Naloxon can save lives

– assessments of the current situation and next steps

Translation of SOU 2022:54

Interim report of the Drug Commission of Inquiry

Stockholm 2022

SWEDISH GOVERNMENT INQUIRIES

Swedish Government Official Reports

SOU 2022:54

The English version of this report is only available in Portable Document Format (PDF)..
Available online: www.sou.gov.se

Layout: Committee Service Unit, Government Offices of Sweden
Translated into English by Språkservice Sverige AB
Stockholm 2022

To Minister Ardalan Shekarabi

On 24 March 2022, the Government decided to commission a special investigator to propose how a continued restrictive drugs policy can be combined with effective drug prevention work, good care for harmful use and addiction and addiction issues that includes harm reduction measures, and measures to ensure that no one dies as a result of medicine and drug poisoning.

The inquiry was also commissioned to analyse, in an interim report on 14 October 2022, whether members of occupations other than health professionals, and if so which ones, should be able to administer naloxone against opioid overdoses and, if necessary, to submit legislative proposals on how this should be regulated. On 24 March 2022, Thomas Lindén, Head of Department at the National Board of Health and Welfare, Department for Knowledge Management in Health care, was appointed as a special investigator.

On 20 June 2022, the following persons were appointed as experts to assist the investigation: Ministry Secretary Kalle Brandstedt, Deputy Assistant Sophia Busk, Area Assistant Linda Mohlin, Deputy Assistant Anders Persson, Deputy Assistant Annika Remaeus and Area Assistant Secretary Helena Rosén. Kalle Brandstedt resigned on 29 September 2022 and Deputy Assistant Hanna M Eriksson was appointed on the same day. On 20 June, the following experts were appointed: Education Advisor Annika Berggren, Acting Director of Operations, Birgitta Dahlberg, Social Law Officer Monica Engström, Chairperson Inger Forsgren, Head of Unit Thomas Hvitfeldt, Senior Physician Sahar Janfada-Baloo, Head of Unit Martin Lardén, Specialist Psychologist and Operations Coordinator Johannes Lundell, Administrator Mikael Malm, Development Manager Jonas Melinder, Administrator Zophia Mellgren, Inspector Ulf Modin, Union Chairperson Sofia Rydgren Stale, Head of Unit Joakim Strandberg,

Medical Expert Pontus Strålin, Head of Unit Marcus Sverdén and Investigator Lena Thunander Sundbom.

On 2 May 2022, Lina Pastorek was appointed as the principal secretary of the commission of inquiry. The secretaries of the commission of inquiry appointed on 1 June 2022, were investigator Martin Lindblom and investigator Helena Löfgren, who was initially employed part-time but beginning on 1 August, worked full-time. On 13 June 2022, Anne Terdén, a legal expert, was hired as secretary of the investigation.

The inquiry has appointed a scientific reference group to assist the commission of inquiry in its work. The scientific reference group consists of Associate Professor Mats Anderberg, Professor Anne Berman, Associate Professor Disa Dahlman, Professor Johan Franck, Professor Markus Heilig, Professor Björn Johnson, Associate Professor Moa Kindström Dahlin, Dr Martin Kåberg, Dr Håkan Leifman, Professor Lena Lundgren and Professor Anette Skårner.

We would like to thank all the staff, representatives of entities and organisations that have contributed their knowledge and experience. In particular, we would like to thank representatives of civil society who have also contributed to the work, as well as Elisabeth Berglind from the Swedish Healthcare Association.

The inquiry hereby submits the interim report *Naloxone can save lives – assessments of the current situation and next steps* (SOU 2022:54).

Stockholm in October 2022

Thomas Lindén

/Lina Pastorek
Anne Terdén
Martin Lindblom
Helena Löfgren

Content

Content **5**

Summary **9**

1 Background and mission **11**

1.1 Directive 11

1.2 Work of the commission of inquiry and details about the component tasks 12

1.3 Delimitation and interpretation of the directive for the interim report 14

1.4 Language use and concepts 16

1.5 Delimitations in relation to ongoing government commission on naloxone 17

2 Description of the problem and state of knowledge **19**

2.1 The medicine naloxone can stop opioid poisoning 19

2.2 Which persons should be given access to naloxone according to national guidelines? 20

2.3 There are limited medical risks associated with the use of naloxone 21

2.4 Mortality due to medicine and drug poisoning 22

2.5 Naloxone can only affect deaths where opioids were taken 23

2.6 When and where is the risk of opioid poisoning at its greatest? ... 24
2.7 Is naloxone effective in limiting deaths as a result of drug or opioid poisoning? ... 26
2.8 Which occupational groups are present at sites where opioid poisoning occurs? ... 27
2.9 International and national initiatives about naloxone and a brief history ... 28

3 International experiences with naloxone ... 33

3.1 The experience of international organisations ... 33
3.2 The situation in the EU ... 34
3.3 France ... 34
3.4 Estonia ... 35
3.5 Italy ... 35
3.6 Norway ... 36
3.7 Denmark ... 37
3.8 Finland ... 38
3.9 Iceland ... 38
3.10 USA ... 39
3.11 Summary of international experiences ... 40

4 Current law ... 41

4.1 Healthcare Act ... 42
4.2 Patient Safety Act ... 44
4.2.1 Who belongs to health professions? ... 46
4.2.2 Health care outside the HSL ... 48
4.3 Patients Act ... 49
4.3.1 Consent in health care ... 50
4.3.2 Exceptions to consent ... 52

4.3.3 The general necessity provision in Chapter 24, Section 4 of the Criminal Code 54

4.4 Prescription, requisition and administration of naloxone 57
4.4.1 Approval and requirements for the dispensing of naloxone 57
4.4.2 Prescribing naloxone 58
4.4.3 Self-care and dispensing of naloxone 60
4.4.4 Administering naloxone 61

4.5 Summary 62

5 Ethical principles and assessments 63

5.1 The ability to save lives is of paramount importance in a hierarchy of values 63
5.1.1 Different values and perspectives that need to be balanced if other professionals are to administer naloxone 63

6 Analysis and assessments 67

6.1 Naloxone is one of several interventions intended to prevent opioid-induced death 67
6.1.1 Reducing medicine and drug-related deaths requires much more than naloxone 67
6.1.2 Implementation of naloxone distribution to individuals needs to be improved 68
6.1.3 A new policy needs to face future challenges 69

6.2 Implementation efforts require both regulation and support 70
6.2.1 Current law creates ambiguity about what occupational groups can and cannot do regarding naloxone 71
6.2.2 Implementation of naloxone outside the healthcare system lags behind 72
6.2.3 The work with defibrillators and CPR can serve as inspiration 73

6.2.4 Willingness and support high up in an organisation play a role in implementation 74

6.3 Should members of other professions and occupations be able to administer naloxone and if so, which ones? 75
6.3.1 Naloxone should be administered by occupational groups outside the healthcare system, as well 75
6.3.2 Should it be an option or an obligation to administer naloxone? 76
6.3.3 The concept of occupational groups needs to be expanded to include entities and places 77
6.3.4 Possible assessment criteria for the continued work of the Drug Commission of Inquiry for proposing which occupational groups should be allowed to administer naloxone 79

6.4 Summary and further investigation 82

7 Legal conclusions 85

7.1 Opportunities and obstacles in existing legislation 86
7.1.1 Legal requirements for health care relevant to other occupations 87
7.1.2 Is the general necessity provision a viable option 88
7.1.3 Possibilities of naloxone administration in healthcare legislation 90
7.1.4 Medicines by requisition 90
7.1.5 Pharmacotherapy with general directives 92
7.1.6 Concluding discussion 94
7.1.7 Further investigation by the Commission of Inquiry 95

8 Conclusions 97

References 99

Appendix 1 107

Summary

Naloxone is a medicine that saves lives by reversing opioid poisoning and does so with limited medical risks. A number of initiatives have been taken in recent years to increase the availability of naloxone in Sweden. We have been tasked with considering whether non-health professionals should be allowed to administer naloxone to a person suffering from opioid poisoning who is unable to administer the drug themselves, and if so, how this should be regulated.

In this interim report, we consider that access to naloxone needs to be included as one of several interventions in a national programme to prevent medicine and drug-associated mortality. Nasal sprays containing naloxone can save lives and are an existing tool that needs to be made more widely available in the community than is currently the case. The Drug Commission of Inquiry will later submit proposals for such a national programme in its final report, in which naloxone is deemed to be one of several components.

Although many cases of opioid poisoning take place at home, this is far from universal. In this interim report, we take the position that, in principle, in order to save lives, it should be possible for non-health professionals to administer naloxone in the event of opioid poisoning as part of their work-related duties. However, for this to be possible, we need to continue the investigative work in order to make proposals regarding the appropriate regulation and support for implementation.

In this interim report, we begin with an analysis of the various professional groups and staff in different entities that could be given the opportunity to administer naloxone. We have two alternative directions for further work, depending on what is deemed legally possible. In order not to exclude any professional group from being able to administer naloxone within the scope of their duties, an exception to the current law could be considered and would then

need to be further investigated. If this cannot be done for legal reasons, we propose different groups of professions and entities as a basis for our further investigation and analysis. This grouping balances different perspectives, knowledge of places, occupations, current research and legal conditions.

Our assessment is that the legal exception of necessity should not be used as a basis for systematic work with naloxone in the community where professionals administer naloxone as part of their work. Therefore, other legally viable solutions need to be identified and we make no legislative proposals in this report. The ability of non-health professionals to administer medicine to individuals without consent raises several legal issues that need to be further investigated and different options analysed. Treatment with medicine is required by law to be carried out in the healthcare sector under carefully regulated conditions. The report discusses possible regulatory ways forward. For naloxone to be administered by others outside the health care system, two conditions are necessary: first, access to the drug is required, and second, the authority to administer it to a person with opioid poisoning is needed. Both of these conditions need to be addressed in future regulation.

In this report, we have also provided an international perspective that shows that some countries, such as the United States, Norway and Denmark, have made naloxone more widely available in society. We will continue to study these solutions in more detail in order to draw inspiration, particularly with regard to the legal conditions these kinds of solutions in Sweden.

In addition to the legal conditions that need to be put in place and clarified to ensure equal treatment across the country, various forms of implementation support or guidance should also be considered.

1 Background and mission

In this chapter, we describe the directive, how we have organised our work, definitions and delimitations, and the issues addressed in the report.

1.1 Directive

At the Government meeting on 24 March 2022, the Government decided to issue a committee directive for a Swedish drug policy adapted to the challenges of today and the future. In brief, the directive provides that a special investigator is to propose how a continued restrictive drugs policy can be combined with effective drug prevention work, good care for harmful use and addiction that includes harm reduction measures, and measures to ensure that no one dies as a result of medicine and drug poisoning.

The aim of the commission of inquiry is to ensure that drug policy is consistent with the requirements of evidence-based care, best practice and harm reduction, and that it evolves and adapts to present and future challenges. These elements are to be reported in the final report by 29 September 2023 and are outside the scope of this interim report. The directive requires the commission of inquiry to submit an interim report by 14 October 2022 on the following component tasks:

> Analysing whether occupational groups who are not health professionals should be allowed to administer naloxone for opioid overdoses and, if so, which groups, and, where necessary, make legislative proposals as to how this should be regulated.

Naloxone is an opioid antagonist and an antidote to all kinds of opioids such as heroin, methadone, fentanyl, buprenorphine, tramadol and oxycodone. Through the use of naloxone, opioid poisoning can be treated and lives can be saved.

1.2 Work of the commission of inquiry and details about the component tasks

The commission of inquiry known as "A Swedish Drug Policy Adapted to the Challenges of Today and Tomorrow" has chosen to call itself the "Drug Commission of Inquiry." The investigator is solely responsible for the content of the report. The report is written in a first-person plural form, with "we" referring to the investigator and the secretariat.

Since the directive for the commission of inquiry was issued in March 2022, we have focused on planning the work ahead, developing work plans, recruiting staff, identifying reference groups and establishing the necessary external contacts. In addition to the expert group appointed by the Government Offices, a scientific reference group has also been established. By the time this interim report is submitted to the Government, both the expert group and the scientific reference group will have met once. In addition, we have held a hearing for civil society and organisations with knowledge in the field of drugs. Views on naloxone from all these meetings have been taken into account in the preparation of this interim report. We have also initiated a collaboration with Samhällsnytta AB at Karlstad University that conduct interviews and meetings with people who use drugs, to ensure that our work and proposals are based on their needs.

We were not fully staffed until August 2022, which limited the ability to conduct a full analysis of the sections regarding naloxone medicines that according to the directive must be reported to the Government by 14 October 2022. We will therefore not now provide a full analysis or legislative proposals. The interim report contains preliminary assessments on which we intend to work further. In line with this, the interim report does not contain an impact assessment.

The interim report is mainly based on reports produced by international and national authorities, research compilations, scientific articles as well as meetings and discussions with individuals, authorities and organisations with experience of naloxone use. The legal part of the report is based on existing law, primarily in the area of medical law and related areas. An international overview has been undertaken in order to gather knowledge from other countries and international organisations about their experiences with naloxone. The overview is mainly based on responses we received from the Ministries of Health of these countries to questions about how they regulated naloxone outside the health sector. This overview is presented in Chapter 3.

Although this interim report covers only part of our directive, it may be worth noting that several elements that are not due to be reported until 29 September 2023 are closely linked to the question of whether it should be possible for other occupations to administer naloxone. These include the link to the points in the directive for the commission of inquiry that require us to:

- Carry out an analysis of the outcome of efforts undertaken in an international context to reduce drug-related deaths,
- Propose a national programme to reduce the number of deaths from medicine and drug poisoning; and
- Propose a model for effective monitoring of treatment for harmful use and addiction, including effective monitoring of the use of naloxone and how this monitoring will evolve over time.

This means that proposals to allow members of occupations other than health professionals to administer naloxone must be linked to any future proposals for mortality reduction programmes. The same applies to the mandate to propose a model for monitoring naloxone use. We intend to return to this in the final report.

1.3 Delimitation and interpretation of the directive for the interim report

The directive for the commission includes the following:

> The availability of naloxone could be further increased if naloxone could be prescribed in such a way that additional professionals could administer the medicine to persons who have overdosed. Having a greater number of groups in possession of, and allowed to administer, naloxone can produce a rapid and effective response to save lives. The Medical Products Agency and the National Board of Health and Welfare determined in 2018 that proposals to enable key groups outside the health sector to possess and administer naloxone to another person need to be investigated in a specific order. These agencies noted that such a proposal would necessitate comprehensive considerations of, among other things, constitutionally protected rights, and any legislative changes this would require would likely have to be made by statute to a large extent. In addition to this, it is important that work environment, responsibility and competence issues are examined in relation to the mission and conditions of the actors involved.

We have interpreted the directive to mean that our mission is not primarily focused on how individuals, such as family members, patients or the general public, should access naloxone. However, this issue is an urgent one. We may wish to return to this issue in our final report when we propose a national programme to reduce mortality from drugs or medicines. In some parts of this report we have also needed to describe the regulatory framework and prescriptions to individuals, as well as the ability of individuals to administer naloxone. Our task is primarily to analyse and investigate the legal possibilities for other occupations outside the health sector to do so, although it is also important to work towards increasing the availability of naloxone for individuals, as well.

Members of occupations other than health professionals are defined as occupations and entities that are not subject to the health regulatory framework (see Chapter 4). Furthermore, we have determined that our task, according to the wording of the commission of inquiry directive with regard to *administering*, is limited to the question of which occupational groups should be able to *administer*[1] the drug to a person who has suffered opioid poisoning and who is unable to

[1] The term "administer" has a more specific meaning than "give". Administering means giving the finished medicine to a patient and is distinct from the concept of handing over the medicine. For example, pharmacists may dispense medicines, but not administer medicines.

administer the drug himself in that situation. *Administering* implies that the occupations in question also have access to naloxone, which is why these considerations are also addressed in the report. We have therefore not investigated whether these occupations could also give in the sense of transferring/dispensing the drug to individuals (such as people who use drugs and relatives). However, this is a pressing issue to which we may need to return in the forthcoming work.

A further important limitation in our work concerns the meaning of the word "*allowed to* give" in our directive, i.e. whether occupations outside the health sector should be *allowed to* give this medication. We interpret this to mean suggesting which these occupations are deemed to need to be able to administer naloxone as part of their job role. *Allowed* could also be interpreted to imply a degree of voluntariness, as opposed to an obligation. We are therefore exploring the issue in terms of both being *allowed to* if you want to as a lay person and the risks and/or challenges it entails, and *being able to do so as part of* one's job as a member of an occupation, with all that this entails.

We have limited the work to focus on occupations that encounter people who engage in harmful use or are addicted. Opioid poisoning can also affect people who use prescribed opioids as part of their medical care, such as patients suffering from pain, in other words, patients without harmful use or addiction. The assessment is that these patients mainly encounter healthcare professionals who are already covered by regulatory frameworks that allow both access to naloxone and administration of naloxone. Therefore, they are excluded in this work. However, these patients' ability to access naloxone may need to be further explained, and we may need to return to this in our final report.

In this interim report, we primarily analyse nasal sprays containing naloxone and not naloxone in other preparations.

In summary, we have limited this interim report to focus on

- Occupations, rather than individuals, outside the health sector,
- The regulatory framework that currently relates to this area,
- The trade-offs that need to be made between different values and interests in order to regulate the area,

- Which occupations will be able to access and administer naloxone, and
- What is required in order for this to be done systematically within the framework of their work-related duties.

1.4 Language use and concepts

An individual in health and social care is sometimes called a patient, sometimes a user and sometimes a client. In order to avoid confusion, we have chosen to use the term *people who use drugs* throughout.

We don't use the word *abuse*, but rather *harmful use and addiction*. The definition is based on one of the diagnostic systems used in Sweden and internationally.[2] In our definition of *people who use drugs* we include *harmful use and addiction*, but our definition also includes people who use drugs without having met the criteria described in the diagnostic systems.

Naloxone can be used for treatment in situations where an individual is intentionally (suicide) and unintentionally (overdose) affected by opioid poisoning, which is why we have chosen to write *opioid poisoning* or *drug and medicine poisoning* throughout the report.

Naloxone is an active substance included in the broader term of opioid antagonist. Although naloxone in various preparations is currently used worldwide, it may be worth considering the use of the term *opioid antagonist*, such as naloxone, in the future, in order to ensure that any legislation is sustainable over time.

Because the concept of *giving* naloxone could be understood as both passing on in the form of distribution and administering as treatment, we use the legal terminology of *administering* the drug when referring to the use of naloxone to a person suffering from opioid poisoning.

Prescribing medicines is currently reserved for healthcare professionals in Sweden. Prescriptions cannot be issued outside the healthcare system. If others pass on naloxone, we write "give" instead (for example, if the person who uses drugs or other entities without healthcare expertise passes on the medicine).

[2] International Statistical Classification of Diseases and Related Health Problems (ICD).

The purchase of prescription medicines by ordering them from a pharmacy is currently only allowed by the health services. We call this *ordering* medicines. For other professionals to have access to naloxone, they need to be able to requisition the medicine.

Lay people is the term we use to describe individuals and professionals outside the health sector in case they are to provide treatment by administering naloxone.

Relatives and other closely-related persons are terms used to describe both family and friends.

1.5 Delimitations in relation to ongoing government commission on naloxone

The National Board of Health and Welfare has been commissioned by the government to work to increase the availability of naloxone.[3] The assignment, which was adjusted in the appropriation letter for 2022, was partially reported to the government on 31 March 2022. According to the interim report, the National Board of Health and Welfare intends to continue working with various knowledge-enhancing initiatives, information, e-learning and so on to stimulate increased availability of naloxone within the current regulatory framework. The National Board of Health and Welfare also believes that there are further opportunities for development for naloxone to be prescribed as self-care (to increase the availability of naloxone among people who use drugs) by nurses in activities outside health care, such as residential care homes (HVB), correctional care, social services or other facilities.[4] In the interim report, the National Board of Health and Welfare explained that the agency, together with the Medical Products Agency, intended to review the possibility of making naloxone available without a prescription to increase its availability in society.[5] The Medical Products Agency has subsequently analysed the issue and published a report in September 2022 in which the agency set out its assessment of the situation regarding prescription-free naloxone. The Medical Products Agency's assessment is that

[3] Assignment to support increased availability of naloxone, Government Offices, 2021-06-10 S2021/04973.
[4] Assignment to support increased availability of naloxone – Interim report on implemented and planned activities within the framework of the assignment, National Board of Health and Welfare 2022.
[5] Ibid.

there is no nasal spray containing naloxone that it is currently legally possible to classify as a non-prescription medication. The MPA outlines various possible ways forward for the approval of a naloxone with over-the-counter status.[6]

Whether or not naloxone can eventually become a non-prescription drug, the question of which non-health occupations can administer naloxone in the event of opioid poisoning needs to be addressed. The Drug Commission of Inquiry is therefore supplementing the National Board of Health and Welfare's current government mandate in these areas.

[6] Non-prescription status for naloxone in nasal preparation, MPA, 2022.

2 Description of the problem and state of knowledge

In this chapter, we describe what naloxone is and how it can be used in cases of opioid poisoning. We also describe more generally the mortality caused by drugs and medicines and when the risk of opioid poisoning is greatest as well as where poisoning occurs.

2.1 The medicine naloxone can stop opioid poisoning

Naloxone is an antidote to all kinds of opioids. Examples of opioids are heroin, methadone, fentanyl, buprenorphine, tramadol and oxycodone. Excessive doses of opioids can cause spontaneous breathing to stop. Without an antidote, a person can suffer from oxygen deprivation and eventually cardiac arrest. Naloxone removes the effect of opioids for about half an hour and allows the person to breathe again.[1] In opioid poisoning caused by fentanyl, which is more potent, a higher dose of naloxone or a higher concentration of naloxone is needed.[2] Naloxone is effective whether the opioid poisoning was caused by narcotic-classified legal drugs or illegal drugs containing opioids, and whether the poisoning was intentional (suicide) or unintentional (overdose). Naloxone is not used to treat an addiction, but to reverse poisoning and immediately save lives.

