioid antagonist. It reverses the effects of natural and synthetic opioids such as codeine, heroin, methadone, morphine and propoxyphene (6).

Naloxone is non-addictive and safe, primarily because it does little else but counter the depressant effects of opiates. Manufacturers specifications recommend storing Naloxone below 25 degrees Celsius and protecting it from light (6), but no other protective measures are necessary for storage. The liquid form (for injection or for nasal insufflations) has a shelf life of at least two years. Naloxone is not patented in Australia.

How it is used

Naloxone is used by medical personnel to reverse opioid overdoses in pre-hospital settings (such as ambulance attendances) or in hospitals (7, 8). Thousands of lives are saved and severe brain injuries prevented each year by Australian paramedics who carry Naloxone as part of their standard practice (9).

Naloxone is generally administered by injection either intravenously in hospital settings, or intramuscularly in a pre-hospital settings. (10). However, it can also be administered via a nasal spray device which converts the Naloxone liquid into a fine mist (11). Nasal administration is an attractive option for practitioners concerned about possible needle-stick injuries (12). Application by nasal spray has been trialled by paramedics in Victoria where it was found to be effective and safe (13).

Naloxone availability in Australia: Who can use it

Although being a non-addictive, safe and an indisputably lifesaving drug, Naloxone Hydrochloride is classified as a Schedule 4 drug by the Therapeutic Goods Administration in Australia (8). This means that it can only be administered by trained medical staff, such as paramedics, or prescribed by a doctor to a person who would then present the script at a pharmacy (4).

Doctors have generally been unwilling to prescribe Naloxone to lay people, for example, a person who is at risk of opioid overdose or the parents of a person at risk. This is usually out of concern that they may face liability if the eventual recipient of Naloxone did not recover or acquired a brain injury. This concern is possibly over-cautious; in the US Naloxone distribution has occurred for more than 10 years without any legal threat (14).

Availability of Naloxone to non-medical personnel in other nations

Increasingly, Naloxone is being made available to those who can be termed “potential overdose witnesses”. Early pilot studies in the mid-1990s in the Emilia-Romagna region of Italy began making Naloxone available to heroin users so that their family or peers can reverse overdose quickly while waiting for emergency medical care to arrive (15). By 2000 reports were emerging from Germany that drug users themselves, when trained to administer Naloxone, could successfully reverse other peoples’ opiate overdoses (16).

Despite legal uncertainties, the first United States program to prescribe injectable Naloxone was established in Chicago in 2001 (17), and by 2010 had distributed Naloxone to more than 15,000 potential overdose witnesses, and received reports of more than 1500 successful overdose reversals. The United States now has more than 50 programs under which Naloxone is provided to potential overdose witnesses who are now credited with saving thousands of lives (4, 18).

Depending on the program, Naloxone is made available to laypeople, including drug users themselves, in various injectable and nasal spray formulations (5, 19).

To address legal uncertainties, several US states have enacted ‘Good Samaritan’ legislation, protecting any person who prescribes or administers Naloxone from liability, providing the Naloxone is given “in good faith”. In Boston City, regulations have been passed under which the city’s Board of Health assumes liability for the work of medical and non-medical personnel involved in the program (19).

In England, 16 sites were selected in 2009 for a pilot program under which Naloxone would be provided to friends, parents and siblings of people at risk of opiate overdose. That program is being administered by England’s National Treatment Agency (20).

Reviews of American and most European Naloxone Distribution Programs (NDPs) reveal several universal findings:

1. Lay persons who have been trained by experienced personnel (medical and non-medical) can accurately identify opiate overdose, and can effectively reverse the overdose using Naloxone.
2. Naloxone’s efficacy in reversing opiate overdose is well documented in the medical literature.
3. Thousands of overdose reversals have been performed by lay people in non-medical settings, with virtually no adverse events (including no severe opiate withdrawal) observed using the formulations and dosages recommended by the NDPs (19).
4. Availability of Naloxone does not exacerbate opiate usage in people who are opiate dependent; programs notice that availability of Naloxone is associated with increased likelihood of accessing addiction treatment (17).

