- Department of Health (https://www.gov.uk/government/organisations/department-of-health)
- Medicines & Healthcare products Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)
- Public Health England (https://www.gov.uk/government/organisations/public-health-england)

See more information about this Guidance (https://www.gov.uk/government/publications/widening-the-availability-of-naloxone)

Guidance

Widening the availability of naloxone

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Naloxone is the emergency antidote for overdoses caused by heroin and other opiates/opioids (such as methadone and morphine).

The main life-threatening effect of heroin and other opiates is to slow down and stop breathing. Naloxone blocks this effect and reverses the breathing difficulties.

On the 1 October 2015, new regulations came into force, which allows for widening of the availability of naloxone.

1. What the new regulations mean

A range of drug treatment services can order naloxone from a wholesaler so that people engaged or employed in their services can, as part of their role, make a supply of the naloxone available to others without a prescription. This is so that the naloxone supplied to others can be used in the case of a suspected heroin (or other opiate) overdose to try and save a life.

2. Who can supply naloxone

People employed or engaged in the provision of drug treatment services in the course of their drugs work can supply naloxone that has been obtained by their service to others, as long as it is supplied to others for the purpose of being available to save life in emergency. A prescription is not needed for the naloxone to be supplied in this way.

'Drug treatment services' for this purpose are those provided by, on behalf of, or under arrangements made by, one of the following bodies:

- an NHS body
- a local authority
- Public Health England (PHE)
- Public Health Agency

The sorts of drug treatment services that meet this definition to be suppliers of naloxone include but may not be limited to:

- drug services commissioned from primary care providers
- drug services commissioned from secondary care providers (including a range of specialised community and inpatient drug services)
- commissioned services providing needle and syringe programmes (including those provided from pharmacies)
- pharmacies providing drug treatment services

For example, a worker in a recognised drug treatment service could supply naloxone for use in an emergency, without the need for a prescription, to a family member or friend of a person using heroin, or to an outreach worker for a homelessness service whose clients include people who use heroin.

Current clinical guidance recommends that such naloxone supply should be accompanied by provision of suitable training and advice for those who are supplied the naloxone.

2.1 Prison drug services

As prison drug treatment services are commissioned by the NHS, they are also covered by the new regulations.

2.2 Local police forces

Local police forces aren't affected by the new regulations, but under existing legislation, police force doctors are able to order stocks of naloxone, which could then be given to individual police officers who, in the course of their duties, may come across heroin (or other opiate) users, eg in custody suites, etc.

2.3 Needle and syringe programmes

Needle and syringe programmes, so long as they are commissioned by local authorities or the NHS, count as lawful drug treatment services for the purposes of naloxone supply.

2.4 Pharmacists providing drug treatment services

Pharmacies providing drug treatment services (such as opiate substitution treatments through supervised consumption schemes) count as lawful drug treatment services for the purposes of naloxone supply.

3. Products that drug services can supply

The regulations specify that the naloxone products that can be supplied without prescription by drug services:

- solely contain naloxone
- are prescription only medicines
- have been produced to be given parenterally

In practice this refers to naloxone products produced for use by injection.

There are different ways in which available products are put together to deliver the naloxone, and in how they are packaged and supported by written information and training. There should be suitable advice and/or training to help those supplying and receiving the product to understand the product and its use.

4. Responsibility for deciding who can actually supply naloxone locally

The organisations locally that are responsible for arranging provision of drug treatment services, and the drug treatment service providers themselves, as part of normal clinical governance arrangements, will need to ensure that naloxone is being supplied by competent individuals employed or engaged in treatment services, and that the supply by them is safe.

See the Further advice section for:

- further guidance on how naloxone products can be provided safely for this purpose
- guidance from PHE on what training should cover and how to respond to an overdose

Advice is also available in the 'Open letter from Professor John Strang (https://www.gov.uk/government/consultations/drug-misuse-and-dependence-uk-guidelines-on-clinical-management), Chair of the 'Clinical Guidelines update working group', indicating "a minimum level of training in how to assemble and use the particular product" is essential and that "other training will also be helpful".