In Sweden, naloxone has long been used in health care to reverse respiratory arrest in acute situations of opioid poisoning. Naloxone is available in several different preparations. It is commonly used in health care for intramuscular injection and intravenous use with

[1] Learn to save lives with naloxone – Information about the opioid antidote naloxone, Swedish National Board of Health and Welfare, 2019.
[2] Naloxone to revert synthetic opioids overdose – evidence summary, EMCDDA, 2022.

infusion liquid and cannula separated. Pre-filled syringes and auto-injectors have previously been marketed in Sweden, but are no longer available on the Swedish market.[3]

In 2017/2018, the Medical Products Agency approved naloxone as a nasal spray for the first time. There are currently two nasal sprays approved for the Swedish market, *Nyxoid* and *Respinal*.[4] According to FASS, *Nyxoid* costs SEK 335 and *Respinal* SEK 449 (both have a preferential price with a prescription and two doses per pack). The regions may have procured this product at lower prices. For non-healthcare use, such as by individuals, naloxone is almost exclusively used as a nasal spray. According to the authorisation, these two nasal sprays containing naloxone may be administered by someone other than the patient himself. At the time of dispensing, the authorisation requires that the recipient of the medicine receives certain training and information on how to administer the medicine.

2.2 Which persons should be given access to naloxone according to national guidelines?

The National Board of Health and Welfare's national guidelines for treatment and support for harmful use and addiction recommends that authorities use various evidence-based approaches.[5] The guidelines include a recommendation of highest priority (Priority 1), which includes naloxone. According to the recommendation

> The healthcare and social services should offer naloxone to people with opioid addictions and at risk of overdose. The key to this recommendation is that the intervention can save lives, whilst its side effects are limited. In addition, there is an absence of other alternative measures for reversing an opioid overdose. The recommendation is based on existing studies and expert judgement, and is also supported by the WHO Committee of Experts' assessment and recommendation on the measure.[6]

[3] When the product was marketed in Sweden, it cost about SEK 330 per pack.
[4] FASS.se aimed at the general public.
[5] Note that the National Board of Health and Welfare's guidelines in this area are addressed to both supervisory agencies, regardless of whether there are regulatory restrictions on either of them providing the intervention, as is the case with pharmacotherapy, for example.
[6] National guidelines for care and support for harmful use and addiction – Support for governance and management, National Board of Health and Welfare, 2019.

The National Board of Health and Welfare has published information material in various formats in order to provide the necessary information to opioid users, their relatives and staff who meet opioid users.

The information material focuses on the use of nasal sprays, although the material also applies to other preparations. The information material is structured as an educational intervention with information on how to recognise opioid poisoning, secure the airway, provide respiratory assistance and naloxone and to call the 112 emergency number.[7]

Chapter 4 sets out the requirements for healthcare professionals who are authorised to administer naloxone. There are also some exceptions that allow other professionals to administer naloxone and in all these cases there is some link to health legislation, which are also set out.

2.3 There are limited medical risks associated with the use of naloxone

The use of naloxone has limited medical risks and side effects. This is true even if the drug is administered to a person who is not suffering from opioid poisoning. Naloxone does not cause intoxication or addiction. The availability of naloxone through naloxone programmes in different countries does not appear to have led to an increase in opioid use or risk-taking among people who use drugs.[8] Even if the drug is administered correctly, there is a risk that the person addicted to opioids may go into withdrawal, which may require medical treatment. A further risk is that opioid poisoning may recur after the drug has worn off and before health professionals arrive.[9] In this case, a second dose may be administered, which the person administering the drug needs to be aware of.[10]

[7] Learn to save lives with naloxone – Information about the opioid antidote naloxone, Swedish National Board of Health and Welfare, 2019.
[8] Does naloxone provision lead to increased substance use? A systematic review to assess if there is evidence of a 'moral hazard' associated with naloxone supply; W. C. Tse, F. Djordjevic, V. Borja, L. Picco, T. Lam, A. Olsen, S. Larney, P. Dietze, S. Nielsen, The International Journal of Drug policy, February 2022.
[9] FASS.se aimed at the general public.
[10] In the case of naloxone intended for injection, other risks may exist, such as if the needle is not clean or similar. As this report only analyses the nasal spray, such possible risks for naloxone in other formulations have not been considered.

Naloxone nasal spray will only have the desired effect if the person administering the medicine carries out the action according to the instructions given in the product leaflet. For example, if the person administering the medicine sprays it into the air and not in the nose (each bottle contains only one dose), the spray has no effect. Knowledge of how to administer the medicine is therefore important.

2.4 Mortality due to medicine and drug poisoning

In recent decades, Sweden has experienced an increasing mortality rate due to medicine and drug poisoning. Between 2012 and 2020, an average of 890 people died annually as a result of medicine and drug poisoning. In the ten-year period 2010–2019, unintentional poisoning mortality increased by 88 per cent.[11] However, since 2019, deaths caused by drugs and medicines have decreased. In 2020, 822 people died from the aforementioned causes of death, a decrease of eight per cent compared to the previous year.[12] In 2021, the mortality rate had decreased further and, according to the National Board of Health and Welfare, 774 people died of medicine and drug-related poisoning that year.[13] People who die from medicine and drug poisoning are a heterogeneous group of individuals, with varying degrees of harmful use or addiction or no harmful use or addiction at all. Several substances in combination often contribute to these deaths. Deaths are categorised in national statistics as intentional (suicide by drugs), unintentional (which is usually referred to as overdose), and poisoning with unclear intent where it has not been possible to determine whether it was intentional or unintentional. Of the deaths in 2012–2020, almost half were classified as accidental poisoning and more than a quarter as suicides. It is common for those treated for drug or medication-induced poisoning in the country's emergency departments to have both a psychiatric diagnosis and a substance-related diagnosis.[14]

[11] Deaths due to drug poisoning – a compilation of statistics, National Board of Health and Welfare, National Agency for Public Health, National Medical Products Agency, National Board of Forensic Medicine, 2022.
[12] Statistics on deaths due to drug poisoning 2012–2020, National Board of Health and Welfare, 2021.
[13] Statistics database of the National Board of Health and Welfare, visited 2022-09-14.
[14] Care processes for drug-related intoxication – Mapping of patient flows, interventions and collaboration and identification of gaps and areas for development, National Board of Health and Welfare, 2021.

In the period 2012–2020, opioids were most common among accidental poisoning cases (overdoses), while anti-anxiety medications and tranquillisers dominated among the intentional deaths (suicides).[15] Unintentional poisoning cases predominantly involve men, while the reverse is true for suicides, where women are over-represented. During the same period, heroin was the most common category of accidental poisoning (overdoses), followed by the opioids buprenorphine and methadone. Deaths can also be categorised according to whether the death was exclusively caused by illicit substances, whether only one substance or several were responsible, or whether one or more medications defined as drug caused the death. The largest category of deaths in 2019 involved one or medicine classified as drugs, with both opioids and benzodiazepines being common.[16] Of the total of 832 poisoning deaths reported by the National Board of Forensic Medicine in 2019, about 63 per cetn had opioids in their blood (521 people) and in 54 per cent of poisoning cases opioids, alone or in combination with other substances, were the cause of death (447 people).[17]

2.5 Naloxone can only affect deaths where opioids were taken

In March 2022, the government adopted a statement that includes the ambition to prevent all deaths that result from medicine and drug poisoning.[18] By increasing the availability of naloxone, more opioid poisoning can be treated. When it comes to naloxone, it is important to consider that naloxone can only help reduce opioid-caused deaths, or deaths where opioids contributed to the death such as in mixed poisoning, but not other deaths caused by drugs or medicines. However, as shown above, opioid poisoning is a common cause of death in Sweden.

[15] Deaths due to drug poisoning – a compilation of statistics, National Board of Health and Welfare, National Agency for Public Health, National Medical Products Agency, National Board of Forensic Medicine, 2022.
[16] Ibid.
[17] Reg No KOMM 2022/00359/S_2022:01-17 Incoming material from the National Board of Forensic Medicine.
[18] A comprehensive strategy for alcohol, drug, doping and tobacco policy and gambling 2022–2025, Government, 2022.

2.6 When and where is the risk of opioid poisoning at its greatest?

Opioid poisoning can happen in many different places. It is important for our work to identify common sites of opioid poisoning in order to then link the site to occupational groups and activities found at such sites, as is done in Chapter 6.

The risk of opioid poisoning is greatest when a person who has used drugs is drug-free and starts using opioids again. Put simply, if a person has been off opioids for a few days, they can tolerate only a smaller quantity of opioids and are more likely to be poisoned. One example of this kind of situation is, for example, upon discharge from inpatient care/treatment in any form of healthcare facility, detention, institution (such as care pursuant the Act (1988:870) on the Care of Addicts in Certain Cases, abbreviated LVM, or Home for Care or Accommodation, abbreviated HVB) or institutional stays. Even when a person has been voluntarily drug-free in a home environment and resumes opioid use, the risk of opioid poisoning is high. It is difficult to predict where a person will be in the event of a poisoning and which occupations will be available. Opioid poisoning can happen at home, outside, in a public toilet or on a train, to give a few examples.

The risk of opioid poisoning is also high when an individual combines different substances and/or alcohol. It can then be more difficult to determine how different substances interact and affect the body. Furthermore, there is a risk of poisoning if preparations contain substances other than what the person who uses drugs thought, such as fentanyl or other high-potency opioids, mixed in with other substances.

According to a study based on forensically investigated deaths in Skåne, those who died from overdoses[19] mainly overdosed at home or in another person's home (about 82 per cent).[20] A smaller proportion occurred in hotels, shelters, group homes or treatment centres (about 9 per cent), public places such as parks or toilets (about 6 per cent) and other places (about 4 per cent). A recently published report analysed deaths due to medicine and drug poisoning for all sub-

[19] Overdose is the term used in the study cited We otherwise use opioid poisoning.
[20] Fatal overdoses often occurred without a person nearby to intervene – knowledge of the presence of witnesses is important for how naloxone programmes should be designed, L. Andersson and B. Johnson, Läkartidningen volume 119, 2022.

stances (not just opioids). In 2019, 55 per cent of these poisoning (leading to death) occurred at home, 26 per cent in another home, 14 per cent in an institution and five per cent in another place. The report also indicated whether the deceased had been alone or with others. In total, 29 per cent were alone at the time of poisoning and among accidental poisoning (overdoses) the figure was 20 per cent, while among deliberate poisoning (suicides) it was 44 per cent.[21]

The registry study in Skåne, focusing specifically on opioid poisoning deaths, showed that it was common for the deceased to have been alone or in a dwelling where another person was either sleeping or in another room and therefore unable to intervene in the event of an overdose.[22]

The data on user-reported naloxone use differ slightly from the data based on actual deaths where the home or other person's residence accounted for a very large proportion of opioid poisoning. It may be that fatal and non-fatal opioid poisoning differ in terms of location and presence of witnesses. Data collection at the Stockholm syringe exchange provides some guidance on where opioid poisoning often occurs, as users also report the location where they used naloxone. Approximately 50 per cent report the location as their own or someone else's home, 9.2 per cent in a public toilet, 30 per cent outdoors, and 12 per cent in other places.[23] In a Norwegian study from 2022, the distribution between the places where opioid poisoning occurred and when naloxone was used was similar to the situation in Sweden. About 59 per cent occurred at home, three per cent at a shelter, and 28 per cent on the street or in public places.[24]

Locations of opioid poisoning also vary according to local and regional contexts. In cities, they may be linked to places where drug sales are common, parks and nearby sites. In smaller towns or rural areas, other local conditions may determine the locations where opioid poisoning is likely to occur.

[21] Deaths due to drug poisoning – a compilation of statistics, National Board of Health and Welfare, National Agency for Public Health, National Medical Products Agency, National Board of Forensic Medicine, 2022.
[22] Fatal overdoses often occurred without a person nearby to intervene – knowledge of the presence of witnesses is important for how naloxone programmes should be designed, L. Andersson and B. Johnson, Läkartidningen volume 119, 2022.
[23] Dnr KOMM2022/00359/S_2022:01-11 Personal communication with Martin Kåberg.
[24] Who is using take-home naloxone? An examination of supersavers; D. Eide, P. Lobmeier and T. Clausen, Reduction of harm Journal, 2022.

2.7 Is naloxone effective in limiting deaths as a result of drug or opioid poisoning?

The National Board of Health and Welfare's assessment is that naloxone is an effective and easy-to-use medicine that can reverse poisoning by opioids, such as heroin.[25] When the National Board of Health and Welfare's guidelines were published in 2019, there were limitations in the scientific evidence for the recommendation based on the highest GRADE criteria. However, there are methodological explanations for this, which is why other knowledge that does not meet the very highest criteria for scientific quality instead serves as a basis for the National Board of Health and Welfare's recommendations in this area.[26] New knowledge and research on naloxone has also developed since then. A review of available studies on naloxone use outside the healthcare system shows a reduction in mortality from opioid poisoning as a result of drug users receiving naloxone and being able to administer the drug to others in the event of opioid poisoning.[27] In Sweden, knowledge from existing naloxone programmes may provide some guidance. According to the syringe exchange programme in Stockholm, which tracked its dispensing of naloxone to patients from January 2018 to April 2022, 1,790 of the 11,950 doses dispensed were used in an overdose situation.[28] The Stockholm syringe exchange programme distributed and/or prescribed the nasal spray to 1,477 people from January 2018 to January 2022 (i.e. a slightly shorter period of time). Over 1,500 cases of overdose have occurred in this group, and the study shows that 95 per cent of those who received naloxone administered in an overdose situation survived.[29]

A study from Skåne on the use of naloxone shows that people with risk factors for opioid poisoning (e.g. injection use, concomitant use of benzodiazepines and previous personal experience of opioid poisoning) were the most likely to report administering naloxone in

[25] National guidelines for care and support for harmful use and addiction and addiction – Support for governance and management, National Board of Health and Welfare 2019.
[26] The National Board of Health and Welfare believes that based on the scientific literature with the highest criteria for scientific quality, it is difficult to conclude that making naloxone available reduces mortality in people with opioid addiction The National Board of Health and Welfare has assessed the scientific support for the measure as insufficient in a systematic review of the research literature, according to the evidence grading method GRADE.
[27] Yousefifard et al, 2020, EMCDDA, 2015, Chimbar, 2018.
[28] This entity uses the term overdose, we in the investigation write opioid poisoning.
[29] High levels of uptake and use of naloxone among participants in a Take-Home-Naloxone program in Stockholm, Sweden, E. Holmén M. Kåberg, 2022.

a poisoning situation. Thirteen per cent of the naloxone dispensed was reported to have been used in cases of opioid poisoning. A majority of opioid poisoning were reported to have occurred in private settings, where the witness was a friend or acquaintance of the victim. Of the 1,079 participants in the study, 22 per cent returned for a refill of naloxone.[30]

Naloxone can therefore save lives and there is evidence that making the medicine available to people who use drugs is effective. Moreover, recommendations to this effect exist in both the EU and the UN. Although many cases of opioid poisoning occur in the home, this is far from being true in every case.

People who are relatives of, or work with, people who use opioids are covered by the international recommendations for naloxone programmes. In order to assess whether other professionals should be able to administer naloxone, the impact of the intervention needs to be evaluated and weighed against the benefits and detriments at the national level. Studies focusing specifically on the provision of naloxone to specific occupational groups are limited in number. Individual studies in the United States that examine the impact of giving police and emergency services the opportunity to administer naloxone in opioid poisoning cases suggest that the intervention may be associated with a reduction in opioid-related deaths and that the majority of the occasions when naloxone was administered had the intended effect.[31]

2.8 Which occupational groups are present at sites where opioid poisoning occurs?

Many different occupational groups may be present in places where opioid poisoning occurs. Information and material used by previous government commissions suggest that public safety officers, security guards and police officers would be those who would often be the first to arrive at the scene of an opioid poisoning incident and where there are grounds to allow them to administer naloxone.[32] Groups who are called to the scene may thus find themselves in situations where

[30] Characteristics of and Experience Among People Who Use Take-Home Naloxone in Skåne County, Sweden: K. Troberg, P. Isendahl, M. Alanko Blomé, D. Dahlman, A. Håkansson, 2022.
[31] Rando et al, 2015, Fischer et al, 2016.
[32] Dnr KOM2022/03 59/S 2022:01-3 Evidence from the National Board of Health and Welfare's dialogue meetings with various professions, activities and user organisations conducted in 2017.

naloxone may be needed to treat the poisoning early on, but have a target group in their work that encompasses more than just people who use drugs. Other occupations that could be involved include staff working in institutions where residents have drug problems. These could be professionals working in one of the compulsory care homes run by the National Board of Institutions (LVM and LVU), HVB homes where treatment for people with harmful use or addiction takes place, prisons or detention centres (Prison and Probation system). As these institutions outside the healthcare system serve as a residence for a period of time for people who use or have used drugs, there is a risk of opioid poisoning there, as well. There are a number of occupations and professions in the social sector working with people with harmful drug use and addiction. These may include shelters, emergency accommodations, civil society and church/faith-based entities, daily activities centres, social centres and others, or social service outreach entities, home care, residential support workers, etc. Entities responsible for these activities may be municipalities, public authorities, companies or the volunteer sector. Finally, there are other occupations that work near or in a place where opioid poisoning is common, such as cleaning staff in public toilets, public transport and county transport staff, people who work around places where drug sales and use are common, such as staff in restaurants or shops, park workers and others.

2.9 International and national initiatives about naloxone and a brief history

Medicine and drug-related mortality in Sweden has prompted a number of initiatives at national level in recent years. In order to put our analyses and assessments in this interim report into context, national and international initiatives in this area are listed below.

- In 2014, the World Health Organization (WHO) launched new guidelines for first-aid interventions in opioid poisoning. The premise is that many lives can be saved by increasing access to fast-acting antidotes such as naloxone. The WHO guidelines call on countries to make the antidote naloxone available to people who use drugs and to those around high-risk individuals. This was called take-home naloxone (THN). Police officers, community

workers, family members and friends of people who use drugs should be able to carry naloxone to respond to opioid poisoning.[33]

- In 2017, the National Board of Health and Welfare and the Public Health Agency submitted a report from a joint government mission to reduce drug-related mortality.[34] In their feedback, stakeholders clarified that Swedish legislation at that time was not compatible with the concept of a naloxone programme, which would make naloxone available to non-medically trained people who were in the vicinity of high-risk individuals.
- In 2017, the National Board of Health and Welfare and the Medical Products Agency (MPA) were given two new tasks by the government. This assignment included investigating the conditions for safely and effectively reducing opioid poisoning mortality by increasing the availability of antidotes in the form of naloxone outside the healthcare system. Within the framework of the assignment, the MPA and the National Board of Health and Welfare were also to propose the necessary legislative changes, as well as how distribution, education and information could take place.[35] The MPA and the National Board of Health and Welfare reported in 2017 and 2018, respectively, on the various government mandates. Regulatory changes extended the possibility of prescribing naloxone to patients for administration outside the healthcare system and gave nurses the authority to prescribe naloxone. The medicine was dispensed at the time of prescription and non-licensed ambulance and emergency services personnel were also given the opportunity to administer naloxone. As regards the question of whether key groups outside the healthcare system should be allowed to possess and administer naloxone, the Medical Products Agency concluded that this needed to be investigated separately and not at the level of the government agencies in the first instance.[36] The National Board of Health and Welfare and the Police Authority also shared this view.

[33] Community management of opioid overdose, WHO, 2014.
[34] National development work to counter drug-related mortality – Action plan with proposals for interventions and actors, the National Board of Health and Welfare and the National Agency for Public Health, 2017.
[35] Assignment on increased availability of certain medicines in order to counteract drug-related mortality, S2017/02196/FS, Government Offices.
[36] Assignment on increased availability of certain medicines in order to counteract drug-related mortality, Report 1.12-2017-029584, MPA, 2018.

- The 2019 revision of the *National Guidelines for Care and Support in Substance Use and Addiction* included a recommendation for naloxone as a top priority.[37]
- The 2020 revision of the WHO and UNODC *International Standards for the treatment of drug use disorders* includes the need for naloxone in and out of health care, in combination with other interventions.[38]
- The *EU Drugs Strategy 2021–2025* includes "naloxone for take-home use" as a key action in points 7.2 and 8.3.[39] The new strategy sets the political direction and priorities for EU drug policy and complements policies of Member States.
- In 2021, the Swedish Parliament informed the Government that more action is needed to increase nationwide availability of naloxone for opioid poisoning. According to Parliament, use should be monitored at national level and an investigation should be carried out into whether more groups outside the healthcare system should be able to administer naloxone for overdoses.[40]
- In 2021, the National Board of Health and Welfare was given the task of increasing the availability of naloxone. The mandate was adjusted in the 2022 appropriation letter and the mandate period was extended to 2024. An interim report was published in the spring of 2022.[41]
- In March 2022, the government adopted a written policy goal that no one should die as a result of medicine and drug poisoning. The same document also describes ongoing work on naloxone.[42]
- In March 2022, the Drug Commission of Inquiry was appointed with the task of analysing in an interim report by 14 October 2022, whether members of occupations other than healthcare profes-

[37] National guidelines for care and support for harmful use and addiction and addiction – Support for governance and management, National Board of Health and Welfare, 2019.
[38] International Standards for the treatment of drug use disorders – Revised edition, WHO and UNODC, 2020.
[39] EU Drugs Strategy 2021–2025, 14 178/1/20, Council of the European Union, 2021.
[40] Social Affairs Committee report 2020/21: SoU20, Alcohol, drugs, doping, tobacco and gambling.
[41] Assignment to support increased availability of naloxone – Interim report of implemented and planned activities within the framework of the assignment, National Board of Health and Welfare, 2022.
[42] Skr. 2021/22:213 A comprehensive strategy for alcohol, drugs, doping and tobacco policy and gambling 2022–2025, Government, 2022.

sionals, and if so which ones, should be able to administer naloxone for opioid poisoning and, if necessary, to submit legislative proposals for how this should be regulated.

- In June 2022, the Parliament announced that the Government should take the necessary measures to increase the availability of naloxone without delay.[43]
- In September 2022, the Medical Products Agency published the report *Prescription-free status of naloxone as nasal preparation*.[44] In the report, the Agency sets out its assessment that there is no medicine containing naloxone in nasal spray form that it is currently possible to classify as non-prescription.

[43] Social Affairs Committee report 2021/22:SoU25, A comprehensive strategy for alcohol, drugs, doping and tobacco policy and gambling 2022–2025.
[44] Non-prescription status for naloxone in nasal preparation, MPA, 2022.