What can occur in Australia to make Naloxone available to potential overdose witnesses

Rescheduling Naloxone

Naloxone can be rescheduled from S4 to either S3 or S2 through an application via the Therapeutic Goods Administration. Anex has been informed that no such application has been lodged since Naloxone was first scheduled as an S4 drug in 1973 (21).

If Naloxone Hydrochloride (as a base) was classified as a Schedule 3 (S3) drug, a person would be able to buy it from a pharmacy after consulting a pharmacist.

If Naloxone was classified as a Schedule 2 (S2) drug it could be available off-the-shelf so that a person could purchase it without needing to consult a pharmacist.

Either of these interventions would need to include widespread education of drug users and other potential overdose witnesses regarding the availability and proper use of Naloxone.

Provision to Needle and Syringe Program services

Needle and syringe programs (NSPs) may be the only health services that people who inject opiates access on a regular basis; usually they are the only health service that injectors trust.

It is Anex's position that NSP staff are in a good position to provide people at risk of overdose and potential witnesses to overdose access to Naloxone in addition to training and advice on how to store Naloxone and it administer it. This model has proved effective internationally, particularly in the United States (7, 12).

It is Anex's position that NSP staff should be trained to administer Naloxone in order that they may reverse overdose that occur in close proximity to the NSP service.

There are a number of situations where there is a greater risk of drug overdose and therefore potential for witnesses to an overdose to access Naloxone. For example, death by overdose following incarceration is a major risk; the prison system should begin providing overdose education to inmates, and distributing Naloxone to them at release. In the same spirit, abstinence-based treatment programs should educate patients that relapse is likely, and that relapse after a period of abstinence carries a high risk of overdose. Abstinence-based treatment programs should educate patients and their families about overdose prevention and recognition, and should make Naloxone available to all opiate-addicted patients who choose to attempt abstinence.

Opioid Replacement Therapy (ORT) practitioners

Current doctor-to-pharmacist ORT systems are suitable for making Naloxone available to potential overdose witnesses, particularly ORT clients themselves. Opiate overdose is not a problem unique to heroin. The early weeks of induction onto methadone, for purposes of maintenance, carries a high risk of overdose (22). Doctors and pharmacists involved in opiate replacement therapy (ORT) should educate patients and their support networks, and make Naloxone available to them from when they commence treatment. Having Naloxone available in the home is also crucial prevention in the case of accidental ingestion by a non-tolerant individual, particularly children.

Family support and consumer organisations

Publically-funded organisations representing people who take illicit drugs exist throughout Australia. Such bodies, known as peer-based organisations, should be involved in establishing Naloxone distribution programs. Family Drug Support and other such bodies are in an ideal position to facilitate access to Naloxone for parents and siblings of people at risk of opioid overdose.

The same potential problems apply with patients being treated with opiates for chronic and acute pain. Any patient who is prescribed high-potency opiates (e.g. oxycodone and fentanyl) should also be given education and access to Naloxone if appropriate. The danger of accidental home ingestion by a non-tolerant individual exists for these prescribed opiates as well.

Recommendations

It is the position of Anex that the following should occur to increase availability of life-saving Naloxone to potential overdose witnesses, including opiate consumers:

- Doctors and pharmacists who participate in ORT be encouraged to make Naloxone available to potential overdose witnesses.
- If rescheduled from S4 to S3, pharmacists who participate in ORT programs should be actively encouraged to stock and sell Naloxone.
- Each State and Territory jurisdiction should amend legislation to legally protect health staff (including needle and syringe program workers) and lay people from legal recourse if they prescribe or administer Naloxone in good faith.
- With haste, a sponsoring agency should be identified and then proceed with an application to have Naloxone in its current product forms rescheduled to S3.
- Naloxone should be provided to NSP service staff who should be trained to make them available to potential overdose witnesses, including family members of people who are at risk of an opiate overdose.
- A mechanism should be put in place to monitor the effectiveness of Naloxone administered in these emergency situations.

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