Local decisions about how best to supply naloxone in line with this guidance may determine which employees or volunteers within the drug treatment service are considered to be suitable to supply the naloxone.

5. People who can be supplied naloxone

The regulations do not limit supply to specific individuals, except to state that the "supply shall be for the purpose of saving life in an emergency". Therefore, naloxone could be supplied to any of the following:

- an outreach worker
- a hostel manager
- a drug user at risk
- a carer, a friend, or a family member of a drug user at risk
- any individual working in an environment where it is considered there is a risk of overdose for which the naloxone may be useful

Although the new regulations do not allow those individuals who have been supplied the naloxone by a lawful drug treatment service to supply it on to others for their possible future use at a later date, it remains the case that in an emergency situation anyone can use naloxone to save a life whatever the source.

6. Patient Group Directions and Patient Specific Directions

The new regulations mean that commissioned drug treatment services are now able to supply naloxone directly to individuals without the need for a prescription or the need for Patient Group Directions (PGDs) or Patient Specific Directions (PSDs). However, PGDs and PSDs are still available and can still be used whenever appropriate. They may be particularly useful in some situations, such as when naloxone is to be

supplied outside of a local-authority-commissioned or NHS-commissioned drug treatment service.

7. Naloxone’s status as a prescription only medicine

Naloxone cannot be sold over the counter. It remains a prescription only medicine (POM) but one that is exempted from the POM requirements under specified circumstances, ie when being supplied by a drug treatment service for the purpose of saving life in an emergency.

8. Using naloxone to save a person’s life without their permission

Under the new regulations, it is legal to provide a family member or friend of a heroin/opioid user with naloxone without the express permission of the person who is using the heroin/opioid, as long as it is being supplied by the drug treatment service in order for the family member or friend to be able to use it to save life in an emergency. There is, however, an ethical question for local areas concerning the appropriateness of such supply without the drug user knowing or agreeing. We would expect that this issue would be addressed within local protocols and through local clinical decision making processes.

9. Clinical governance in drug treatment services

The new regulations do not create any legal requirements or make recommendations to services on the clinical governance procedures they should have in place covering the acquisition, storage or use of naloxone. However, authoritative guidance has been produced recommending that relevant advice and training should be provided alongside the arrangements for supply of naloxone under these new regulations. This may include developing suitable local protocols covering choice and supply of naloxone (which may include summarising indications for supply locally, product choice, training, storage, monitoring and record keeping).

10. Guidance for hostels/homeless shelters/housing associations, etc

10.1 Acquiring and storing naloxone

You should contact your local drug treatment service and discuss with them, with the support of commissioners, issues such as how much naloxone your staff, residents, volunteers etc may need to have supplied, its safe storage and review, and suitable record keeping of any supply and use.

10.2 Storing and using naloxone

There are no legally set protocols. However, it would be good practice to ensure that you have robust protocols in place covering your use of naloxone, eg training, record keeping, storage, access and use in emergency. PHE recently published advice on naloxone (http://www.nta.nhs.uk/uploads/phetake-homenaloxoneforopioidoverdosefeb2015rev.pdf), including points around record keeping, which you may find helpful.

We would suggest that you also discuss these issues with the drug service that is providing the naloxone.

10.3 Paying for the supply of naloxone and training

You should contact your local drug treatment services and work with them to see whether and how, with the support of commissioners, they can train and support relevant members of staff and/or volunteers and/or services users.

While the new regulations enable lawful drug treatment services to supply naloxone to individuals without the need for a prescription, this does not address the issue of funding. Decisions will need to be made within local areas about the funding mechanism and who pays for what.

11. The cost-effectiveness of widening availability

It is very difficult to carry out definitive research to prove that widening the availability of naloxone is cost effective, not least because of the scale of the studies that would be needed. However, there is consensus that widening the availability of naloxone increases the potential impact for saving life.