3 International experiences with naloxone

In this chapter, we report on the regulation and management of naloxone outside the health sector in other countries. We have sent questions to a selection of countries and to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the World Health Organisation (WHO) and the United Nations Office on Drugs and Crime (UNODC). As responses have been received in different languages, with varying degrees of detail and the time available to respond has been limited, so our account in this chapter should be seen as a general overview and inspiration for further work, rather than a comprehensive description of the regulatory regimes in different countries.

3.1 The experience of international organisations

Guidelines on take-home naloxone (THN) were published by WHO in 2014.[1] We refer to it hereafter as the naloxone programme. The intervention is also included in treatment guidelines issued by WHO and UNODC.[2] Neither WHO nor UNODC has done any monitoring of compliance with the recommendation. Naloxone programmes exist in 11 EU countries and Norway.[3] Programmes also exist in Australia, Canada and the USA. The WHO/UNODC SOS (*Stop Overdose Safely*) project in Ukraine, Tajikistan, Kazakhstan, Kyrgyzstan are also naloxone programmes. The programmes target people who use opioids, their families, friends and others outside the healthcare

[1] Community management of opioid overdose, WHO, 2014.
[2] International Standards for the treatment of drug use disorders, UNODC and WHO, 2020.
[3] EMCDDA website https://www.emcdda.europa.eu/publications/topic-overviews/take-home-naloxone, 2019.

system who may witness opioid poisoning. The fact that naloxone is a medicine means that in most countries there is a requirement for prescriptions by health professionals to a patient, which has made it difficult to make naloxone available in the way recommended by WHO since 2014. Different countries have tried to find solutions and make exceptions to regulations that otherwise apply to medicine management, prescribing, health care and treatment.

3.2 The situation in the EU

The commission of inquiry has taken note of the responses that the Medical Products Agency has received from other countries in its efforts to consider whether naloxone can be made available without a prescription.[4] Questions were sent to all EU Member States plus Norway and Iceland. 23 countries responded and none of them allow nasal sprays containing naloxone without a prescription. Most countries report that naloxone can only be prescribed by a doctor and to a patient, but not to groups, relatives or other professionals. However, patients receiving naloxone are encouraged to inform friends and other staff with whom they are in contact of the location of the nasal spray so that it can be used in an emergency situation. Some countries report that they have a system in place to manage naloxone outside the healthcare system. These countries are Portugal, Denmark, Norway, Estonia, Italy and France.

We have made our own enquiry to a selection of countries and we report the responses from their Ministries of Health or equivalent bodies, below. This has also been supplemented with material from official websites.

3.3 France

In France, access to nasal sprays containing naloxone requires a prescription. The nasal spray is distributed by health services, in various treatment facilities, in low-threshold activities and in the prison system. However, naloxone for injection is non-prescription and can be pur-

[4] Dnr KOMM2022/00359/S_2022:01-4 received from the Medical Products Agency.

chased in pharmacies by any adult who wishes to do so.[5] Both preparations are covered by social insurance and, if dispensed from a pharmacy, 65 per cent of the cost is reimbursed, while the medicine is often free of charge in low-threshold facilities and treatment centres. In France, the national recommendation is that everyone receiving medication-assisted treatment for opioid addiction (LARO) should be offered naloxone, including information on how to identify opioid poisoning.[6] Training regarding naloxone and how to recognise opioid poisoning is also provided to staff working with people who use drugs. Such training is available both in person and online.[7]

3.4 Estonia

Estonia, like Sweden, is considering how naloxone can be administered by non-health occupations. No such legal solution has yet been identified. For the time being, naloxone is prescribed to patients within the healthcare system. In addition, there is the possibility for health professionals to distribute naloxone through various social and low-threshold activities to the target group of people using opioids. However, this distribution must be documented in accordance with healthcare regulations.[8]

3.5 Italy

In Italy, naloxone can be purchased over the counter in pharmacies, as has been possible since the early 1990s. Naloxone programmes aimed at persons who use drugs and their relatives, where naloxone is distributed and training is provided, have been in place in Italy for twenty years. These programmes are unevenly distributed across the country and are mainly run by mobile units. The use of nasal sprays containing naloxone is still limited in Italy.[9]

[5] We have not been able to follow up the reasons why naloxone in injection form has been approved as non-prescription in France and Italy.
[6] https://solidarites-sante.gouv.fr/IMG/pdf/naloxone-fichememo-pros-maj-janv2022.pdf.
[7] Dnr KOMM2022/00359/S_2022:01-6 reply to questions received from France.
[8] Dnr KOMM2022/00359/S_2022:01-10 reply to questions received from Estonia.
[9] Dnr KOMM2022/00359/S_2022:01-7 reply to questions received from Italy.

3.6 Norway

In Norway, naloxone can be obtained by prescription from the health services, as well as by picking up the nasal spray at one of the 120 different distribution points established for naloxone distribution. The latter is organised as a project and started in 2014 as a sub-component of a national overdose strategy.[10]

The distribution points participating in the project have a doctor associated with them and the doctor can order a maximum of 500 packs at a time. The requisition goes to one of the three coordinators of the project in Bergen, Oslo and Trondheim, who in turn forwards the requisition to one of the four pharmacies in Stavanger, Bergen, Oslo and Trondheim, which are all connected to the University Hospital in Oslo. The scheme is based on state funding of the medicines requisitioned under the project. The nasal spray is then delivered to the distribution point. The staff at the distribution point must be employed by the municipality, but need not be health professionals. Each dispensing point needs to have a doctor attached to it who is the person responsible for requisitioning the medicine and delegated distribution responsibility to the municipal employees at the dispensing points. The distribution of medicines is accompanied by a short and targeted training on the signs and symptoms of opioid poisoning and on the use of nasal sprays containing naloxone. This is done without an individual prescription. Some dispensing sites target opioid users only, while others are open to all (including family members and other professionals).[11]

In order for other occupations who think they may need to use naloxone to gain access to naloxone, they must take part in a training intervention. The training can take between 5–30 minutes and can be delivered face-to-face or digitally and covers how to recognise opioid poisoning, how naloxone works and should be used and how to register use (as this is important for monitoring, evaluation and research). Experience from the Norwegian naloxone programmes shows that other groups who participate in training are various outreach activities, such as criminal justice staff, mobile services for people

[10] National Overdose Strategy 2014–2017 "Sure you can quit drugs – but first you have to survive", Helsedirektoratet, 2014.
[11] www.nalokson.uio.no.

with harmful use and addiction, psychiatric services, ACT services[12] and more.

Norway is currently reviewing the possibilities for further developing the work to allow relatives or others in a patient's network and vicinity to have access to naloxone.[13]

3.7 Denmark

Denmark has had naloxone projects for more than ten years, whereby, for example, people with harmful drug use and addiction, their relatives and certain groups (police, social workers, etc.) can receive naloxone for the purpose of administering it in the event of opioid poisoning. A prerequisite for receiving naloxone is participation in a training course on first aid and the use of naloxone. In 2019, the work in Denmark was complemented by the fact that anyone participating in substitution treatment with, for example, buprenorphine or methadone for harmful use or addiction on opioids, must be offered the corresponding training and can receive naloxone as a nasal spray after completing the training. Experiences and comments made during the project period resulted in the need to clarify the rules on who may prescribe and dispense naloxone, and updated legal and regulatory provisions came into force on 1 May 2022. One of the changes is that nurses are also authorised to dispense naloxone (previously only doctors were). Another change is that administration of the drug naloxone is exempt from the otherwise applicable provisions that only doctors may administer prescription medicines. The exemption is based on the fact that naloxone nasal spray has no addictive potential, that the risk of harm or side effects is very limited compared to other risks that may arise from untreated opioid poisoning, and that no patient safety risks known to the health authorities have arisen during the period of the projects in Denmark. In the context of the statutory amendments that came into force in May 2022, changes were also made to allow the nasal spray to be prescribed by non-healthcare providers. An exemption for nasal sprays was introduced in the pharmaceutical legislation, which means that establishments no longer need to seek authorisation from the Danish Medicines

[12] Assertive Community Treatment, ACT.
[13] Dnr KOMM2022/00359/S_2022:01-12 response to questions received from Norway.

Agency to requisition naloxone. Pharmacies can now obtain a requisition from doctors and nurses affiliated with a municipal institution offering treatment for harmful use or addiction, a regional psychiatric entity or treatment institution or a naloxone project run by a civil society organisation. These entities often employ staff who are not doctors or nurses, but who, through their association with a nurse or doctor, may distribute naloxone. Naloxone can thus be distributed free of charge to people who want and need the medicine for the purpose of administering it in opioid poisoning ("the public").[14]

3.8 Finland

There are no established naloxone programmes in Finland yet. However, naloxone can be prescribed by doctors to patients, but as the medicine is relatively expensive, prescribing and demand has been limited, according to the Finnish Ministry of Social Affairs and Health. There is some work underway in Finland in various groups that deal with the reduction of harm to establish naloxone programmes. There is some demand for programmes aimed at allowing groups working with people who use opioids to receive naloxone and to be able to administer it in the event of opioid poisoning. However, there are no political decisions in this direction. There have also been initiatives to enable police officers to administer naloxone, but the demand for such interventions has been deemed low and has not been advanced to the national level. At present, some treatment entities, as well as forensic and criminal investigation laboratories, have access to naloxone.[15]

3.9 Iceland

Beginning on 1 July 2022, there has been state funding for naloxone, which will thus be free for people who use drugs and no longer dispensed only in hospitals. National efforts are underway to make nasal sprays containing naloxone available along with educational and training activities. It is expected that the distribution and administration of the medicine will include the following entities: the Icelandic Red Cross at *Fru Ragnheidur* (harm reduction activities) and the *Ylja* con-

[14] Dnr KOMM2022/00359/S_2022:01-5 response to questions received from Denmark.
[15] Dnr KOMM2022/00359/S_2022:01-8 replies to questions received from Finland.

sumption room, the police, health care, emergency services and the municipality's social services and others working with people with opioid harmful use or addiction.[16]

3.10 USA

The United States has both federal and state regulatory frameworks for naloxone. The federal administration unveiled a model in the autumn of 2021 to help states regulate naloxone to make it even more widely available, in a legally secure manner.[17] In most states, the person who has the authority to prescribe medicine (such as a physician) can also prescribe naloxone to an entire organization or operation through a "standing order" without each individual needing to have a separate prescription. This means that non-health care staff (such as shelter staff, social workers and police) can requisition the drug. Pharmacists are also able to prescribe naloxone in pharmacies to people who use drugs, even without a prescription from a doctor, if the pharmacy has established an opioid prescription agreement. If the person has health insurance, the cost of the medicine can be reimbursed; otherwise, people who use drugs may have to pay for it themselves. However, low-threshold facilities also distribute naloxone free of charge, either as a nasal spray or as a pre-filled disposable syringe/auto-injector. The regulatory framework for how other groups (with a focus on police, emergency services and ambulance personnel) are allowed to administer the drug is based on "compassionate use/Good Samaritan" legislation.[18] A total of 35 states have this legislation to provide immunity from civil and criminal liability for anyone who administers naloxone or an opioid antagonist to a person with opioid poisoning. This means that a person who has acted in good faith to save a life is not at risk of punishment, so specific and detailed regulation of who can administer naloxone was not deemed necessary.[19] The widespread use of opioids in the US and the associated high opioid-related mortality, has made efforts to prevent opioid-related poisoning a high priority at both the federal and state

[16] Icelandic Ministry of Health website.
[17] White House website.
[18] It should be noted that in the United States it is common for individuals to be sued, which may explain the emergence of "merciful Samaritan" legislation.
[19] Model expanding access to emergency opioid antagonist act; LAPPA (Legislative Analysis and Public Policy Association), 2021.

levels. Mortality prevention efforts have come to encompass many different sectors of society. Among the police, a dedicated leadership pushed for naloxone to be carried and administered by police officers so that the role of the police is not only to prosecute crimes but also to help save lives.[20]

3.11 Summary of international experiences

As legal systems or frameworks for health care and medicines are complex and difficult to compare across countries, we provide a more general overview of the regulatory framework for naloxone in a selection of countries, which may serve as an inspiration for our further work. In summary, several countries have taken steps to make naloxone available in the community in different ways. For many, however, there are legal challenges in bringing about such a regime. Several countries have indicated that the availability of naloxone as a nasal spray has facilitated this work.

In the United States, naloxone can be administered outside the healthcare system by, for example, police, emergency services and ambulance personnel. In Norway, there is a national project to reach out with naloxone to people who use opioids, but also to other groups. Denmark has recently enacted legislation in this area to allow both access to and administration of naloxone outside the healthcare system. Other countries, such as Estonia, are also reviewing how other groups outside the health sector can administer naloxone. In France and Italy, naloxone preparations for injection are available without prescription.

In several countries, the medicine remains available by prescription, but in practice, it has been handled as some form of "over-the-counter". This is done by distributing naloxone to people who use drugs, as well as to their family or close friends and to occupational groups. The distribution takes place through activities linked to and administered by a doctor, but where other staff are not medical professionals.

[20] Meeting notes drawn up after meeting with the USA, ONDCP. Dnr KOMM2022/00359/S_2022:01-13.

4 Current law

Current law requires treatment for opioid poisoning to be provided within the healthcare system. This includes the power to prescribe or requisition naloxone and to administer the treatment. There are essentially no corresponding provisions for other groups, who are considered lay persons in this respect. Naloxone is an authorised medicine subject to specific conditions as regards prescribing, requisitioning and dispensing from pharmacies. Upon approval, it can be administered by someone other than the patient. In concrete terms, this requires that the person administering naloxone both has the medicine and the right to administer it to a person in an emergency situation.

This chapter sets out the key features of the laws governing health care. It focuses on the purpose of the laws, the division of responsibilities and organisation, and the obligations and rights of staff and patients. The general emergency provision in the Criminal Code is discussed after the Patients Act (2014:821). The reason is that in health care there is a requirement that the patient must consent to measures and treatment. This means that no one may be given or forced to undergo care or treatment without consent or without support in law. However, if this is the case, the lack of consent may be challenged by the emergency provision. Finally, some key provisions of the legislation on medicines and the relevant regulations of the National Board of Health and Welfare are presented. This is done with the reservation that there may be duplication of regulations.

We have limited the presentation to those parts and provisions that are deemed to be of the greatest importance for our further investigation. We will return to the issues of public access and confidentiality and the processing of personal data in the final report.

4.1 Healthcare Act

Health care has long been regulated by a few laws. The most important of these is the Healthcare Act (2017:30) HSL, which has strong links to the Patient Safety Act (2010:659) (PSL) and the Patients Act (2014:821). The HSL contains provisions as to how health care should be provided and organised. It lacks a universal definition of health and instead uses concepts depending on financial resources, the level and development of science, various environmental conditions and so on.[1]

The care provided should be equal and available to all, and those most in need of care should have priority access to it.[2] The principle of need-based care on equal terms has a broader meaning in law than the principle of municipal equality. In health care, this principle aims to ensure that social, personal or other factors do not influence access to care. Furthermore, the activities must be carried out in such a way that the requirements of good care are maintained. This means that care should:

- Be of good quality with a good hygienic standard,
- Meet patients' needs for safety, continuity and security,
- Be based on respect for the patient's autonomy and integrity,
- Promote good relations between the patient and the healthcare groups; and
- Be easily accessible (Chapter 5, Section 1, HSL).

The concept of health care underscores the purpose of the law that health care has the dual role of treating and preventing diseases and injuries. This is explicitly stated in Chapter 3, Section 2 of the HSL in that health care must work to prevent ill health.

In terms of the division of responsibilities, there are the concepts of supervisory agency and provider. Chapter 2, Section 2 of the HSL states: 'In this Act, the term "supervisory agency" refers to the region or municipality that is responsible for providing health and

[1] Govt Bill 1981/82:97 p. 113 to HSL (1982:763) and Vahlne Westerhäll, Health and Medical Care At (2017:30) Chapter 3, Section 1 Karnov (JUNO) (visited 2022-07-15).
[2] Chapter 3, Section 1 HSL.

medical care under the Act. Within the geographical area of a supervisory agency, one or more care providers may operate.

Regions and municipalities are designated as supervisory agencies and are responsible for providing health care in their geographical areas. The provision defines the term supervisory agency. The legislative preparatory documents stated the following about the supervisory agency.

> It follows from the definition that the central element of supervision is the responsibility to provide health care. The supervisory agency is not obliged to provide the care itself, but the provision of care may be entrusted to someone else. However, the supervisory agency always retains ultimate responsibility for the provision of health care in its geographical area.

Quality monitoring is an important task[3] in view of the fact that it is the supervisory agency that is ultimately responsible for health care.

A healthcare provider is defined as a state authority, region, municipality, other legal entity or a sole proprietor that carries out healthcare activities. The term thus refers to anyone who carries out healthcare activities.

A supervisory agency is generally both a healthcare provider and the operator of health care within its region or municipality. The supervisory agency does not have to carry out the healthcare activities itself, but may enter into an agreement with another healthcare provider to carry out the activities. However, it is not possible for the supervisory agency to contract out its principal function, and tasks such as the exercise of public authority may not, under the HSL, be transferred to a legal person or an individual.[4]

According to Chapter 5 of the Social Services Act (2001:453), abbreviated SoL, the social services have special responsibility for, among other things, elderly people and people with disabilities[5] and must set up special accommodation for these groups. The aim is to provide support in the home for those who belong to this group and need such support. The provisions also cover elderly and disabled people who are only staying in the municipality. In these cases, the municipality is the supervisory agency under the HSL and must provide health care in the accommodation, so-called municipal health-

[3] The National Board of Health and Welfare's regulations and general guidelines (SOSFS 2011:9) on management systems for systematic quality work.
[4] Chapter 15, Section 1 HSL.
[5] Act (1993:387) on support and services for certain disabled persons (LSS).

care.[6] It is also possible to remain in one's own home and have access to health care there. The same requirements for access and quality apply as for health care in general, with the exception of care provided by doctors. Health care in special housing is usually provided by a nurse responsible for medical matters (MAS). Depending on the specialised nature of the home, other qualified groups may also be in charge.

Social services also have legally mandated specific responsibilities for people with harmful use and addiction.[7] For this group, there is no corresponding obligation in the HSL for the municipality to set up special accommodations and thus provide health care. This group has to apply for assistance or emergency aid for accommodations or, in some cases, shelters. How the municipality should organise its housing services is not regulated. There is no obligation to provide health care in these accommodations.

4.2 Patient Safety Act

The purpose of the Patient Safety Act (2010:659), abbreviated PSL, is to promote good patient safety in health care and certain other areas. The Act has a legal link to the HSL, with the difference that the scope of the PSL is broader.[8]

The PSL relates to healthcare providers, health care groups and the supervisory role of the Inspectorate for Health and Social Care (IVO). Of these, the Act relates primarily to health professionals and their obligations towards patients. Patient safety is a key concept and is defined as protection against harm to patients under Chapter 1, Section 6 of the PSL.

The IVO supervises the health care sector and its supervision is aimed at checking whether the obligations in Chapter 3 of the PSL are complied with. There are various forms of supervision and the IVO has the power to take measures and impose sanctions if shortcomings are detected in the care provided. It is also possible for in-

[6] Chapters 11–13. HSL.
[7] Chapter 5, Section 9 of the SoL.
[8] See Johnsson, The Patient Safety Act, a commentary, Chapter 1, Section 2 of the PSL Karnov (JUNO) (visited 2022-07-18) commentary to Chapter 1, Section 2 of the Patient Safety Act. The Patient Safety Act also covers several other laws, including the Act (2009:266) on trade in medicines.

dividuals to submit complaints about care to the IVO, which investigates complaints of a more serious nature.

The National Board of Health and Welfare examines questions of licensing and other questions of competence for health and medical professionals under Chapter 4 of the PSL. Decisions are subject to appeal to the General Administrative Court. With regard to the revocation of a licence, the IVO notifies the Health and Medical Services Board (HSAN), which examines the cases in accordance with Chapter 9. PSL.

The PSL also establishes the obligation of healthcare providers to carry out systematic patient safety work.[9] Patient safety is closely linked to the concept of good care as set out in Chapter 5, Section 1 of the HSL. Care that is not in accordance with science and proven experience may entail a risk of harm and a danger to patient safety. The legislative preparatory documents stated that

> It must be a healthcare entity. The word "operates" implies that the healthcare measures are part of a regular activity. It is irrelevant whether the activity is public or private. In practical application, the word "operates" can sometimes give rise to doubts. In the preparatory work for the now repealed former Healthcare Act, see Govt. Bill. 1981/82:97, p. 33, the Government rapporteur stated the following. By 'care provider' I mean the person or entity who actually provides the care, whether this is based on an obligation or is purely voluntary.[10]

This clarification is still deemed to apply. Healthcare providers are obliged to carry out systematic patient safety work[11] and to ensure that their entity meets the objectives and requirements set out in the various regulations. In concrete terms, this means that healthcare providers must plan, manage and monitor their activities in a way that results in the requirement for good care under the Healthcare Act being maintained. In addition, healthcare providers must take the necessary measures against deficiencies in care and investigate and report incidents to the IVO.

There are also more detailed provisions in the National Board of Health and Welfare's regulations and general guidelines (SOSFS 2011:9) on management systems for systematic quality work. There

[9] Chapter 6, Section 1 of the Patient Safety Act.
[10] See Vahlne Westerhäll, Patient Safety Act (2010: 659) Chapter 1, Section 6 Karnov (JUNO) (visited 2022-7-18), see also Johnsson, Patient Safety Act, a commentary, Chapter 3. Section 1 of the PSL(JUNO).
[11] Chapter 3 of the Patient Safety Act.

must be a management system for the management of entities, which must be used to manage, plan, control, monitor and evaluate the entities.[12] There is nothing to prevent the care provider from setting higher goals and requirements. The statute only sets a minimum level.

As part of patient safety efforts, the law aims to strengthen patients' rights. Good quality is based on clear requirements and obligations for the staff working in the field and on the various professions performing their tasks in line with science and tested practice. The obligations of health professionals include the safe storage, handling and, where appropriate, dispensing of medicines under their care.[13]

4.2.1 Who belongs to health professions?

Health professionals comprise several groups with clearly defined responsibilities. In general, the concept of health professionals covers all those who work in health care and are involved in the provision of health care. It also includes staff who do not have direct contact with the patient, such as laboratory staff. Health professionals are under the supervision of the IVO.

Chapter 1, Section 4 of the PSL specifies the groups that belong to the healthcare personnel category. These are staff who are licensed or working in health care, or assisting someone who is licensed. Pharmacists and staff at the Poisons Information Centre are also considered health professionals. Compared to the previous legislation, new groups have been added. For the purposes of the PSL, staff at emergency centres and health advice centres are also health professionals. The latter are groups whose tasks lie at the interface between treatment and information.

A crucial factor for being considered a health professional is that the employee participates in the provision of care. What is important is the link with the health service and not the formalities of employment itself. This means that contract workers are also covered. It is also irrelevant whether the assistant lacks training and other skills for his or her tasks.

In the case RÅ 1997 note 28, a manager without medical training was involved to some extent in a private clinic where hair transplants

[12] See Johnsson, Patient Safety Act, JUNO version 1 (Dec. 3, 2020) commentary on Chapter 3, Section 1 of the Patient Safety Act
[13] Chapter 7, Section 1 of the Patient Safety Ordinance.

were performed. According to the Supreme Administrative Court, the manager was considered to have assisted with healthcare tasks to such an extent and with such regularity that he or she belonged to the healthcare staff.[14]

The requirement of good health care implies the availability of well-trained and generally competent staff to provide the best possible care for the patient. Chapter 6. PSL regulates the basic obligations for health professionals. These are supplemented by the Patient Safety Ordinance (2010:1369) and a large number of regulations in this area.

The basic principle is that health professionals should carry out their work in accordance with science and proven experience. A patient is to be provided with competent and caring health care that meets these requirements. Care shall be designed and implemented in consultation with the patient as far as possible.[15] The chapter states that health professionals have several obligations in their activities, such as contributing to a high level of patient safety, reporting deficiencies, providing the right level of patient care and giving appropriate and sufficient information. Some of these obligations are primarily set out in the provisions of Chapter 6 of the PSL. There is a link here to patients' rights in the Patients Act. The content and limits of professional activities are also set out in, *inter alia*, the regulations of the National Board of Health and Welfare. As a rule, healthcare professionals can only perform care-related measures that fall within the scope of what can be characterized as care attributed to expert and attentive care. The matter has been examined in the court case reported at RÅ 2009 ref. 65, which illustrates the requirements for healthcare personnel and the importance of good patient safety:

> A doctor had diagnosed heavy metal poisoning and electrohypersensitivity on several occasions and over a long period of time without sufficient scientific support and without considering other possible diagnoses that could explain the patient's symptoms. On the basis of those diagnoses, he had carried out treatments which were not in accordance with science and proven experience, and which he had not been able to justify on any other basis. The treatments had not been risk-free. The deficiencies were systematic and deliberate. He had not taken corrective action following repeated criticism from the National Board of Health

[14] See Johnsson, Patient Safety Act, JUNO version 1 (Dec. 3, 2020) commentary to Chapter 1, Section 4 of the Patient Safety Act.
[15] Chapter 6, Section 1 of the Patient Safety Act.

and Welfare. In view of this, he was deemed to have been grossly negligent in his professional practice and his licence was revoked.[16]

In summary, healthcare personnel must perform their duties in line with the obligations set out in Chapter 6, Section 1 of the HSL and other statutes regulating healthcare.

4.2.2 Health care outside the HSL

Chapter 5, Section 1 of the Patient Safety Act regulates what applies if someone professionally is engaged in certain healthcare entities outside the healthcare system. The provision is not exhaustive and there may be restrictions, for example in the field of medicines.

The basis for the provision, which has counterparts in the old Quackery Act and then in Chapter 4 of the Act (1998:531) on professional activities in the field of health care (LYHS), is that anyone may perform activities in the field of health care and use alternative medical treatment methods. This is linked to the freedom to conduct a business, which on the other hand is restricted in Chapter 5, Section 1 of the PSL.[17]

The scope of the provision has been drafted in a negative way. This means that the provision enumerates the measures that are prohibited to be taken professionally by persons other than health professionals. In line with this, what is listed as prohibited should only be done in the context of health care provided under the HSL. The prohibitions relate to serious medical conditions and treatment methods, as well as the requirement for an examination before any treatment is indicated. It is also prohibited to examine or treat children under the age of eight and to try out contact lenses.

As stated in the previous section, health professionals must carry out their work in accordance with science and best practice. There are no corresponding obligations for the non-health occupations to whom Chapter 5, Section 1 of the PSL refers.

The activities of such a professional are primarily limited by the prohibitions in Chapter 5, Section 1 of the PSL. In line with this, it is not possible to require a person operating under Chapter 5, Sec-

[16] See Johansson, Patients' Safety Act, a commentary JUNO version 1 (visited 21022-07-28) commentary to Chapter 5, Section 1 of the Patients' Safety Act.
[17] See Vahlne-Westerhäll, The Patient Safety Act, a commentary Karnov (JUNO) (visited 2022-07-28).

tion 1 to take a particular action, as the law only specifies what is prohibited. As long as the person in question does not violate Chapter 5, Section 1, or any other regulation relevant to the professional activity, there is no restriction on the methods that may be used.[18] However, it is possible to penalise those who violate the prohibitions in the provision.[19]

Penalties and other provisions for violation of Chapter 5, Section 1 of the PSL are contained in Chapter 10, Sections 6 to 8 of the PSL. It states that the fact that the offender, due to lack of training and experience, could not have recognised the nature of the disease or foreseen the harm or danger does not exempt the person in question from liability. Since lack of knowledge and understanding of what can be treated is associated with risks, these activities should be carried out within the framework of health care. It is this risk with other activities that Chapter 5, Section 1 of the PSL addresses.

The prohibitions in Chapter 5, Section 1 of the PSL may also be punishable under provisions of, *inter alia*, the Criminal Code. If an act would be subject to a more severe penalty in another law than the PSL, those rules take precedence, see Chapter 10, Section 7 of the PSL. Furthermore, Chapter 10, Section 8 states that the IVO may prohibit such activities if someone has been convicted under Chapter 10, Section 6. The prohibition may be accompanied by a fine.[20]

In summary, anyone can provide health care outside the regulated healthcare system. Since these persons are not subject to the requirements of regulated health care, certain medical conditions and certain methods of treatment are prohibited and any inaccuracies may lead to criminal liability.

4.3 Patients Act

The Patients Act aims to strengthen the position of patients and to promote their integrity, self-determination and participation. A patient is anyone who, on their own initiative or otherwise, has estab-

[18] See Johnsson, Patient Safety Act, JUNO version 1 (Dec. 3, 2020) commentary on Chapter 5, Section 1 of the Patient Safety Act (visited 22-07-28).
[19] Chapter 10 and Section 8 of the Patient Safety Act.
[20] See Johnsson, Patient Safety Act, JUNO version 1 (Dec. 3, 2020) commentary on Chapter 5, Section 1 of the Patient Safety Act (visited 22-07-28).

lished contact with a healthcare professional regarding their own health condition.[21] The Patients Act has the same definitions as the HSL and applies to care provided under that Act.[22]

Stating that the patient has rights implies that the patient should have a say in the care that may be provided. The reason is that, unlike what was the case in earlier times, patients need to have a more active role in their care and receive more and better information in order to influence their health and their need for care. Furthermore, care should be voluntary, the patient's consent to the care is required.

Information on health care of a more general nature, such as information on the quality and outcomes of care, can be difficult to find. This can lead to patients in an elective situation not knowing about alternative providers and treatment methods. In light of this, access to information is a prominent patient right. Information is often provided by health professionals in face-to-face encounters with the patient. Receiving information or having access to information is a prerequisite for the patient's right to self-determination and for the realisation of the patient's right to privacy.[23]

The rights of the patient correspond to obligations for the administrative agency, care providers, and the medical personnel. This is not a legislation dealing with rights in the sense that the rights can be demanded of a person in authority and then appealed to the courts.[24]

4.3.1 Consent in health care

Being a patient means being in a situation of dependency. This raises questions about the patient's autonomy as to care and treatment. The legal basis for the protection of the individual in this context is laid down in the Swedish Instrument of Government, one of the documents that together comprise the Swedish Constitution.

Chapter 1, Section 2 of the Instrument of Government states that public power shall be exercised with respect for the equal value of all persons and for the freedom and dignity of the individual. Chapter 2, Section 6 of the Instrument of Government applies to

[21] Govt Bill 1993/94:149 p. 73.
[22] Govt Bill 2013/14:106 p. 45.
[23] See Lönnheim, Patients Act (2014:821) 2–3 chap. Karnov (JUNO) (visited 2022-07-19).
[24] See Lönnheim, Patients Act (2014:821) Introduction Karnov (JUNO) (visited 2022-07-19).

the health sector. The aforementioned section provides that every citizen shall be protected against involuntary bodily intervention vis-à-vis public authorities, even in cases other than those referred to in Sections 4 and 5, which concern protection against torture and capital punishment. It further provides that each person has the right to protection of his or her bodily integrity vis-à-vis the public authorities. The protection of bodily integrity from individuals is regulated by criminal law.

The protection of bodily integrity is a relative right and may be limited by law as provided for in Chapter 2, 6 and 20 of the Instrument of Government. This means that the protection of bodily integrity in health care can only be restricted if the interest in carrying out a bodily intervention outweighs the interest in protecting bodily integrity. The legislature has mandated that any restrictions of the protection of bodily privacy require a parliamentary act.[25]

The concept of bodily interventions thus covers both minor and serious healthcare measures. These include medical examinations, vaccinations and blood tests, and phenomena usually referred to as physical examinations. Even an examination of a fully clothed patient is included. This means that everyone is protected from healthcare treatments. In other words, treatment may not be given against someone's will, i.e. by force, unless specifically stated by law.

The principle of consent to health care is fundamental and is regulated in Chapter 4, Section 1 of the Patients Act. There is no equivalent in the older or current HSL but there were rather formulations such as consultation, care and respect. Preparatory legislative material for the older HSL indicates that the patient, as a rule, had an unlimited right to refrain from treatment and that he or she can demand that a measure be immediately discontinued or never taken.[26] In practice, the meaning of consultation, consideration and respect has been interpreted as meaning that consent was required.

Procedures carried out for the purpose of investigating and treating diseases or injuries are also covered. This means that even a measure that is objectively of the greatest benefit to a patient may not be taken against the patient's will.

A case concerning a breast operation is referred to in the annual reports of the Supreme Administrative Court under 6:69/86. It con-

[25] Chapter 2, Section 20, p. 2 of the Instrument of Government.
[26] Govt Bill 1981/82:97 p. 118.

cerns a complaint from a woman who did not consent to the procedure to remove her entire breast. In the patient's medical record it was noted, among other things:

> Surgery is carefully discussed, pat does not want to undergo ablation even if the change turns out to be malignant.

The liability of the doctor who performed the operation was examined by the Court of Appeal. The court found that no matter how justified an operation may have been from a medical point of view, the removal of the entire breast was not permitted without the patient's consent.

It should be added that all healthcare providers must maintain patient insurance. This applies to both public and private healthcare providers. The detailed conditions for receiving compensation are regulated in the Patient Injuries Act (1996:799).

4.3.2 Exceptions to consent

When the issue of consent was addressed in the preparatory work for the Patients Act, the situation where the patient's will cannot be ascertained was also discussed. Among other things, the following was stated.

> In health care, situations often arise where, for various reasons, people are unable to give consent to necessary healthcare interventions. These are mainly emergency situations where, for example, a person is unconscious and medical intervention must be taken immediately to save the person's life or otherwise to avoid serious consequences for the person's health.
>
> The legal support that can be invoked in such situations is possibly Chapter 24. 4 of the Criminal Code, which regulates the conditions under which an act in an emergency situation can be exempt from criminal liability. According to this provision, distress may exist when danger threatens, inter alia, life or health. An act committed by someone in distress constitutes a crime only if it is inexcusable having regard to "the nature of the danger, the harm caused to others and the circumstances". In the view of the commission of inquiry, the intervention of healthcare services in this type of situation should be based on the legislation governing the status of the patient and not on the interpretation of general rules in the Criminal Code.[27]

[27] Govt Bill 2013/14 p. 61 and p. 120.

The special explanatory memorandum made the following statement on the reasons for introducing a provision exempting consent.

> The patient shall receive the health care necessary to avert a danger which is an urgent and serious threat to his or her life or health, even if his or her will cannot be ascertained because of unconsciousness or for any other reason.
>
> The provision is an exception to the main rule in Article 2 and allows health professionals to provide health care in an emergency situation to a patient who is unable to consent to the care.
>
> Only care that is necessary to avert a danger that is an urgent and serious threat to the patient's life or health may be provided without the patient's consent. It must therefore be necessary care that cannot be postponed until a patient is able to decide on the measure himself. The provision applies only in situations where the aim is to save the patient's life or otherwise to avoid serious consequences for his or her health.
>
> This paragraph refers to situations where a patient's will cannot be ascertained due to unconsciousness or for any other reason. Reasons for the patient's inability to give consent other than unconsciousness may be that the patient is unresponsive due to shock, is going into unconsciousness or is under the influence of, for example, narcotic drugs.
>
> The provision also applies when a person who is more permanently incapacitated is in an emergency situation.[28]

In Chapter 4. 4 of the Patients Act regulates the exemption from the requirement that the patient must consent to health care. It applies to necessary care that cannot be postponed and where the patient is unable to express his or her will with regard to the care intervention, for example in cases of unconsciousness or under the influence of narcotic drugs. The provision is intended for emergency situations where the aim is to save the patient's life or to avoid serious consequences to his or her health.

As long as it is necessary care in an emergency response, it is an emergency situation. Thereafter, care cannot be provided on the basis of the exception rule even if the patient is unable to express his or her will. This means that the exception does not apply to continuing care for a person who is permanently incapable of deciding on the need for health care. In these cases, the legal basis for providing care should continue to be the emergency provision of the Criminal Code.[29]

[28] Govt Bill 2013/14:106 p. 121 and 160.
[29] Govt Bill 2013/14:106 p. 121.

In summary, exceptions to consent apply to people in acute emergencies who are, for example, unconscious or so under the influence of drugs that their will cannot be ascertained.

4.3.3 The general necessity provision in Chapter 24, Section 4 of the Criminal Code

The previous section dealt with what applies in emergency situations when medical action is taken by health professionals. It was shown that treatment in these situations can take place because there is support in law to make exceptions to the patient's consent. This section focuses on what applies when members of the public, lay people or members of non-health occupations need to provide treatment to a person in an emergency situation.

The fact that everyone is protected against physical interference by the public means that no one (normally[30]) can be forced to seek health care. When a person has suffered from opioid poisoning, their life and health may be threatened, and they are in an acute emergency. Legally, two constitutionally protected rights are at odds: the right to life and the right to be protected from bodily harm. In such a situation, the question arises whether the necessity provision in Chapter 24, Section 4 of the Criminal Code may be applicable.

In Swedish law, the necessity provision was introduced when the Criminal Code entered into force. Like self-defence, necessity is an objective ground for exemption from liability, which means that the purpose of the act is irrelevant for the purposes of criminal law.[31] The provision is negatively framed with the presumption that when someone in distress commits an act, it is an offence only if, viewing the nature of the danger, the harm caused to another and the circumstances in general, it is inexcusable.

During the period of the Penal Code, a right of necessity was accepted without explicit legal support. This meant that no one could be punished for an act that was unavoidably necessary to save life, health or property of significant value. The threat had to be particularly significant[32] in relation to the harm caused by the emergency

[30] There is coercive legislation that regulates the conditions for providing care against one's will in psychiatric care and under the law on infection control.
[31] Govt Bill 1993/94:130 p. 35.
[32] See Bäcklund et al. Commentary on the Criminal Code 18 June 2022, Version 20 (JUNO).

act. Societal interests could also be covered. The wording of the necessity provision has been amended since its introduction in the Criminal Code without any substantive changes. Chapter 24. Section 4 of the Criminal Code reads as follows: "An act committed by a person out of necessity, other than as previously mentioned in this Chapter, constitutes an offence only if, having regard to the nature of the danger, the harm caused to another and the circumstances, it is inexcusable.

Necessity applies when danger threatens life, health, property or any other important interest protected by law. This provision is subordinate to the right of self-defence, i.e. it is to be applied only when discharge under this provision is not applicable. It is clear from the text of the law that life, health and property are priority interests for protection. It may also concern another important interest protected by the legal order, such as a public interest. If a public interest is threatened, the right of necessity must be used restrictively or the public interest must be of the utmost importance.[33]

A prerequisite for exemption from liability when an act is done out of necessity is that it should not be "inexcusable". An act of necessity may be considered to be unreasonable if its consequences are disproportionate to the danger or harm threatened, or if the person claiming necessity had the possibility of avoiding the danger or harm in a way other than by committing a punishable act.[34] This means that the scope for acts of necessity is narrower than for acts of self-defence and that the person acting in necessity must to a greater extent put his or her own interests aside. As a rule, the act committed out of necessity must be motivated by an interest of significantly greater importance than that which is sacrificed. The necessity rule is intended to apply only in exceptional cases.[35]

There is no need for there to be a criminal act for the necessity rule to apply, nor does the rule presuppose that the person committing the act is himself in distress, but, unlike the right of self-defence, necessity also covers third parties. Another difference is that necessity, unlike self-defence, does not require the commencement or imminence of an attack on a protected interest.

[33] Govt Bill 1962:10, part B, p. 337 and Govt Bill 1993/94:130, p. 34.
[34] See Zila, Commentary to the Criminal Code ((1962:700) Chapter 24. Karnov (JUNO) (visited 2022-07-20).
[35] Ibid.

The provision is primarily aimed at emergency situations, but recent practice does not exclude the possibility of a more permanent situation. An emergency situation refers to interests protected by the legal order, including public interests. However, the necessity provision does not allow individuals to intervene in matters which the authorities have to manage or enforce. As a rule, public interests of paramount importance are required, for example, the prevention of a spy from disclosing secret information on national defence.[36]

NJA 2018 p. 1,051 concerns whether a detention in a municipal care home was permissible on the basis of necessity or social adequacy. The case illustrates that necessity or unwritten rules are applied restrictively as a basis for discharge in emergency situations in healthcare and related entities. A member of staff had deprived a patient of his liberty by blocking the door to the patient's living room with an armchair and sitting in the armchair himself. Chapter 2, Sections 8 and 20 of the Instrument of Government provides that every person is protected against deprivation of liberty without law.

The Supreme Court concluded that there had not been an emergency in the sense that there were reasons for the member of staff to keep the patient in custody.[37] Nor was it deemed to be a matter of social adequacy, in other words, such unwritten rules that indicate that from the perspective of the public interest, an act should be allowed even though it may actually constitute a crime. The basis is that unwritten rules should be applied restrictively with the consequence that the deprivation of liberty was not allowed even on the basis of social adequacy[38]

In summary, the necessity provision may be used when an emergency precludes any other solution, unless the measure taken is deemed to be unreasonable in relation to the interest at stake. Public interests are also considered worthy of protection and applicable to necessity, but this must be done restrictively and not largely apply to a matter that the authorities must deal with.

[36] Digital legal commentary JUNO version 20 published in June 2022.
[37] NJA 2018 ref 1051: In the District Court's opinion, there has not been such a danger to life, health or property as to constitute an emergency situation and that the measure to keep the target confined in his room was justified.
[38] NJA 2018 ref 1051: grounds for judgment p. 11 and 12.

4.4 Prescription, requisition and administration of naloxone

4.4.1 Approval and requirements for the dispensing of naloxone

The basic statutes relating to the management of medicines are the Medicines Act (2015:315) and the Act (2009:366) on trade in medicines. There are also a large number of regulations in this area.

The main rule for a medicine to be marketed is that it must first be authorised or registered[39] which is an implementation of EU law.[40]

Two medicines containing naloxone in the form of nasal sprays have been approved in Sweden since 2017. They are approved through different procedures at European level and are both classified as prescription-only medications. The approval states that certain requirements must be met, including training requirements, in order for the medicine to be prescribed or dispensed. If a medicine and its conditions are to be changed, new legal processes are initiated at national and European level. The summary of the Medical Products Agency's report states the following.

> Due to the requirements for risk minimisation measures regarding educational activities in all conditions for the approval of naloxone nasal spray, the products are available on prescription in Sweden and in all EU/EEA countries that responded (23 out of 30 member states) to the MPA survey on prescription status for naloxone. From a legal point of view, these conditions cannot be disregarded in a reclassification.
>
> A reclassification of the prescription status can take place, for example, if the marketing approval holder applies for it.[41]

For prescription medicines such as naloxone, Chapter 2, Section 9a of the Act regarding Commerce with Medication sets out the following requirements. When dispensing a prescription, a pharmacist must provide information and advice in accordance with Section 6, point 11 and perform other tasks of particular importance for the safe handling and use of the medicine.

The aim of the regulation is for the pharmacist to ensure, as far as possible, that the medicine will be used correctly. The obligation

[39] Chapter 5, section 1, paragraphs 1 and 2 of the Medicines Act.
[40] Articles 2 and 6 of Directive 2001/83/EC(2).
[41] Non-prescription status for naloxone in nasal preparation, MPA 2022.

to give the necessary instructions when a medicine is dispensed from a pharmacy is also set out in Chapter 3, Section 5 of the Medical Products Agency's regulations (HSLF-FS 2021:75) on the prescription and dispensing of medicines and methylated spirits. These regulations do not apply to dispensing prescriptions for medicines to be used in hospitals. Chapter 8, Section 1 of the same regulations also emphasises the importance of the pharmacist providing information and advice at the time of dispensing and performing the tasks that are important for the safe handling of the medicine.

4.4.2 Prescribing naloxone

Prescribing means that an authorised professional issues a prescription for a medicine to a patient who needs the medicine and will use it himself. [42] It is only possible to prescribe directly to a patient and not to a third person who does not need the medicine himself but who intends to treat someone else. Prescribing requires the prescriber to make an individual medical assessment of the patient's needs and determine whether the medication is appropriate in the particular case.[43] Prescription can also be made for the medicine to be administered by the healthcare system, the National Board of Health and Welfare regulations and general guidelines on the prescription and management of medicines in the healthcare system (SOSFS 2017:37, formerly 2000:1).[44]

Only a registered doctor or nurse is authorised to prescribe naloxone. This is provided in the regulations (HSLF-FS 2021:75) on the prescription and dispensing of medicines and methylated spirits. The regulation does not apply to the prescription or dispensing of medicines and technical spirits to be used in hospitals.[45] The term prescribing covers both the prescription of medicines and the issuing of requisitions for medicines.