Research from the USA, modelling the likely cost-effectiveness, found that naloxone distribution "was cost-effective in all deterministic and probabilistic sensitivity and scenario analyses, and it was cost-saving if it resulted in fewer overdoses or emergency medical service activations". [1]

12. Risks associated with widening availability

12.1 Evidence of risk of increasing overdose or risky behaviours

Surveys of people who use opiates suggest that widening the availability of naloxone does not encourage overdose or risky behaviours. As naloxone can induce rapid and unpleasant withdrawal from opioid drugs, its use is likely to be something that people who use these drugs are generally keen to avoid. However, lawful drug treatment services, as part of normal clinical governance will continue to consider any evidence of new harms from treatments they have provided.

12.2 Misuse of naloxone

Naloxone has no psychoactive properties itself, and it therefore has no intoxicating effects or dependence potential. Using it can, in fact, cause uncomfortable opiate withdrawals.

If any new evidence of misuse of naloxone was identified by drug treatment services, it would be normal clinical governance practice for them to consider any actions that may be needed in response, including any sharing of this information, and to incorporate any lessons learned for future practice.

12.3 Dangers associated with naloxone

Like other medicines, naloxone can cause side effects in some individuals. Side-effects reported include:

- feeling or being sick
- tremor
- sweating
- over-breathing (associated with an abrupt return to consciousness)
- fast heart beat or disturbed heart rhythm
- increased or decreased blood pressure
- fluid on the lungs
- fits

However, as naloxone in this context would be given to an individual who is believed to be facing a potentially imminent fatal opiate overdose, such risks of side-effects would be largely irrelevant in the decision whether to use it or not. However, the possibility of reducing unnecessary side-effects and discomfort, through careful, graduated, use of naloxone according to the instructions for the particular product involved, will be likely to a common element of advice and training provided. Such careful use may also have the benefit of limiting the unpleasant withdrawals the heroin/opioid user may otherwise feel as they come round.

An additional important, uncommon, side-effect reported from naloxone use, particularly if high doses of naloxone are given rapidly, is the risk of triggering cardiac problems in susceptible people, which in some cases could be fatal. As noted above, given that the naloxone is intended be given to an individual already facing the risk of a fatal overdose, the small risk of triggering such a serious cardiac problem is not a reason to avoid its use. The advice on using naloxone for overdose already addresses its careful use to try to mitigate such risks. It is recommended to start with a sufficient but relatively small dose of naloxone, providing further small doses as needed. Taking this graduated approach to giving the naloxone, in simple steps, will be a key element of any locally provided information materials and/or training.

12.4 Risk of using the naloxone kit to inject illegal drugs

Injecting equipment is already freely and widely available from needle and syringe programmes, primarily to prevent the spread of blood borne viruses, for which purpose the use of 'clean' needles and syringes is clearly recommended. It is recommended that anyone in need of such equipment should be directed to their local needle and syringe programme so that they don't try to use needles and syringes provided for naloxone that are less suitable and may cause health problems, such as damaging veins, if used repeatedly.

13. Further advice

Public Health England has produced guidance (http://www.nta.nhs.uk/uploads/phetake-homenaloxoneforopioidoverdosefeb2015rev.pdf) for commissioners and providers.

The Clinical Guidelines Update Working Group, which is updating the UK Guidelines on the Clinical Management of Drug Misuse and Dependence, has set up a sub-group on naloxone which prepared preliminary advice (http://www.nta.nhs.uk/uploads/chairsletter-naloxone-22july2015.pdf) on the use of naloxone.

More detailed advice will be included in the updated guidelines, expected to be published in 2016.

Your local drug treatment service will also be able to offer advice and help. Their details can be found through NHS Choices (http://www.nhs.uk/Service-Search/Drug-and-alcohol-Services/LocationSearch/496).

You can also email the Department of Health.

1. Coffin PO and Sullivan SD, 'Cost-effectiveness of distributing naloxone to heroin users for lay overdose reversal', Annals of Internal Medicine, 2013 Jan 1;158(1):1-9. ↩