In this context, the prescription of naloxone dispensed from over-the-counter pharmacies is the responsibility of the licensed

[42] The National Board of Health and Welfare's regulations (SOSFS 2009:6) on the assessment of whether a healthcare measure can be performed as self-care.
[43] The report of the National Board of Health and Welfare and the Medical Products Agency published on Socialstyrelsen.se June 2017 (article number 2017-6-6).
[44] The National Board of Health and Welfare's regulations and general guidelines (HSLF-FS 2017:37) on the prescription and management of medicines in health and medical care.
[45] The Medical Products Agency's regulations (LVFS2012:8) on the supply of medicines to hospitals contain provisions on the handling of medicines by hospital pharmacies.

physician and nurse.[46] The right to requisition a medicine is linked to the right to prescribe the medicine, Only the person authorised to prescribe a medicine has the power to prescribe it.

Chapter 6, Section 1 of HSLF-FS 2021:75 states that a person who is an authorised prescriber under Chapter 2 may also order and receive items covered by the authorisation. The same provision states that a requisition may be issued under Section 7. These are special provisions for requisitions issued by someone other than a prescriber. This provision specifies the different groups that may issue a requisition and Article 8 specifies the requirement for the requisition to be in writing. The following groups may requisition medicines for different purposes:

- Group 1 consists of the head of a scientific institution or equivalent.
- Group 2 consists of experts who hold manufacturing or wholesale authorisations for medicines.
- Group 3 are pharmacists serving in a unit of the Armed Forces.
- Group 4 consists of masters of ships or a person holding an equivalent position related to regulations on medical care and pharmacies on ships. The requirements for certain medical services on ships are laid down in international conventions and primarily concern the personnel working on board, but also to some extent passengers.
- Group 5 is aimed at individuals who carry out electrical welding work professionally and need eye drops for acute eye pain.

In summary, the possibility of issuing prescriptions for non-prescribers targets different groups. Some of these groups need conduct emergency medical care as part of their operations and this cannot be done by an authorized healthcare prescriber.

[46] HSLFS-FS 2021:75, Chapter 2.

4.4.3 Self-care and dispensing of naloxone

When naloxone is prescribed to a patient, the person is unlikely to be able to use it themselves without help from someone else. The licensed physician or nurse has the opportunity to assess whether the patient can use the medicine according to the provisions of regulation SOSFS 2009:6 which regulates self-care.[47]

Self-care means that the patient is able to perform a treatment intervention. The term also includes treatment interventions that the patient needs help with from their social network, both private and professional. The idea is that patients who, because of a mental or physical disability, need help in administering medicines should be able to receive such help from staff or relatives who are familiar with the patient. The prescriber makes an assessment of whether self-care is appropriate and must carry out regular follow-ups in the interests of patient safety, as set out in Chapter 1, Section 2 of the Regulation. It is important to note that self-care does not count as health care as defined in Chapter 2, Section 1 of the same Regulation.

In the case of naloxone, prescribers also have the right to dispense the medicine, as set out in Chapter 3, Section 4 of the Medical Products Agency regulations (HSLFS-FS) (2021:75). That regulation provides that prescribers may dispense medicines containing naloxone to patients who are at risk of overdosing on opioid preparations due to harmful use or addiction and who, according to their authorisation, may be administered by persons other than healthcare professionals. This dispensing requires that the prescriber be authorised to prescribe the medicine and that the patient can be offered treatment for harmful use or addiction. At the time of disclosure, the prescriber shall ensure that the necessary training on the measures to be taken in the event of an overdose, including the administering of the medicine, has been completed.

The provision thus requires that other measures be taken in parallel with the patient receiving naloxone for self-care.

[47] The National Board of Health and Welfare's regulations (SOSFS 2009:06) on the assessment of whether a health and medical care measure can be used as self-care.

4.4.4 Administering naloxone

Provisions on the supply of medicines to and within hospitals can be found in the Medical Products Agency's regulations (LVFS 2012:8) on the supply of medicines by hospitals. Provisions on the prescription and administering of medicines in the healthcare system can be found in the National Board of Health and Welfare's recommendations and general guidelines HSLFS-FS (2017:37) on the prescription and administering medicines in the healthcare system. Doctors, dentists, and nurses have a general authorization to administer medicines, while other professionals have a limited competence to administer. It is possible for other healthcare professionals to administer and hand over medicines if the task has been delegated by the doctor or nurse. The conditions for delegation are regulated in the National Board of Health and Welfare's regulations and general guidelines (SOSFS 1997:14) on delegation of tasks in health care and dental care.

There are also other non-licensed professionals who have a limited authorisation to administer certain medicines. This type of authorisation is possible according to the provisions of HSLFS-FS Chapter 6, Section 6 (2017:37), the physicians' general directive on pharmacotherapy. A general directive must be in writing and healthcare providers must have procedures in place that specify which doctors are authorised to issue general directive and that it is ensured that the medicines are dispensed in a manner that is safe for patients. The rule in question is intended to be used in exceptional circumstances and should be applied restrictively.

The purpose of the general directive is to enable doctors to prescribe medicine to a group of patients with whom they are familiar and who have a similar medical situation. After the general directive has been issued, before it is prepared and administered or given to the patient, a nurse must carry out an assessment of the patient's need for the medication. The nurse must also check the indication and contraindications of the medicine and document his/her assessment in the patient's medical record in accordance with Chapter 6. Section 7 of the above-mentioned regulation.

Of interest in this context are the National Board of Health and Welfare's regulations (SOSFS 2009:10) on ambulance care. Chapter 7 deals with personnel who provide first aid while waiting for an

ambulance. The basis for the assignment is an IVPA[48] agreement based on Chapter 3, Section 2 of the Act (2009:47) on Certain Municipal Powers. The aim is to ensure that people in acute emergencies receive first aid with simple aids while waiting for an ambulance to arrive. The agreement must state whether defibrillation is included in the assignment. The same applies to treatment with oxygen and naloxone.[49] IVPA staff are considered to be health professionals when they provide treatment with defibrillation or oxygen and naloxone. The staff is under the supervision of the IVO and must document the treatment in the patient's record.

4.5 Summary

In this chapter, we have outlined some key provisions in health law and how the general necessity rule has been updated in this area. Health care is a clearly defined area of law in which responsibilities, rights and obligations are central, as are the constitutionally protected rights to life and protection against bodily harm not supported by law. In health care, the question of who can do what is carefully regulated by different statutes and regulations at different levels of norms. There are also detailed rules on how different situations should be handled and who is responsible if things go wrong. A fundamental principle in health care is systematic quality work; all with a view to promoting patient safety and preventing the risk of harm in care as far as possible. We will later view Chapter 7 together with legal conclusions on the impact that regulation is expected to have on the ability of other professionals to administer naloxone.

[48] Waiting for an Ambulance, IVPA.
[49] Sections 1–3 of the SOSFS (2009:10) on ambulance care.

5 Ethical principles and assessments

In this chapter we provide a brief ethical reflection on the values and ethical principles that will underpin our future work.

5.1 The ability to save lives is of paramount importance in a hierarchy of values

Assessment: The ability to save lives should be accorded a high level of importance in relation to other values, risks and principles that may conflict with the principle of saving lives. This will have an impact on our future proposals on which other activities and professionals should be able to administer naloxone.

5.1.1 Different values and perspectives that need to be balanced if other professionals are to administer naloxone

Legislation is typically guided by value rationality, in which the system created should reflect and promote the values the legislature wants to guide society with. As a rule, this always involves trade-offs between different values. The central ethical question in our mission is whether it is acceptable for members of non-health occupations to perform physical and therapeutic interventions on an unconscious person without their consent, in order to save their life.

Principles such as saving lives and *doing good* are of great importance in ethics. For example, in the United States, the possibility of saving lives has laid the foundations for the way naloxone work is

carried out (with "Good Samaritan laws" and "standing order" exceptions from other applicable laws).

One of the basic principles of medical ethics is *autonomy* or the right to self-determination. This principle means that people should be able to decide for themselves about their own lives and actions, provided that this does not violate the right to self-determination of others.[1] This is also largely transposed to medical law by requiring, as a general rule, the patient's consent to treatment and other healthcare interventions. This is discussed in Chapter 4.

The principle of *do no harm* is another important principle. Harm can include many different actions that affect a person negatively; physically, psychologically, socially, in terms of integrity, and so on. All use of medicines involves some form of risk of harm. In the case of naloxone nasal spray, we have stated in previous chapters that side effects or harm resulting from naloxone appear to be limited.

A risk of harm of a more privacy-related nature is the forced physical intervention itself. In previous government commissions, concerns were raised about power imbalances and abuse of power if members of non-health care professions were too broadly allowed to administer naloxone.

> Several key groups highlighted the importance of trust between the potential practitioner and the user. If naloxone is made too widely available in society, a potential risk could be the creation of anxiety among users about being treated against their will. This could be perceived as a power shift and potentially lead to a loss of trust in authorities and key groups and, in the worst case, could scare people who use drugs away from public places and care and support services.[2]

Concerns were also raised that members of these occupations might have difficulty identifying whether the overdose was really an overdose in which the individual needed naloxone, or whether the individual was "just" under the influence of drugs. In the latter case, a possible negative consequence from the user's perspective could be the lack of effect of the opioid. Now, naloxone nasal sprays have been available in Sweden for a few years and, based on current experience, we believe that the concerns that existed some years ago are

[1] Statens Medicinsk-etiska råd, Quelques medicinsk-etiska begrepp, www.smer.se visited 2022-08-29.
[2] Assignment on increased availability of certain medicines in order to counteract drug-related mortality, MPA, 2018.

no longer relevant and that the risk of harm of a privacy nature is low.[3]

The principle of human dignity is another principle of great importance in this context. Human dignity is not tied to our traits or characteristics, but is linked to each individual human being regardless of performance.[4] Many times people who use drugs, or engage in harmful use or are addicted, are met with fear, loathing and rejection.[5] It is a question of the attitudes of the environment and society, of the attitudes of different professionals, and of the way in which health and social services treat people. In a recent population survey, a high proportion of the public responded that alcohol and drug addiction was more likely than other psychiatric diagnoses to be self-induced. This finding is in line with studies showing that the public rarely perceives alcohol and drug addiction as a psychiatric condition and that people with these conditions are more often blamed than those with other psychiatric conditions.[6] The moral conclusions that develop as a result of such perceptions can lead to stigmatisation. The consequences of stigma may be that people with drug addiction feel they receive less treatment for physical health problems or may not seek treatment at all. Stigma directed at persons with addiction can also indirectly affect how resources are prioritised and allocated. There is therefore a need to work in a variety of ways to reduce the stigma attached to people who use drugs and to strengthen and develop access to interventions that can improve health and save lives in this group. The equal value and right to life of all people is therefore also a basis for our future work.

Proportionality is an important aspect of ensuring that measures do not go beyond what is necessary for the purpose. This means that the measure of expected impact of the intervention needs to be considered in the overall assessment. Extending to other occupations the possibility of administering naloxone, or perhaps even considering it an obligation or commitment in specific cases, may be associ-

[3] In the United States, for example, where the police have been administering naloxone for some time, this dilemma has not been recognised or become a reality. Nor do user organisations in Sweden seem particularly concerned about such a development today, as the Drug Commission of Inquiry sought views on at a hearing for civil society on 8 September 2022.
[4] Statens Medicinsk-etiska råd, Quelques medicinsk-etiska begrepp, www.smer.se visited 2022-08-29.
[5] From parts to whole – a reform for coordinated, needs-adapted and person-centred interventions for persons with co-morbidity, SOU 2021:93.
[6] Views on mental illness and suicide – A population survey on knowledge and attitudes, Swedish National Board of Health, 2022.

ated with both costs and training that must be considered in an overall assessment. In our work, we view both the possibility of administering naloxone on a voluntary basis as an individual, and on the basis of some form of opportunity to do so as part of professional practice. In the latter case, it may not be proportionate to impose this task on everyone in a particular profession, even if it could save a human life. In entities or occupations where a possible opioid poisoning could be a rare event and more of a hypothetical situation, it would probably not be proportionate to impose an obligation to obtain naloxone, ensure proper medicine management and train all staff in how to administer the medicine.

Our overall assessment is that the opportunity to save lives weighs heavily in the balance between different values, while our analyses and proposals need to be proportionate to the expected impact. Our assessment is that the risk of harm from an increased number of people being allowed to administer naloxone can be considered low and that the benefits of different entities and groups being able, or perhaps even in some cases, being advised or required to, administer naloxone, outweigh the risks. Our assessment is that the possibility of saving lives also outweighs the risk of a possible invasion of privacy. In the codes of ethics that apply in society, the right to life of all should apply equally regardless of whether the intervention is to prevent suicide attempts, resuscitate in cases of cardiac arrest or resuscitate using naloxone, even if it may involve a violation of a more privacy-related nature. These assessments will inform further work regarding making naloxone available to more groups.

6 Analysis and assessments

This chapter is based on the background provided in the previous chapters and analyses the availability of naloxone as part of a broader preventive effort to reduce medicine and drug-related mortality. We evaluate whether other occupational group groups should be able to administer naloxone and whether regulations or other support may be needed. These assessments will inform our further investigative work and need to be further developed.

6.1 Naloxone is one of several interventions intended to prevent opioid-induced death

Assessment: Broad access to opioid antagonists, such as naloxone, for the purpose of administering the medicine to people who are subjects of opioid poisoning should be included as one of several interventions in a national programme to prevent medicine and drug-related mortality. The Drug Commission of Inquiry will later submit proposals for this type of national programme in its final report.

6.1.1 Reducing medicine and drug-related deaths requires much more than naloxone

Harmful drug use and addiction is a complex phenomenon, and we therefore believe that many different interventions are needed at various levels of society to prevent mortality caused by drug or medicine poisoning. Naloxone may be an important part of the solution, but much more needs to be done. Prevention and easy access to care

and support seem to be crucial for the long-term impact of drug-related mortality.

Further interventions in the field of harm reduction, alongside naloxone, also need to be evaluated as possible components to reduce drug-related mortality. These are issues we intend to address in the final report and in efforts to propose a national programme to reduce drug-related mortality.

6.1.2 Implementation of naloxone distribution to individuals needs to be improved

It is now possible to prescribe naloxone to people who use drugs. The National Board of Health and Welfare has on two occasions evaluated whether the regions have begun systematic work to prescribe naloxone to patients. In 2019, of 20 regions, 13 responded that they are carrying out systematic work to make naloxone available to patients.[1] In a follow-up survey a year later, 18 out of 21 regions responded that they were doing so.[2] Although efforts to prescribe naloxone to patients have begun in many regions, there is scope to further improve implementation. For example, not all LARO clinics[3] have started systematic naloxone prescribing despite the possibility of doing so. In other countries (e.g. Denmark and France) the offer of training and naloxone distribution is standard for patients in LARO treatment and in Sweden the recommendation of naloxone is a top priority in national guidelines. In Sweden, access to naloxone for patients prescribed opioids, for example for pain, is limited, at present. More systematic efforts regarding naloxone for these patients, as well, needs to be considered in the future.

Naloxone can be prescribed for persons in correctional facilities or in one of the institutions of the National Board of Institutional Care (e.g. LVM) under the current regulatory framework. Although efforts to improve implementation have begun, there remains much to do. The National Board of Health and Welfare and the Swedish Association of Local Authorities and Regions (SKR) are currently

[1] The state and development of healthcare and dental care - Status report 2020, The National Board of Health and Welfare, 2020.
[2] Addiction, substance-related diagnoses and gambling – Thematic follow-up of needs, care and support in relation to the national ANDT-work and gambling, National Board of Health and Welfare, 2021.
[3] Medication-assisted treatment for opioid addiction.

working to support the Prisons and Probation Service and the various regions in their efforts to increase naloxone prescribing within the Prisons and Probation Service.[4]

In order to increase the availability of nasal spray containing naloxone, the Medical Products Agency, in collaboration with the National Board of Health and Welfare, has investigated the possibility of making the drug available without a prescription. The Medical Products Agency's report, published in September 2022, states that there is currently no available medicine containing naloxone in the form of a nasal spray that it is legally possible to classify as a non-prescription medicine. The MPA outlines the options available for approving a naloxone with over-the-counter status in the future, but none of these pathways are simple or quick. Fundamentally, the non-prescription problem relates to the educational requirements associated with the authorisation of the medicine, to national law on the authorisation of pharmacists and, finally, to the way in which the authorisation of medicines within the EU is regulated.[5] In our view, making naloxone nasal spray a non-prescription medication could be a way to make it easier for relatives and friends, for example, to access the medicine. Others, such as organisations and companies that see a need to have the medicine available, would then also be able to buy it from pharmacies.

In our opinion, the prescription and distribution of naloxone needs to take place in more facilities than has been the case so far in order to achieve easy accessibility and the full impact of this tool. The work of the National Board of Health, and other stakeholders, to support implementation at national level therefore needs to continue.

6.1.3 A new policy needs to face future challenges

The National Guidelines for Care and Support in Substance Use and Addiction of the National Board of Health and Welfare, and the scientific evidence on which the recommendations in the guidelines are based, focus on individuals who engage in harmful use of, or who are

[4] Assignment to support increased availability of naloxone – Interim report on implemented and planned activities within the framework of the assignment, National Board of Health and Welfare, 2022.
[5] Non-prescription status for naloxone in nasal preparation, MPA 2022.

addicted to, opioids.[6] However, opioid poisoning may also occur among individuals who have not developed harmful use or addiction. It is also possible that an individual who uses drugs other than opioids may encounter opioid poisoning. In the United States, fentanyl mixed with other drugs has caused many deaths. In Sweden, this still seems to be rare, although there have been some reports of fentanyl in benzodiazepines in individual municipalities.[7] However, it is not possible to predict whether this trend in the USA may also occur in Sweden in the future. As part of our work, we will be presenting proposals for a drug policy adapted to the challenges of today and tomorrow. We do not rule out the possibility that any regulation of naloxone or other interventions would also cover a broader target group than people with harmful opioid use and addiction (who are currently the primary risk group for opioid-induced poisoning), should this medication prove to be effective. We also do not rule out the possibility that opioid antagonists other than naloxone may be developed, so any future efforts need to take these circumstances into account.

6.2 Implementation efforts require both regulation and support

Assessment: In order for other occupational groups (and other activities) outside the health sector to be able to administer opioid antagonists (such as naloxone) in their work, the current regulatory framework should be clarified and complemented. Furthermore, national support for the implementation of naloxone programmes may need to be strengthened in order to increase the availability of naloxone among people who use drugs and others.

[6] National guidelines for care and support for harmful use and addiction and addiction – support for governance and management, National Board of Health and Welfare, 2019.
[7] Customs has not made any seizures of amphetamines, tramadol or heroin that also contain fentanyl in 2022 or earlier years. Heroin mixed with fentanyl is found in other countries, but neither Customs nor the police's analyses indicate that it is present in Sweden. Seizures of fentanyl and fentanyl analogues are now extremely rare and in 2021 and 2022 have only occurred as fentanyl patches. The Public Health Agency is responsible for the Drugs Warning System (VSN), a national information and warning system that aims to facilitate the exchange of information between connected actors from national authorities, health and medical services and social services. In the VSN, there has been a single report of fentanyl mixed with other substances in 2022.

6.2.1 Current law creates ambiguity about what occupational groups can and cannot do regarding naloxone

The discussions we have had have shown that there is uncertainty, particularly in social work settings, about whether or not staff should and may administer naloxone in a situation where a person has suffered from opioid poisoning. The same is stated in the National Board of Health and Welfare's interim report on the government directive.[8] Thanks to the work done in recent years to increase the availability of naloxone among people who use drugs, we have received confirmation in various discussions that nasal sprays containing naloxone are available in many cases, for example at low-threshold residential facilities. Users may have forgotten the spray, which is then taken care of and stored by staff. Others give the spray to staff as part of self-care (as described in Chapter 4). Thus, although the entity in question may not have had the opportunity or right to requisition the medicine, it may still be available. However, the question of whether staff may administer the medicine is unclear, which means that currently, in the absence of national guidance or regulations, directors do not have a clear enough opportunity to order, allow or recommend staff to administer nasal sprays containing naloxone.

In light of these ambiguities, the Police Department has taken the position that in the event of opioid poisoning, police officers should use CPR until healthcare units arrive to assist.[9]

In National Board of Institutional Care (SiS) youth homes and LVM homes, groups who are not covered by the healthcare regulations can administer naloxone after receiving delegation from a nurse in accordance with the regulations of the National Board of Health and Welfare.[10] Patients, for whom there is a risk of opioid ingestion in the institution, are prescribed naloxone as an emergency medication. This enables staff who have delegation under the SiS delegation regulations to administer naloxone when a licensed healthcare professional is not present and in accordance with the SiS drug recommendations 2022. For patients who do not have a prescription for

[8] Assignment to support increased availability of naloxone – Interim report on implemented and planned activities within the framework of the assignment, National Board of Health and Welfare, 2022.
[9] Dnr KOMM2022/00359/S_2022:01-02 Material received from the police on the response to the discovery and administration of Naloxone
[10] HSLF-FS 2017:37 prescribing and handling of medicines in healthcare and SOSFS 1997:14 delegation of tasks in healthcare and dental care.

naloxone, the medicine is included in the agency's list of general directives. In order to administer medication based on the basis of a general directive, contact with a registered nurse is required. As part of youth care, there is a national nurse hotline that can be contacted.[11]

The Prisons and Probation Service aims to eventually allow correctional staff to administer nasal sprays containing naloxone, but has not yet identified how the training will be implemented and whether all staff will receive it or only selected staff with some form of delegation.[12]

We have not had the opportunity to investigate how other actors, such as non-profit or corporate organisations, do this.

The lack of clear regulation creates room for different interpretations by stakeholders, which does not promote equal access to naloxone across the country. In Chapter 7, we will justify why legal support and supplementation of a regulation or guidelines may be needed to enable non-healthcare occupational groups to administer naloxone as part of their work in a systematic way.

6.2.2 Implementation of naloxone outside the healthcare system lags behind

With regard to entities and occupational groups outside the healthcare sector, since 2018 emergency services personnel and non-licensed ambulance personnel have had the opportunity to administer naloxone, as we reported in Chapter 4.[13] We believe that for these occupational groups there is already clear regulation that they can administer naloxone, but that support for implementation may need to be developed. Our discussions revealed that work has generally not begun, with the exception of a single region, despite the fact that support is available in guidelines. For emergency services to have access to naloxone and adequate training, the issue needs to be covered by an agreement between the region and the emergency services, and this does not exist in most regions. This may be because the agreements as to who goes on the call differ across the country, the needs are not deemed to exist, or neither have the emergency

[11] Dnr KOMM2022/00359/S_2022 :01-15 Reply received from the National Board of Education.
[12] Dnr KOMM2022/00359/S_2022 :01-14 Response received from the Prison Service.
[13] Sections 1–3 of the SOSFS (2009:10) on ambulance care.

services nor the regions pursued these issues. Furthermore, the availability of naloxone also needs to be addressed in the context of such agreements, as the emergency services are currently not allowed to requisition medicines from pharmacies.[14]

We believe that any regulatory changes to allow other occupational groups to administer naloxone need to be accompanied by supportive work. The changes to the regulatory framework for emergency services and non-licensed ambulance staff have shown that, despite this, the necessary steps have not been started to any significant extent. This suggests a need for follow-up and implementation support, which is essential if additional professions and occupations are to be allowed to administer naloxone.

6.2.3 The work with defibrillators and CPR can serve as inspiration

In our work, we have discussed whether naloxone should be managed in a similar way to the national work on defibrillators. There may be a lot of similarities and the work on CPR is both systematic and urgent. Defibrillators are defined as a product. The work on increasing the availability of defibrillators in the community, as well as training and registration of defibrillators, is managed by the Swedish Council for Cardiopulmonary Resuscitation (CPR Council). The CPR Council is a national knowledge and education organisation. The CPR Council calls for all defibrillators to be registered in the Swedish Defibrillator Register and for all activities related to defibrillators outside hospitals to be registered in the Swedish Cardiopulmonary Resuscitation Register (SHLR), a quality register run by the CPR Council.[15] The CPR Council has three main target groups for increasing the use of defibrillators.[16]

[14] Conversations with the emergency services and IVPA managers in the country.
[15] https://www.hlr.nu/organisation/.
[16] National Strategy for Sudden Cardiac Arrest in Sweden, CPR Council, 2021.

- Emergency personnel, primarily emergency services and police, equipped with defibrillators. These can be alerted in parallel with the ambulance in case of suspected cardiac arrest.
- Trained lay people with a duty to act. This may be within a structured programme and may include security guards, hotel staff or lifeguards.
- Defibrillators available to the public, so-called "wild" defibrillators that are not part of a programme. These have a fixed position and are used by both untrained and trained lay people.

Both naloxone and defibrillators aim to save lives. But there are also several differences that need to be taken into account, such as the fact that defibrillators are a product and not a medicine. Our assessment is that the work on defibrillators can provide inspiration for further research, even if there are differences.

6.2.4 Willingness and support high up in an organisation play a role in implementation

In addition to clear regulation and support for implementation, there are other factors that influence whether interventions are implemented. In implementation research, political will is not infrequently highlighted as a significant factor in facilitating the implementation of initiatives and policies. In our international outlook, these were also circumstances that we highlighted as crucial. The clearest example is the United States, where opioid-related deaths have risen to such levels that the situation is described as a national crisis. In that situation, everyone needed to help, and senior officials inside and outside the police department drove the point home that first responders need to be able to contribute to the effort. There was a willingness in the organisation's leadership to perform tasks that were not previously considered part of the police work. At the same time, there was sufficient clarity in the regulations that well-intentioned actions could not be punished because the possibility of saving lives was a priority.[17]

[17] Dnr KOMM2022/00359/S_10 meeting notes meeting USA.

In Norway, naloxone work has been conducted as a project with a national link. The work was included in a national strategy and there was a clear political will to implement the intervention, which has also worked well.[18]

Regions in Sweden with clear mandates and funding for naloxone also appear to have made progress in implementing naloxone programmes.

6.3 Should members of other professions and occupations be able to administer naloxone and if so, which ones?

Assessment: Occupational groups who frequently find themselves in situations where opioid poisoning occurs should be allowed to administer opioid antagonists such as naloxone, as part of their job duties.

We have two directions for further work, depending on what is deemed legally possible. In order not to exclude any occupational group from being able to administer naloxone within the scope of their duties, an exception to the current law could be considered and would then need to be investigated further. In this case, occupational groups would not need to be specified. If this cannot be done for legal reasons, we propose various occupations and entities as a basis for our further investigation and analysis. Such a grouping balances different perspectives, activities, locations, occupations, current research and legal conditions.

6.3.1 Naloxone should be administered by occupational groups outside the healthcare system, as well

Our assessment is that the possibility of saving lives with naloxone needs to be prioritised in Sweden. We believe that in the future there should be support for naloxone being administered by occupational groups and entities that often encounter situations where naloxone

[18] National Overdose Strategy 2014–2017 "Sure you can quit drugs – but first you have to survive", Helsedirektoratet, 2014.

could save lives.[19] However, these occupations and entities need to have clarity on issues such as the legal basis for this action in a regulation or ordinance, who is responsible, whether it is an obligation or an option to administer naloxone, and so on. This needs to be investigated further, and we will return to this matter in the following sections.

6.3.2 Should it be an option or an obligation to administer naloxone?

In the continuing efforts to propose a regulatory framework for non-health occupational groups to have access to and be able to administer naloxone, this area can be regulated either as an option (can/may) or an obligation (should/must) for different occupations or entities.

It is important that as many people as possible in society be allowed to administer naloxone, for example through some form of broad regulation that does not exclude anyone. This would create the best conditions to contribute to the goal adopted by the government of no one dying from drugs or medicines. At present, other non-health occupational groups, like the general public or lay people, can act in an emergency situation by administering naloxone provided that naloxone is available, as we describe in Chapters 4 and 7. Such a situation is based legally on the person administering naloxone doing so voluntarily and on his or her own responsibility and on the basis of the general necessity provision in the Criminal Code.

However, in analysing whether other occupations or entities should be able to administer naloxone, we begin with the assumption that we need to identify an arrangement that enables an intervention within the context of work. In this context, the employer is responsible for the intervention and the actions of the individual in question. This requires a clear regulatory framework. It also means that trade-offs of effectiveness and proportionality are taken into account. If the administration of naloxone is to be made an obligation and a requirement for specific entities, some form of national support most likely needs to be developed. We will return to these issues in our further investigation.

[19] In addition to the non-healthcare occupational groups who already have such opportunities today, as described in Chapter 4.

6.3.3 The concept of occupational groups needs to be expanded to include entities and places

Our directive instructs us to investigate whether occupational groups outside the health sector should be able to administer naloxone. An occupational group is often a group of people who share certain characteristics. These characteristics include, for example, differentiation from other occupations, possession of specific knowledge, tasks involving unique or varied elements, independence in the exercise of the occupation, and a specific professional code. Not infrequently, the occupation may have a title that in some way requires specific training or skills, such as nurse, social worker, police officer, security guard, etc.

We do not consider it useful to only focus on the concept of *occupations* in our work. This is because people who use drugs, some of whom are at increased risk of opioid poisoning, have at least as many interfaces with entities and places as with occupations. These are the entities and locations that these individuals frequently visit, stay in or live in. Thus, location, entities and occupations are all important in determining which occupational groups should be able to administer naloxone, as illustrated in the examples below.

An example could be low-threshold housing for people with harmful use or addiction. In such a facility, there are several occupational groups who could treat opioid poisoning if they had the ability to administer naloxone. This could include the professional social workers, but also staff that are not social workers, but who work with residents, such as security guards, cleaners, occupational therapists or other staff present in the facility. Particularly at night, social services often lack staff with specific skills or training. In such cases, it would be more appropriate to extend the possibility of administering naloxone to the entire staff of an entity and not only to professional social workers, to give one example.

Another example in which the entities themselves provide an interface with people who use drugs is the prison system. It is common for people who use drugs to serve sentences in the prison system and thus have contact with prison staff. As more and more clients serve sentences with electronic monitoring (ankle bracelets), the work of the probation service, such as home visits to check compliance with the conditions of enforcement, will also have to increase. Although

it is not considered particularly common for a person to suffer from opioid poisoning when visiting their contact person or caseworker in the prison service, individual assessments may need to be made. Systematically requiring all staff in the prison system to administer naloxone, and their employers to procure the medicine, would probably have a limited effect on opioid-related mortality in Sweden even if the activity itself constitutes a contact point with the target group.[20] This makes it clear that there may be different needs to administer naloxone within the same entity that interfaces with the target group.

Another example where a specific geographical location is important are the vicinities of places where drug use is common. Police officers whose job is to patrol open drug scenes or outdoor environments in city centres where drug use is common would be more likely to find themselves in a situation where there might be a need to administer naloxone, than a police officer tasked with investigating crime in an office. Thus, the occupation of police officer alone does not provide a sufficient effect, while the combination of occupation and location would yield the greatest benefit. Similarly, social workers working with cases regarding the exercise of public authority are less likely to find themselves in a situation where they need to administer naloxone to a person visiting the social services office than a social worker working in an outreach setting (in people's homes or outside) among people who use drugs.

In conclusion, our assessment is that it is complicated to solely consider occupational categories without taking into account location, entities, context or regional/local conditions when deciding who should be able to administer naloxone in a systematic way. If an exemption for administering naloxone outside the healthcare system is not granted in our future work, several different criteria will provide a basis for determining which entities and occupational groups are most important in future efforts to regulate the area appropriately.

[20] On the other hand, such an occupational group and entity may be relevant in terms of dispensing naloxone to people who use drugs, but this is outside the ambit of our directive for this interim report and the limits we have set out in Chapters 1 and 2.

6.3.4 Possible assessment criteria for the continued work of the Drug Commission of Inquiry for proposing which occupational groups should be allowed to administer naloxone

In our international outlook, we have seen that countries such as the United States, Norway and Denmark appear to have dealt with naloxone outside the health sector as some kind of broader exception to the law otherwise in force. These countries' regulatory frameworks are not deemed to exclude any occupational group if the need for the intervention exists or arises. This is not to say that everyone in these occupations is obliged to administer naloxone.

If it is not possible to propose a similar framework in Sweden, taking into account, among other things, the constitutionally protected rights of an individual, we believe that we need to identify the most urgent occupational groups and entities where it should be possible to administer naloxone in the future. In order for regulation to be sustainable in the context of both current and future challenges, such as the emergence of new occupational groups, the development of new substances and medicines, etc., it is important that the design is not too rigid. We base our work on the occupational groups proposed by the Swedish Parliament and the Government and on the occupational groups identified by the National Board of Health and Welfare in the context of previous government mandates.[21] Based on the account in Chapter 2 of where fatal opioid poisoning most often occurs and where naloxone has been used, we propose a grouping of which occupational groups or entities have the highest priority for administering naloxone and which we intend to investigate further. We weigh different perspectives, locations and occupations. The grouping is preliminary and intended to guide our further work, if needed. It does not currently provide guidance on whether it should be introduced as an option or an obligation. The grouping is based on the following assessment criteria:

[21] Dnr KOMM2022/00359/S_2022:01-3 Documentation from the National Board of Health and Welfare.

- Those occupational groups and entities that are most often involved in opioid poisoning situations and where the intervention is therefore deemed proportionate and likely to have an impact,
- Those occupational groups and entities that constitute a recurrent contact point for people who use drugs,
- Those occupations and entities that have some form of link to the public sector, which facilitates the possibility of regulation, supervision and accountability,
- Those occupational groups and entities operating in places where there is a risk of opioid poisoning; and
- Those occupations and entities where it is deemed possible to regulate the area in an appropriate and legally secure manner.

Family and close friends are not an occupational group and are therefore not included in the group classification. Increasing access to naloxone for family and friends, or the wider public, has been outside the directive of this interim report, but is an issue for our forthcoming work on developing a national programme to reduce drug and medicine poisoning mortality.

Group 1: Staff in entities where people who use drugs reside for long periods

- Prison (Prison and Probation Services).
- LVM homes (Act on the Care of Addicts in Certain Cases, run by the National Board of Institutions).
- HVB (Home for the care and accommodation of adults with harmful use or addiction). Operated by different actors (municipality, SiS, individual actors, civil society).
- HVB for children and young people up to the age of 21. The National Board of Institutional Care (in care under LVU or LSU). Can be run by municipalities, individual actors or civil society.
- Special housing in the municipality such as various group homes and support homes.

- Shelters for people exposed to violence that provide places for women with harmful use or addiction.

Group 2: Staff in social or therapeutic entities which are partly or entirely aimed at people who use drugs

- Police detention in connection with drug rehabilitation (Police).
- Remand detention facilities (Prison and Probation Service).
- Probation (Prison and Probation Service).
- Shelters and emergency accommodations (municipality, individual actors, civil society, church/faith community).
- Social psychiatry (municipality, individual actors, civil society, church/faith community).
- Home care services (municipality, individual actors, civil society, church/faith community).
- Staff in entities such as Housing First such as Case Managers (municipality, individual actors)
- Residential support workers (municipality, individual actors).
- Social entities such as daily activities, social centres, food distribution (municipality, individual actors, civil society, church/faith community).
- Fieldworkers and outreach workers (people working on behalf of the municipality, individual actors, civil society, church/faith communities).
- Treatment entities for people with harmful use and addiction (municipality, individual actors, civil society, church/faith community).

Group 3: Staff and entities that can be called upon by 112 in the event of opioid poisoning, or who act as emergency responders in some way

- Health care (already have and use naloxone in these situations).
- Ambulance and rescue services (these already have this possibility through a general directive).
- Police.
- Security guards.[22]
- Public order officers.

Group 4: Staff in other entities

This priority group includes other entities and occupational groups who do not target people who use drugs, but who work in places where drug use and opioid poisoning are likely to occur. These may include conductors on trains where toilets are available or staff on night or county transportation, staff in restaurants, shops, cleaners or park workers, etc. who work near places where drug use is common, such as open drug scenes. Priority Group 4 is also the one that may have the most difficulty in finding forms of appropriate regulation if they are to be allowed to administer naloxone. This can be a very heterogeneous group of occupational groups, differing across the country and largely made up of private companies with very limited links to the health and social care sector.

6.4 Summary and further investigation

We believe that naloxone is an important piece of the puzzle in preventing deaths from opioid poisoning, but that it needs to be combined with other interventions in a national programme. We have been asked to propose such a programme in our final report. The

[22] Security guards can only intervene in the same way as anyone else in society, so-called "citizen's arrest ". It involves arresting someone who has committed a crime, punishable by imprisonment, and is found in the act or on the run. Public order officers on the other hand have limited police powers and may detain people who are drunk or disorderly in public places. They are trained and appointed by the police, who also supervise them.

focus of this interim report is naloxone for non-health occupational groups, but in our future work, wider availability of naloxone is also important. This may involve increasing the outreach of naloxone to persons who use drugs, their families and loved ones, strengthening the prescription of naloxone to patients receiving opioids in LARO or for pain problems, or continuing to work towards prescription-free naloxone.

In order for non-health care occupational groups to administer naloxone for opioid poisoning, we believe that changes to the current regulatory framework are needed. Implementation support is also an important effort to advance these efforts.

We believe that in the future it should be possible for other occupational groups and entities outside the healthcare system to administer naloxone, but that further investigation is needed for proposing which occupational groups. We have analysed the concept of occupational groups and believe that it needs to be adapted to where opioid poisoning often occurs, and that there may be different needs for naloxone administration even within an occupational group. We have identified occupations and entities that we intend to investigate further whether it is possible to make an exception to the current regulatory framework. We will also return to the question of whether there should be an obligation or possibility for these occupations and entities to administer naloxone.

7 Legal conclusions

This chapter describes the opportunities and barriers that we currently view as preventing occupations other than healthcare-related professions from administering naloxone in the event of opioid poisoning. The starting point is healthcare legislation, primarily the legislation discussed in Chapter 4, but other legal issues are also raised. At this stage of the study, we are not analysing the need for any separate legislation. The reason for this is that we consider it appropriate to first examine the possibilities for legislative proposals within the framework of existing law.

First, there needs to be an analysis of the legal requirements for health occupations that are relevant to the assessment of the ability of other occupations to administer naloxone. The aim is to draw conclusions and analyse what is required for other occupations to have an equivalent or comparable position to health occupations. We have the following fundamental bases for our reasoning:

1. The right to life and health of people who use drugs,
2. Opioid poisoning is a major societal problem on an overall level and
3. Enabling other occupations to administer naloxone for opioid poisoning under conditions that are medically safe, legally regulated and without personal risks unrelated to the occupations in question.

7.1 Opportunities and obstacles in existing legislation

At present, non-health occupations, like the general public or lay people, can respond to an emergency by administering naloxone provided the drug is available. This is in many respects the same regime as for CPR, for example. Such a situation is legally based on the fact that the person administering naloxone in an emergency situation does so on his or her own initiative and responsibility. There are thus three elements that characterise such a situation: voluntariness, responsibility and interpretation of the general necessity provision.

Our conclusion is that such a procedure is associated with several difficulties that may affect the willingness of staff to administer naloxone and thus not have the intended effect of reducing opioid poisoning mortality. We also do not believe that the necessity provision is intended to be applied in the systematic manner required for other occupations to administer naloxone in various work situations. This does not change the fact that the necessity provision is always a legal option in the absence of other regulation.

We have chosen to use a comparative approach. This means that we begin with the legal requirements for healthcare occupations to identify opportunities and barriers to safe management if members of other occupations are to administer naloxone. With this as a starting point, we assess the position of other occupations in relation to health law and discuss possible implications. We intend to answer the following questions:

1. What are the legal implications of allowing other occupations to systematically administer naloxone in activities where they meet, treat. or otherwise support people who use drugs?
2. Is the general necessity provision a viable option?
3. Is it necessary to impose the same or equivalent requirements on other occupations as those that apply to health occupations?
4. Is this possible, in whole or in part, within the framework of current health legislation?
5. If not, what are the possible solutions?

7.1.1 Legal requirements for health care relevant to other occupations

Healthcare law is extensive and consists of a number of statutes that regulate various aspects of the field. There are several important principles governing health care, such as that it should be accessible, of good quality and safe for patients. In addition, the staff working in these entities must have the right skills for the job. Treating patients with medicines is one of the most important, and perhaps the most common, method of treatment used by staff in health care. The management of medicines is therefore directly linked to the different categories of health professionals who may administer medicines. There is an extensive and detailed regulatory framework regarding medicines in regulations issued by both the National Board of Health and Welfare and the Medical Products Agency. In order to ensure the quality requirement, healthcare providers are responsible for carrying out systematic quality work within their respective entities. In this sense, health care is sharply separated from other activities. It follows that all health care occupations have responsibilities and obligations towards the patient when carrying out their duties. Ultimately, any shortcomings in patient safety may be subject to supervision. The obligations of staff are matched by the rights of patients, including the right to be adequately informed about treatment options and to consent to care. There is also patient insurance in case patients are injured by the care.

In summary, the following key legal requirements for health care are identified:

1. Health care is a clearly defined legal area in which powers may be used under given conditions in the health field by health professionals,
2. Health care may be provided only by the staff listed as health professionals in laws and regulations,
3. Care should be characterised by accessibility and good quality and patient safety,
4. Supervisory agencies and healthcare providers are responsible for systematic quality work in health care and for preventing harm,

5. The patient has the right to information and his or her consent is required for care and treatment measures,
6. If treatment needs to be provided in an emergency, there is legal support for health professionals to take such action; and
7. Treatment with medicine is the most important, and perhaps the most common, method of treatment.

In comparison, the fundamental difference for the mission of this commission of inquiry is that other occupations do not operate in the legal area where the power to take healthcare action or treatment is allowed. In other words, the conclusion is that there is no legal authority for occupations outside the healthcare system to administer naloxone. This is true both within the healthcare system and in the settings where these groups work. It also means that the issues of safety and liability for possible harm to health are unclear, as well as the risk of personal liability and damages for the person who has administered naloxone. Employer responsibility for tasks that are not work related and supervision are also unresolved issues.

7.1.2 Is the general necessity provision a viable option

Assessment: The general necessity provision should not be used systematically as a legal basis for allowing other occupations to administer naloxone. In addition, it appears problematic in terms of labour law to pass on the question of liability to an individual in the performance of his/her duties

Chapter 4 deals with the purpose and applicability of the necessity provision. In this section, we focused on the consequences of using the provision as a legal basis for giving naloxone to a person with opioid poisoning in the absence of other legal support for treatment in acute emergency situations.

Opioid poisoning puts a person's health and life at risk. These are legally protected interests, and this means that the necessity provision may apply in certain cases. It presupposes that there is such an emergency and that the act of the person administering the naloxone is deemed permissible. Here, the law is pitted against the law because

the person is at the same time protected against forced bodily intervention by the form of government (and by extension the conventions with which Sweden must comply, here mainly the European Convention). The use of the necessity provision is examined to determine whether an emergency situation existed and whether or not the act was inexcusable. There is no examination of the right to bodily integrity as this is not a matter of criminal law. Based on the circumstances of the individual case, the court considers whether there has been a criminal offence and if so, whether it is indefensible. In our opinion, it is normally justifiable to save life by administering naloxone in an emergency situation.

The difficult question is whether the public interest that other non-health occupations are supposed to protect (by administering naloxone) is legally considered worthy of protection. In this respect, case law is not entirely clear. There are clear statements that public interests are also worthy of protection, while stressing that the provision should be applied restrictively. There are also statements to the effect that individuals should not take actions that are the responsibility of public authorities or that have been the subject of assessment by the legislature.

Furthermore, the necessity provision is an exceptional provision that is primarily intended to protect situations that the legislature could not foresee and legislate for. The test is whether, in an emergency situation, a criminal act has been committed and whether there are grounds for exempting the actor from liability.

In summary, the test for the necessity provision is whether there is an urgent emergency and whether or not the act is considered to be unreasonable in relation to the threatened interest, including that it could not have been done otherwise. Even if public interests are considered worthy of protection and applicable to an emergency, this doctrine should be done in a restrictive manner and not fundamentally apply to a matter for the authorities to deal with. Against this background, our conclusion is that the general necessity provision is not intended to be used systematically in the way that is needed if other occupations are to be able to administer naloxone. In addition, it appears problematic in terms of labour law to shift the issue of liability to an individual in the exercise of his or her duties.

7.1.3 Possibilities of naloxone administration in healthcare legislation

As stated earlier, two prerequisites are necessary for other occupations to administer naloxone for opioid poisoning. Doing so would require access to this medicine and the authority to administer it to a person suffering from opioid poisoning. Naloxone is a prescription medicine, which means that the authorised prescriber (doctor or nurse) must make an assessment of the need for the medicine for an identified patient. We will outline below, the options currently available in addition to such prescribing.

7.1.4 Medicines by requisition

Assessment: The possibility for non-prescribers to requisition medicines, through an amendment to Chapter 6, Section 7 of HSLF-FS 2021:75, should be further investigated within the framework of the Drug Commission of Inquiry. This would mean that members of non-medical occupations could requisition naloxone and thus gain access to that medicine.

For individual patients, authorised prescribers issue prescriptions for prescription medicines or dispense the medicine. Authorised prescribers such as doctors or other licensed occupations are empowered to prescribe medicines in their respective areas of responsibility.

It is also possible to obtain medicines by a prescriber issuing a prescription for medicines used in health care. The procedure and requirements for requisitioning are regulated in Chapter 6. HSLF-FS 2021:75. Section 7 of the same chapter and regulation further provides for the possibility for someone other than a prescriber to issue a requisition. This is the provision we will review in this section. The stated provision lists five groups, all of whom may requisition medicines. The groups are listed in Section 4.4.2.

In brief, the first two groups consist of directors of research institutes and experts in activities involving manufacturing and wholesale distribution authorisations for medicines. These groups are not relevant as the purpose of the requisition is other than treatment. The other three groups (pharmacist, ship's master or equivalent and

welders) may requisition medicines intended for treatment in the relevant entities or in the case of the last group, by the actual welder.

In particular, it should be noted that the prescription of medicines on board ships is closely governed by other regulations and is intended for emergency situations far out at sea. It is linked to the regulation of pharmacies at sea and is a matter of patient safety and employer's responsibility for the personnel on board the ship and to some extent also for passengers. The prescriber should be able to administer the medicine to those working on board or, in some cases, to passengers. International conventions require the ship's master to have undergone the necessary training to be able to provide and administer medicines. Quality systems are also in place to ensure good care for persons receiving medicines.

The fifth group consists of welders. This group is usually licensed for eye drops intended for emergency situations related to welding work. They can therefore order and collect the medicine from a pharmacy. The need for the medicine is often very urgent and the welder administering the eye drops has his or her own personal responsibility.

The purpose of allowing non-prescribers to requisition medicines is to meet the need for pharmacotherapy for a person who cannot obtain the necessary treatment by other means. The person must use the medicine himself and is personally responsible for its administration. Prescriptions are not intended to be used for group treatment.

The groups listed in Chapter 6, Section 7 of HSLF-FS 2021:75 are not homogeneous and have different conditions and are in different contexts. However, the personal element and responsibility for administration are common to the latter two groups. In group four, the commander of a ship, or someone occupying an equivalent position has a clear major responsibility, while personal responsibility is apparent in group five. For both groups three and four, there is a link to the health sector. Welders may only requisition eye drops for their own treatment and administration.

In conclusion, an addition to this provision that would allow non-health occupations to prescribe naloxone is an issue that should be explored further. While this provision may appear to contradict its purpose, the nature of opioid poisoning, argues against personal liability being triggered. Groups three to five consistently relate to very acute situations.

These are situations where the traditional healthcare system is not sufficient and the needs of those people who fall outside the healthcare system may not be able to receive emergency care in any other way. The same situation applies to opioid poisoning, which is very acute and occurs in places where access to health care is often lacking. Other relevant circumstances are that the medical risks of naloxone are deemed to be small, and that this medicine is authorised for self-use.

7.1.5 Pharmacotherapy with general directives

Assessment: Within the framework of the Drug Commission of Inquiry, the issue of whether other occupational groups than the healthcare sector should be able to make use of general directives should be explored. This would allow these occupations to administer naloxone to people who have suffered opioid poisoning in various contexts.

Chapter 6, Sections 6–7 of the HSLF-FS 2017:37 contains provisions on general directives for pharmacotherapy in health care.

A general directive on pharmacotherapy allows for dispensing medicines without an individual prescription to patients in a specific unit and for specific conditions, if necessary. The general directive procedure can be seen as an exception to the main principle that medicine should be prescribed individually for each patient. Only doctors can issue requisitions.

The aim of a general directive is for doctors to prescribe pharmacotherapy to a group of patients with whom they are familiar and who have a similar medical status. It is intended to be used in exceptional situations and is applied restrictively.

After the general directive has been issued, before the medicine is prepared and administered or given to the patient, a nurse must carry out a needs assessment regarding the patient's need for the medicine. The nurse must check the indications and contraindications of the medicine and document them in the patient's medical record (Chapter 6, Section 7 of the HSLF-FS 2017:37).

There are no detailed rules on the situations in which general directives may or may not be used. The responsibility for ensuring that

general directives are issued in a patient-safe manner lies with the healthcare provider. The healthcare provider's procedures must describe how the healthcare provider ensures that general directives on pharmacotherapy are issued in a safe manner. The general rule is that only doctors can issue general directives.

General directives have been in place for a long time. They may concern a group of care recipients in communal housing, such as for people with disabilities or elderly people. There has been a trend toward allowing healthcare providers to determine the situations in which general directives should be issued. A recent example is vaccination programmes carried out by healthcare providers in relation to covid-19.[1]

In summary, general directives should be used restrictively and are intended for healthcare patients only. In conclusion, the question of whether general directives could be an option for non-health care occupations needs to be further explored. The purpose of general directives to treat a group of patients argues for such a possibility. The obstacle is that such pharmacotherapy should be provided within the healthcare system. This can be weighed against the fact that societal developments indicate that healthcare needs to be managed in new ways and outside the traditional healthcare structure and that the right to life and health should be ensured as far as possible for all groups in society. One example is the police authority medical officers, who have the power to issue general directives for police task forces, for treatment with medicines, such as for painkillers. This treatment administered in these cases is intended for the police personnel, only. In this case, an exception has been made for the needs assessment by the nurse and legally there is no prescription. The person administering the medicine makes an assessment of need according to the specifications given by the doctor. The exemption has been granted by an administrative decision of the National Board of Health and Welfare. There is also an example concerning the emergency services. There, the exemption from the nurse's needs assessment is regulated in Chapter 7, Section 8 of the HSLF-FS 2017:37.

In conclusion, there are several indications that there has been some expansion of the general directive, and the fact that healthcare providers are increasingly empowered to set general directives also points in the same direction. The current review of the delegation

[1] https://www.socialstyrelsen.se/coronavirus-covid-19/vaccinationer-covid-19/.

rules in the health sector is also motivated by the need to give healthcare providers more influence in their activities.

7.1.6 Concluding discussion

At the outset, we noted that healthcare is legally a delimited area and that healthcare interventions must be carried out by health occupations. We have also discussed the appropriateness of the necessity provision and the use of requisitioning and general directives as alternative options.

Requisitioning is largely done in the healthcare sector. We have reported that some other groups may issue requisitions. These groups differ in form, content and, to some extent, in the purpose of the requisition. The legal situation is not clear and raises questions that need to be further explored regarding the corresponding possibility for non-healthcare occupations.

General directives are intended for use in the health sector and only doctors are entitled to issue such a directive. A different framework does not seem legally justifiable in light of the purpose, use and development of the general directive. Such an unravelling would lead to a re-evaluation of many of the fundamental principles on which health care is based. It would also require a doctor responsible for care to issue the directive. A general directive would also not bring other occupations within the scope of health legislation.

The closest comparison is the National Board of Health and Welfare's regulation on ambulance care (SOSFS 2009:10). Chapter 7 of the regulation states that municipalities may conclude agreements on first aid while waiting for an ambulance and on what treatment is covered by the agreement. The possibility of signing an IVPA agreement is provided for in Chapter 3, Section 2 of the Act (2009:47) on certain municipal powers. The IVPA agreement must state whether staff may provide treatment with naloxone in the event of opioid poisoning. If this is the case, the staff are considered to be healthcare occupations and must document in the patient record and be under the supervision of the IVO. The regulation thus provides a legal link that enables IVPA staff to administer naloxone.

7.1.7 Further investigation by the Commission of Inquiry

Assessment: The occupations that would be able to administer naloxone should have a legal link to health legislation. Issues such as contracts, quality and patient safety, consent to care, delegation and who is a health professional should be further explored by the Drug Commission of Inquiry.

In the further investigation, we intend to more closely explore several issues that we have discussed in this chapter. We also intend to carry out a detailed analysis of the advantages and disadvantages of the two different options. Other issues may also arise that are worthwhile to investigate, such as the possibility of introducing an exemption without specifying occupational groups.

One of the questions raised is whether a similar arrangement to that for IVPA staff would be feasible if agreements were made under Chapter 15, Section 1 of the HSL. This provision states that regions and municipalities with retained supervisory responsibility may enter into agreements with others to perform tasks for which the region or municipality is responsible under the Act. Furthermore, the contract must state the specific conditions that apply to the transfer. If deemed feasible, a contract could ensure several issues related to responsibility and quality, training and issuing general directive. Furthermore, it is legally possible to delegate healthcare tasks to non-licensed personnel.

Our initial assessment is that an agreement can ensure accountability, quality and patient safety issues. The issue of other occupations is to be considered as health occupations needs to be regulated in a different way. This would require other statutory changes. Chapter 1. 4 of the PSL lists the categories that are to be regarded as health occupations. The provision is also accompanied by an authorisation for the Government to issue regulations to the effect that other groups of healthcare occupations are to be covered by the Act. There is thus scope – within existing law – to add a group of other healthcare occupations, such as other occupational groups. Other provisions of health legislation may be applicable, such as the exemption from the requirement for consent and the possibility to access and administer naloxone.

In summary, we have started from the basic idea that treatment with medicines should be carried out by responsible health professionals under legally and medically safe conditions. Our overall assessment is that, in line with this, other occupations need to be legally linked and covered by healthcare legislation in order to administer naloxone in the required situations.

8 Conclusions

Our work to date has led to the assessments outlined in Chapters 5, 6 and 7. We have not had sufficient time to undertake a full analysis or to propose statutory or regulatory changes to allow naloxone to be administered by non-health occupations. The assessments we make have not been sufficiently discussed with by the relevant entities to be developed into proposals at this stage. The assessments in the interim report will therefore form the basis of our further work.

The issue is urgent and needs to be addressed soon, but we still do not consider it reasonable to propose new rules at this stage. Further study is needed to draw on all the experience to a sufficient extent and to ensure legal certainty. We therefore believe that any proposals for making naloxone available and allowing it to be administered by non-healthcare occupations should be made in conjunction with the report on the other tasks of the Drug Commission of Inquiry. If the proposals are submitted together in a final report, this will put the commission of inquiry in a better position to take a position on naloxone as a whole and, in our view, will also increase the chances of others understanding the proposed measures.

As we are not making any legislative or regulatory proposals in this interim report, we are not making any assessments of fundamental rights and freedoms, compatibility with the proportionality requirements of the Instrument of Government or impact assessments. Nor are any assessments made of the impact on local self-government and the principle of financing, or of the consequences for authorities, businesses, the national economy and public finances.

References

Governmental bills and proposals

Government Bill 1962:10, part B.

Government Bill 1993/94:130.

Government Bill 1981/82:97

Government Bill 1993/94:149.

Government Bill 2013/14:106.

Government Bill 2016/17:43.

Reports from Swedish Official Government Reports

From the parts to the whole – a reform for coordinated, needs-adapted and individual-centred interventions for persons with co-morbidity (Från delar till helhet – en reform för samordnade, behovsanpassade och personcentrerade insatser till personer med samsjuklighet) Swedish Official Government Report (SOU) 2021:93.

Governmental strategies and publications

A comprehensive strategy for alcohol, drug, doping and tobacco policy and gambling 2022–2025 (En samlad strategi för alkohol-, narkotika, dopnings- och tobakspolitiken samt spel om pengar 2022–2025) The Government Offices of Sweden, 2022.

Assignment to support increased availability of naloxone, The Government Offices of Sweden, 2021-06-10 (Uppdrag att stödja ett ökat tillgängliggörande av naloxon).

www.regeringen.se/49d064/contentassets/bfdff98cec224c4389afe1bb001b023b/uppdrag-att-stodja-ett-okat-tillgangliggorandeav-naloxon pdf visited 2022-08-29.

Assignment on increased availability of certain medicines in order to counteract drug-related mortality S2017/02196/FS, The Government Offices of Sweden, 2017 (Uppdrag om ökat tillgängliggörande av vissa läkemedel i syfte att motverka narkotikarelaterad dödlighet).
https://www.regeringen.se/contentassets/dfd46cd72bf44f0eaa6c2bcf9dcc2668/uppdrag-till-socialstyrelsen-och-lakemedelsverket-om-okat-tillgangliggorande-av-vissa-lakemedel-i-syfte-att-motverka-narkotikarelaterad-dodlighet.pdf.

Parliamentary publications

A comprehensive strategy for alcohol, drugs, doping and tobacco policy and gambling 2022–2025 (Socialutskottets betänkande 2021/22:SoU25 En samlad strategi för alkohol-, narkotika-, dopnings- och tobakspolitiken samt spel om pengar 2022–2025) Social Affairs Committee report 2021/22:SoU25.

Reported court cases

NJA 2018 ref 1051

Supreme Administrative Court Year Book (RÅ) 6:69/86.

Supreme Administrative Court Year Book (RÅ) 2009 ref. 65.

Supreme Administrative Court Year Book (RÅ) 1997 note 28.

Agency publications

Non-prescription status for naloxone as a nasal preparation (Receptfrihetsstatus för naloxon i nasal beredning) Swedish Medical Products Agency, 2022.

Views on mental illness and suicide – A population survey on knowledge and attitudes (Synen på psykisk ohälsa och suicid – En befolkningsundersökning om kunskaper och attityder) National Agency for Public Health, 2022.

Assignment to support increased availability of naloxone – Interim report on implemented and planned activities within the framework of the assignment (Uppdrag att stödja ett ökat tillgängliggörande av naloxon – Delredovisning av genomförda och planerade aktiviteter inom ramen för uppdraget) National Board of Health and Welfare, 2022.

Deaths due to drug poisoning – a compilation of statistics, National Board of Health and Welfare, National Agency for Public Health, National Medical Products Agency (Dödsfall till följd av läkemedel och narkotikaförgiftningar – en statistiksammanställning) National Board of Forensic Medicine, 2022.

Care processes for drug-related intoxication – A survey of patient flows, interventions and collaboration and identification of gaps and areas for development (Vårdprocesser för narkotikarelaterad förgiftning – Kartläggning av patientflöden, insatser och samverkan samt identifiering av brister och utvecklingsområden) National Board of Health and Welfare, 2021.

National development work to counter drug-related mortality – Action plan with proposals for interventions and actors (Nationellt utvecklingsar-bete för att motverka narkotikarelaterad dödlighet) National Board of Health and Welfare and the National Agency for Public Health, 2017.

National guidelines for care and support for harmful use and addiction – Support for governance and management (Nationella riktlinjer för vård och stöd vid missbruk och beroende – Stöd för styrning och ledning) National Board of Health and Welfare, 2019.

Statistics on deaths due to drug poisoning 2012–2020 (Statistik om dödsfall till följd av läkemedels och narkotikaförgiftningar 2012–2020) National Board of Health and Welfare, 2021.

The current state and development of healthcare and dental care – Status report 2020 (Tillståndet och utvecklingen inom hälso- och sjukvård samt tandvård – Lägesrapport 2020) The National Board of Health and Welfare, 2020.

Addiction, substance-related diagnoses and gambling – Thematic follow-up of needs, care and support in relation to the national ANDT-work and gambling (Missbruk, substansrelaterade diagnoser och spel om pengar – Tematisk uppföljning av behov, vård och stöd i förhållande till det nationella ANDT-arbetet och spel om pengar) National Board of Health and Welfare, 2021.

Learn to save lives with naloxone – Information about the opioid antidote naloxone (Lär dig rädda liv med naloxon – Information om opioid-motgiftet naloxon) Swedish National Board of Health and Welfare, 2019.

Assignment on increased availability of certain medicines in order to counteract drug-related mortality (Uppdrag om ökat tillgängliggörande av vissa läkemedel i syfte att motverka narkotikarelaterad dödlighet) Report 1.12-2017-029584, Swedish Medical Products Agency, 2018.

Making naloxone available to patients and people outside the health care services- possibilities within current legislation (Tillgängliggöra naloxon för patienter och personer utanför hälso- och sjukvården – möjligheter inom ramen för dagens rättsliga regleringar) Report of the National Board of Health and Welfare and the Medical Products Agency published on Socialstyrelsen.se June 2017 (article number 2017-6-6).

Legislative commentaries on the Internet

Bäcklund A. et al. Commentary on the Criminal Code 18 June 2022, Version 20 (JUNO).

Johnsson, LÅ. The Patient Safety Act, a commentary, chapter 1. Section 2 of the PSL Karnov (JUNO) visited 2022-07-18.

Lönnheim, C. Patients Act (2014:821) 2–3 chapter Karnov (JUNO) visited 2022-07-19.

Lönnheim, C, Patients Act (2014:821). Introduction Karnov (JUNO) visited 2022-07-19.

Zila, J. Commentary to the Criminal Code ((1962:700) Chapter 24. Karnov (JUNO) visited 2022-07-20.

Vahlne Westerhäll, L. Health and Medical Care Act (2017:30) Chapter 3, Section 1 Karnov (JUNO) visited 2022-07-15.

Vahlne Westerhäll, L. Patient Safety Act (2010: 659) Chapter 1, Section 6 Karnov (JUNO) visited 2022-07-18.

Other materials

Andersson, L. and Johnson, B. (2022). *Fatal overdoses often occurred without a person nearby to intervene – knowledge of the presence of witnesses is important for how naloxone programmes should be designed*, Läkartidningen. Volume 119, 9 (Dödlig överdos skedde ofta utan person nära som kunde ingripa) https://lakartidningen.se/klinik-och-vetenskap-1/artiklar1/temaartikel/2022/01/dodlig-overdos-skedde-ofta-utanperson-nara-som-kunde-ingripa.

Chimbar, L. & Moleta, Y. (2018). *Naloxone effectiveness: A systematic review.* Journal of Addictions Nursing, 29 (3).

Eide, S. Lobmeier, P. Clausen, T. Harm Reduction Journal

2022. https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-022-00647-z visited 2022-08-29.

EMCDDA (2015) *Preventing fatal overdoses: a systematic review of the effectiveness of take-home naloxone.* EMCDDA Papers, Publications Office of the European Union, Luxembourg. https://www.emcdda.europa.eu/system/files/publications/932/TDAU14009ENN.web_.pdf visited 2022-09-12.

EMCDDA (2019) *Take-home naloxone.*

https://www.emcdda.europa.eu/publications/topic-overviews/take- home-naloxone, 2019. 2022-08-29.

EMCDDA, *Naloxone to revert synthetic opioids overdose – evidence summary,*
https://www.emcdda.europa.eu/bestpractice/evidence-summaries/naloxone-revert-syntheticopioids-overdose_en visited 2022-09-12.

Council of the European Union 2021. *EU Drugs Strategy 2021–2025,*
https://eur-lex.europa.eu/legalcontent/SV/TXT/?uri=OJ:C:2021:102I:TOC visited 2022-08-29.

Fisher R. O'Donnell D. Ray B, Rusyniak D (2016). *Police Officers Can Safely and Effectively Administer Intranasal Naloxone.* Prehosp Emerg Care. 2016 Nov–Dec;20(6):675-680. doi: 10.1080/109.

French Ministry of Health 2022. Fiche memo à l'attention des professionnels. https://solidarites-sante.gouv.fr/IMG/pdf/naloxonefichememo-pros-maj-janv2022.pdf.

Government of Iceland 2022. https://www.stjornarradid.is/efst-abaugi/frettir/stok-frett/2022/06/30/Naloxone-nefudi-verdiadgengilegur-um-allt-land-og-notendum-ad-kostnadarlausu/ visited 2022-08-29.

Helsedirektoratet Norway, 2014. *National Overdose Strategy 2014–2017 "Sure you can quit drugs – but first you have to survive"*,
https://www.emcdda.europa.eu/system/files/att_237935_EN_Norway%20-%20Health%20Directorate%20%282014%29%20Nationaloverdose-strategy-2014-2017.pdf visited 2022-08-29.

Holmén, E. och Kåberg, M. 2022. *High levels of uptake and use of nalox-one among participants in a Take-Home-Naloxone program in Stockholm, Sweden.*
https://az659834.vo.msecnd.net/eventsairaueprod/productionashm-public/f6a770e3105a4a2e9d83b0e2c429cace visited 2022-08-29.

Legislative Analysis and Public Policy Association (LAPPA) 2021. *Model expanding access to emergency opioid antagonist act.*
https://legislativeanalysis.org/model-expanded-access-to-emergency-opioid-antagonists-act/ visited 2022-08-29.

LIF. *FASS för allmänheten.* http://www.fass.se/LIF/startpage.

Press release 2021. *White House Releases State Model Law to Help Make Access to Naloxone Consistent Across the Country.* https://www.whitehouse.gov/ondcp/briefingroom/2021/11/17/white-house-releases-state-model-law-tohelp-make-access-to-naloxone-consistent-across-the-country/ visited 2022-08-29.

Rando J. Broering D. Olson J. Marco C. Evans S (2015). *Intranasal naloxone administration by police first responders is associated with decreased opioid overdose deaths*, The American Journal of Emergency Medicine, Volume 33, Issue 9, 2015.

The Swedish National Council on Medical Ethics, *Some medical ethics concepts* (Några medicinsk-etiska begrepp) https://smer.se/etik/nagra-medicinsk-etiska-begrepp/ visited 2022-08-29.

The National Board of Health and Welfare's questions and answers (Socialstyrelsens frågor och svar). https://www.socialstyrelsen.se/coronavirus-covid-19/vaccinationer-covid-19/.

CPR Council, 2021. *National Strategy for Sudden Cardiac Arrest in Sweden* (Nationell strategi för hjärtstopp i Sverige). https://www.hlr.nu/wpcontent/uploads/2021/11/Nationell-strategi-2021.pdf visited 2022-08-29.

Wai Chung Tse, Filip Djordjevic, Viandro Borja, Louisa Picco, Tina Lam, Anna Olsen, Sarah Larney, Paul Dietze, Suzanne Nielsen. *Does naloxone provision lead to increased substance use? A systematic review to assess if there is evidence of a 'moral hazard' associated with naloxone supply.* The International Journal of Drug Policy, February 2022.

Troberg, K. Isendahl, M. Alanko Blomé, D. Dahlman, A. Håkansson, 2022. *Characteristics of and Experience Among People Who Use Take-Home Naloxone in Skåne County, Sweden.*

https://www.frontiersin.org/articles/10.3389/fpubh.2022.811001/full. Obtained on 2022-08-29.

World Health Organization (2014). *Community management of opioid over-dose.* https://apps.who.int/iris/handle/10665/137462.

World Health Organization and UNODC 2020. *International Standards for the treatment of drug use disorders – Revised edition.* https://www.who.int/publications/i/item/internationalstandards-for-the-treatment-of-drug-use-disorders obtained on 2022-08-29.

Yousefifard M. Vazirizadeh-Mahabadi MH. Madani Neishaboori A. Rafiei Alavi SN. Amiri M. Baratloo A. Saberian P (2020). *Intranasal versus Intramuscular/Intravenous Naloxone for Prehospital Opioid Overdose: A Systematic Review and Metaanalysis.* Adv J Emerg. Med. 2020;4(2):e27.

Committee Directive 2022:24

Translated June 2022 by the Inquiry on Drugs

A Swedish drugs policy adapted in line with current and future challenges

Decision at the Government meeting held on 24 March 2022

Summary

The inquiry chair shall propose how a continued restrictive drugs policy can be combined with effective drug prevention work, good care for substance abuse and addiction issues that includes harm reduction measures, and measures to ensure that no one dies as a result of drug poisoning. The aim of the inquiry is to ensure that Sweden's drugs policy is compatible with the requirements for evidence-based care, proven experience and harm minimisation, and that it evolves and adapts in line with current and future challenges.

Among other things, the inquiry chair shall:

– Suggest which measures should be taken at national, regional and local levels to strengthen drug prevention work in Sweden.

– Propose how care and support measures can be developed to ensure good, equitable quality based on the needs and experiences of users and patients. This also includes analysing whether special care and support activities should be designed for children and young people.

– Propose whether – and, if so, how – care and support measures can be offered in a more systematic way to those convicted of minor drug offences.
– Propose how collaboration can be strengthened so that the care chains remain in place when the responsibility of the National Board of Institutional Care (SiS) or the Swedish Prison and Probation Service ceases, including collaboration in connection with individuals who are repeatedly sentenced for drug offences or are taken into compulsory care under the Compulsory Care of Substance Abusers Act (1988:870) (LVM).
– Propose measures to strengthen cooperation between healthcare services, the Swedish Police Authority and social services to ensure that individuals with harmful use or dependence receive adequate assistance.
– Explore how existing harm reduction measures, including medication-assisted treatment for opioid dependence (LARO) and syringe exchange services, can be developed and implemented more widely and become more equitable, gender equal and accessible nationwide.
– Propose a national programme to reduce the number of deaths due to drug poisoning.
– Explore the experiences of countries that have introduced the generic classification system for new psychoactive substances.
– Propose a model for effective monitoring of addiction and dependence care, including monitoring naloxone use, and how this monitoring shall be developed over time.

An interim report shall be submitted by 14 October 2022 for the following subsidiary remit:

– Analyse whether professional groups other than health professionals – and, if so, which ones – should be able to administer naloxone for opioid overdoses, and if necessary submit legislative proposals on how this should be regulated.

The remainder of the remit shall be reported on by 29 September 2023.

Background

The Swedish drug situation

Cannabis is the most commonly used drug in Sweden, but the Swedish drug market includes traditional illegal drugs, new psychoactive substances and non-prescribed use of narcotic drugs. In the Public Health Agency of Sweden's latest national public health survey – the 2020 'Health on equal terms' survey – 3.8 per cent of the population aged 16–64 reported having used cannabis during the previous 12 months (5.0 per cent of men and 2.5 per cent of women). This compares with 2.8 per cent in 2010. More men than women had used cannabis. In the 16–34 age group, 7.6 per cent reported having used cannabis during the past 12 months (9.5 per cent of men and 5.4 per cent of women). This compares with 6.2 per cent in 2010. In its 2020 survey on drug use, the Swedish Council for Information on Alcohol and Other Drugs (CAN) found that 7.8 per cent of boys and 5.5 per cent of girls in year 9 reported having used cannabis at some point. The results for cannabis use in CAN's survey have remained at about the same level for the past ten years.

The Swedish Police Authority estimates that the illegal drugs market is continuing to grow, in terms of both overt and covert dealing. In May 2021, the Swedish Police Authority published a report summarising the knowledge generated from the communications sent via the EncroChat encrypted service used within organised crime in Europe. In it, the police significantly revised the scale of drugs being smuggled into Sweden. According to the report, 100–150 tonnes of drugs are smuggled into Sweden every year, and this is done on an almost industrial scale. The previous estimate from CAN was that 15 tonnes were smuggled into the country each year. The Swedish Police Authority estimates that the money changing hands and the costs of importing drugs amount to billions to kronor annually. A large part of the proceeds of crime generated in Sweden is converted into euros and sent abroad for reinvestment in new consignments. Currency exchange is a central function in the smuggling chain. The Swedish National Council for Crime Prevention's September 2021 report on the drug markets in Sweden confirms this development, and shows that the availability of drugs for buyers has increased as a result of the growing number of digital and physical marketplaces.

Drugs are available throughout Sweden. The Swedish Police Authority also states that there is extensive production of doping substances in the country. In 2019, police and customs seizures of drugs in Sweden increased by around 4 per cent compared to 2018. Cannabis accounted for more than half of all seizures made in 2019, but seizure data shows an increase in the number of amphetamine, heroin and cocaine seizures, among others. Drug-related crime is one of the crime categories where the number of reported offences is largely influenced by police and customs investigation and intervention operations. Around 124 000 offences under the Narcotic Drugs Act (1968:64) were reported in 2020. Most of these related to personal use and possession of drugs.

According to data from the National Board of Health and Welfare's patient register, SiS's evaluation and documentation system (DOK) and the Prison and Probation Service's official register, 34 629 people received treatment for dependence or harmful use of drugs in 2019, which is about the same number reported in 2018. Of these, 69 per cent were men. Of those who received care for drug-related reasons, just under 32 000 received inpatient or specialist outpatient care, more than 2 000 received care within the Swedish Prison and Probation Service, and just under 500 received care under LVM. In 2019, the majority of those treated were aged 15–44 at the start of treatment, with the largest age group being those aged 15–29 (38 per cent).

The National Board of Health and Welfare notes that younger people have more drug-related problems than older people. Socio-economic factors, such as educational background, can influence the development of substance-related problems. Only having lower secondary education is significantly more common among those seeking or receiving care for drug-related problems. Among those who have received care for a substance-related diagnosis, receiving care for other psychiatric conditions is also common.

During the period 2012–2020, an average of 890 people died each year from drug poisoning. Drug poisoning is more common among men than women. Among men, accidental poisoning (overdose) is the most common, while among women, suicide is the most common.

The drug situation in the EU and internationally

Both the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the UN Office on Drugs and Crime (UNODC) note that there are major challenges in the EU and internationally linked to drugs, in terms of illegal cultivation, production and dealing, and the wide range of high-potency, high-purity psychoactive substances. The European Commission estimates that the illegal drugs market in the EU has a minimum retail value of EUR 30 billion per year, which represents a major source of income for organised criminal groups in the EU. The drugs market has an indirect negative impact through links to organised crime and through the contribution of drugs to disruption in the legitimate economy. Drugs contribute towards violence within society and environmental damage, and are a driving force for corruption that can undermine good governance. Drugs also contribute towards increased vulnerability and premature deaths for individuals who have developed an addiction. The availability of drugs in Europe is high.

During the past 24 years, the THC content of cannabis has increased by as much as four times in some parts of the world. At the same time, the proportion of young people who perceive cannabis to be harmful has decreased by up to 40 per cent, despite the scientific evidence that cannabis use is associated with many different health-related and other forms of harm, particularly with long-term use. An estimated 36 million people worldwide have an addictive disease. (Gender-disaggregated statistics are not available.) Access to care and support for harmful use and dependence is often poor. A large number of people die both in the EU and internationally as a result of drug poisoning. The drug situation in the world poses major challenges for society.

Harmful drug use and dependence is a public health issue

In addition to an increased risk of acute poisoning and loss of life, drug use also carries an increased risk of longer-term medical and social harm. Compared to the rest of the population, those who use drugs and those with harmful use and dependence are more likely to suffer from other illnesses and die prematurely. People who use opioids, or who use drugs frequently and in high doses or with high

levels of purity, are at the highest risk of ill health, injury and death. People who start using drugs at a young age, people who inject drugs and people who use multiple different substances at the same time are also at increased risk of ill health, injury and death. People with harmful drug use or dependence are at a significantly increased risk of developing mental illness or mental disorders, and suicide is common. There is often also a high degree of comorbidity between dependence and some other psychiatric diagnosis or related condition, and there are often significant somatic care needs among the target group.

People with harmful use and dependence may experience vulnerability

People with harmful use and dependence are often vulnerable. In addition to the increased risk of ill health, other possible negative consequences of drug use include stigmatisation, exclusion and marginalisation, lower levels of education and limited livelihood opportunities, and crime related to drug use. For example, many people with long-term and high-risk drug use experience financial problems because they have no stable link to employment. These people are often excluded from various social arenas, and may experience vulnerability. It is therefore important to identify those who have not yet developed harmful use or dependence early on. Women with harmful use or dependence are also relatively more vulnerable to violence and sexual exploitation, and are at greater risk of being exploited via prostitution.

Harmful use and dependence affects loved ones

Problems with drug use primarily affect the individual, but also have negative consequences for families and loved ones, including a reduced quality of life. The family perspective is central to Sweden's drugs policy. Relatives risk suffering from a reduced quality of life. Public health experts note that people who use drugs and their loved ones report poorer health compared to the rest of the population. In addition to the increased risk of poorer health, parents of adult children with drug dependence suffer in various ways, most commonly through theft or psychological violence. Extortion and physical violence are less common. Children growing up in a family with

parents with harmful drug use or dependence may experience anxiety, unreasonable responsibilities, changes in everyday life and difficult experiences, which can lead to children experiencing difficulties at school, ill health and other negative consequences in the long term. Harmful use of and dependence on alcohol, doping substances and drugs is a risk factor for violence.

Sweden's drugs policy has become more public health-oriented in recent years

The Government pursues a public health-based drugs policy with the aim of reducing health inequalities. The drugs policy is part of public health policy. Since 2018, there has been a new overall national goal for public health policy (Govt Bill 2017/18:249, Committee Report 2017/18:SoU26, Riksdag Comm. 2017/18:406). The aim is to create the right conditions within society for good and equal health for the entire population, and to close the controllable health gaps within a generation. The national public health policy is in line with the UN's Sustainable Development Goals (Agenda 2030). Restrictiveness fits within the framework of a public health-based policy. A restrictive approach aims to reduce the negative consequences of drugs for individuals and for society as a whole. In recent years, the Government has taken the initiative to develop its drugs policy. Initiatives have been carried out to reduce the number of deaths due to drug poisoning, and to reduce the medical and social harm caused by drug use (see the sections 'What constitutes a harm-reduction measure and which harm-reduction measures should we have in Sweden?', p. 17, and 'How will Sweden's drugs policy contribute towards fewer deaths from drug poisoning?', p. 19).

The task of evaluating Swedish drugs policy and proposing measures that should be taken to develop Sweden's work to combat drugs

In March 2020, the Riksdag announced that the Government should evaluate the current drugs policy (Committee Report 2019/20:SoU7 point 7, Riksdag Comm. 2019/20:174). According to the announcement, a continued restrictive drugs policy must be combined with

good addiction and dependency care that includes harm reduction measures, such as reducing the spread of blood infections. The drugs policy should be evaluated to ensure that it is compatible with the requirements for evidence-based care, proven experience and harm minimisation. On the basis of the announcement, the Government deems it important to review Sweden's drugs policy from a broad perspective to see which elements need to be developed in order to adapt the drugs policy in line with current and future challenges. In their work, the inquiry chair needs to consider perspectives and areas including the following: public health, addiction, evidence-based care and support, equality and gender equality, socioeconomics, children, young people and the elderly, crime prevention and fighting crime.

When carrying out the remit, the inquiry chair shall take into account the knowledge and proposals presented by the Comorbidity Inquiry in its report 'From parts to a whole: A reform for coordinated, needs-adapted and person-centred interventions for people with comorbidity' (SOU 2021:93). In their work, the inquiry chair may also take into account the Government's announced homelessness strategy.

How should preventive work be developed to reduce drug use?

Preventive work is essential in order to reduce the negative social and health-related consequences of drugs. It is also important to help reduce access to drugs, and to promote a safer society. Preventive work requires a long-term approach and various types of interventions, policies and strategies in different arenas and at different levels of society. Wherever possible, preventive efforts should be based on evidence. However, the fact that there is limited scientific support for individual drug prevention methods in some cases should not mean adopting a passive approach or lower ambitions. In such cases, monitoring and evaluation are all the more important. Experience of preventive work in other sectors can also be drawn upon.

Sweden has an established structure for drug prevention work. Municipalities play a central role in this work, but other actors are also active in the field, such as civil society. In 2019, the majority of municipalities had a designated coordinator for drug prevention

work. The coordinators carried out various activities and also participated extensively in the networks arranged by the county administrative boards to support them via the county administrative boards' alcohol, narcotics, doping and tobacco (ANDT) coordinators. The Public Health Agency has shown that municipal working hours spent on coordinating and planning ANDT prevention work fell between 2011 and 2018 from 148 FTEs to 89. The number of municipalities with a comprehensive document – a political programme – describing their preventive work within the field of ANDT also decreased during the period, as did local collaboration on ANDT prevention work.

Thus, despite a sound basic structure, there are differences between municipalities when it comes to these basic conditions, and in terms of preventive activities. Analyses of data from the county administrative boards' reports have shown that municipalities with a more vulnerable sociodemographic situation, e.g. in terms of educational level, carry out high quality ANDT prevention work to a lesser extent.

It is important to improve the conditions for stronger local work where all municipalities have the right conditions to carry out drug prevention work that can contribute towards the national goal of good and equal health for the entire population. Drug prevention work also needs to be strengthened at regional and national levels.

Protecting children and young people is particularly important. Children and young people are at greater risk of harm from drug use, and therefore need special protection. At the same time, children and young people are the main users of drugs in society today. There are signs that attitudes among children and young people towards cannabis in particular have changed. Specific preventive measures therefore need to be directed at this group.

There is an opportunity to gain inspiration and further knowledge by learning about the drug prevention work carried out in other countries or proposed by international organisations.

The inquiry chair shall therefore:

- Investigate experiences and give examples of how joint development initiatives and cooperation models are organised.
- Suggest which measures should be taken at national, regional and local levels to strengthen drug prevention work in Sweden.
- Propose a specific programme for preventing drug use by children and young people.

How can access to good quality care and support be improved for people with harmful drug use and dependence and harm, and for their families and loved ones?

The care and support landscape is fragmented in terms of key overall responsibility and actors. It is hard to get an accurate picture of the care and support provided. The regions are responsible for offering good quality healthcare to those who live in the region. Within the regions' area of responsibility, people with harmful use and dependence receive psychiatric and emergency healthcare measures. Under the Social Services Act (2001:453), municipalities are responsible for addiction and dependency care. Social services are also responsible for social support services, such as housing, employment, support, and assistance for children and relatives. The National Board of Health and Welfare has drawn up national guidelines for care and support for substance abuse and dependence. Many people within the Swedish Prison and Probation Service's operations have harmful drug use or dependence. SiS treats young people with serious psychosocial problems and adults with substance abuse problems.

The National Board of Health and Welfare notes that there was an increase in care for people with substance abuse and dependence problems in inpatient and specialist outpatient care during the period 2009–2019. The number of people receiving care for drug-related diagnoses has increased by around 40 per cent in the last ten years. Within outpatient care, there has been a rise in the number of measures for people being treated for drug-related diagnoses.

At the same time, the number of inpatients remains constant. There may be several explanations for the increase in the number of people being treated for drug-related diagnoses, but it cannot be ruled out that the proportion of individuals in the population developing drug-related diagnoses has increased. The Board also notes that institutional care for substance abuse granted by social services has reduced in terms of both the proportion of individuals receiving care and the length of care. Social services' out-patient interventions have also decreased over time.

People with harmful use and dependence are at increased risk of exposure to violence. Despite this, few shelters state that they accept people with substance abuse or dependence problems. Violent women with harmful use or addiction are often not identified by

social services due to a lack of interventions for the target group, which means that they risk falling through the gap between addiction care and psychiatry.

In order to provide more equal addiction care across the country, it is important to improve our knowledge about how addiction and dependency care is currently provided. Measures and actors need to be defined to ensure greater comparability. There is also a need to clarify how data will be gathered in order for authorities to compile and present an up-to-date picture of the care and support landscape on a regular basis. There are unjustifiably large regional differences in Swedish healthcare. Access to healthcare measures is also unequal in view of socioeconomic status and between women and men.

Coordinated measures are of great importance. Municipalities and regions have a shared responsibility for providing care and support to people with harmful use or dependence based on their areas of responsibility. Effective cooperation and coherent care chains are important if these measures are to produce the best possible results. Social services and healthcare have a joint responsibility for signing cooperation agreements. Such formalised cooperation has not been established in all parts of the country. There is also a need to develop cooperation between municipalities and regions, on the one hand, and the state – via the Swedish Prison and Probation Service and SiS – on the other. Internal coordination of the various measures provided within the social care and healthcare sectors is also important. One particularly vulnerable group is people with comorbidities in the form of mental health and dependence problems. The Government has therefore appointed an inquiry, the Comorbidity Inquiry, to review the division of responsibilities between the responsible authorities with regard to people with comorbidity (Dir. 2020:68).

The quality of the care and support measures offered needs to be made visible. It is important that the care and support provided is evidence-based, and is provided in accordance with current guidelines. It is also important to define what constitutes good quality and which results are sought from a professional perspective and from a patient and user perspective. Good quality and the desired results are linked to physical and mental health, housing, livelihood and financial stability, work and employment, crime, safety and security, relatives' situations, social networks, independence, reduced stigmatisation and a greater sense of belonging. The individual user's or patient's

desired results from various measures do not necessarily need to be in line with the perceptions of professionals or loved ones. However, it is important to reach a consensus on what constitutes quality within substance abuse and dependency care, and to improve the quality of the measures offered. In addition, quality needs to be monitored over time through available statistics.

Good access to care and support measures is important. A lack of availability with long waiting times has been a general problem within the entire healthcare service for many years. The Government has appointed a Delegation for Increased Accessibility in Healthcare, which presented its interim report, *Vägen till ökad tillgänglighet – långsiktig, strategisk och i samverkan* ('The road to increased accessibility – long-term, strategic and in collaboration', SOU 2021:59), on 30 June 2021. The National Board of Health and Welfare has reported data showing that the trends are moving in different directions in terms of access to municipal substance abuse and dependency care. The Board has also shown that access to care and support within social services for people with substance use and dependence has remained relatively unchanged during the past three years. Furthermore, the availability of medication-assisted treatment for opioid dependence (LARO) varies across the country, and this treatment is also sometimes offered at SiS institutions and within the Swedish Prison and Probation Service. The current care guarantee, which involves regions being obliged to provide treatment within 90 days from the date of the treatment decision, may be insufficient. A strengthened care guarantee that gives people with dependence problems the right to care and support considerably more quickly than is currently the case needs to be considered. The Delegation for Increased Accessibility in Healthcare has been tasked with investigating the advantages and disadvantages of an expanded care guarantee. It is important to have measures in place for people with harmful use or dependence when there are grounds to address the problems at hand. Motivation is a key factor when it comes to successful treatment results for an addictive disease, which is why measures need to be in place as soon as possible for those seeking care and support. By improving access to care and support for people with substance misuse, harmful use and dependence, and by strengthening preventive work, the demand for drugs can be reduced.

Primary care plays a central role in supporting people with harmful drug use and dependence, to ensure that the right care and support measures are offered at an early stage and as needed. Rehabilitation needs to be designed based on different individuals' differing objectives, preferences and conditions. For people with addictive diseases, social support measures are also a key component of care and support measures. In order to strengthen the individual perspective, there is a need to analyse the role of being drug-free within care and support for people with drug dependence, based on various services' requirements to be drug-free and the consequences these requirements have on users and their loved ones.

People who use drugs may have harmful use or addiction. Studies show that stigma can have a profound impact on individuals who use or have used drugs, including those who are considering seeking help for an addictive disease. Stigma can reduce an individual's motivation to cope with their drug use, and can lead to reluctance to seek care and support, result in social exclusion and present barriers to rehabilitation. Stigma can be caused by many different factors. It is important to work to promote non-stigmatising attitudes and good access to care and support. There is a need to review whether measures are needed to reduce the perception of stigma as a barrier to seeking care and support.

The inquiry chair shall therefore:

- Map the care and support landscape and clearly define actors and measures, and highlight geographical and socioeconomic differences and differences for women and men.
- Propose how care and support measures can be developed to ensure good, equitable quality based on the needs and experiences of users and patients. This also includes analysing whether special care and support activities should be designed for children and young people.
- Propose which actions should be carried out to ensure good access to care and support. This includes analysing whether a stronger care guarantee, giving people with dependence problems the right to care and support much more quickly than is currently the case, should be introduced and, if necessary, submitting the necessary legislative proposals.

– Analyse the role of being drug-free within care and support, including the extent to which people with harmful use or dependence are required to be drug-free in order to access other types of care and support measures, for example in connection with exposure to violence, and any consequences this has for users and their loved ones.
– Submit proposals for improving access to and the quality of measures for relatives and loved ones.
– Investigate whether – and, if so, to what extent – people with harmful use or dependence refrain from contacting social services and healthcare and, if so, the reasons for this.
– Propose measures to ensure that people with harmful use and dependence do not experience stigmatisation in their contact with social services and healthcare, resulting in them choosing not to seek care and support.

The justice authorities and measures

Care and support for people who commit drug offences

Various types of illegal drug use are criminalised under the Swedish Narcotic Drugs Act. A general criminalisation of drug possession, including for personal use, has been deemed necessary to counter the spread of drug abuse within society. Since 1988, it has also been a punishable offence to use drugs, i.e. to consume them or to introduce them into the body in any other way. The criminalisation of personal use was introduced as a clear and unambiguous expression of society's rejection of all forms of involvement with illegal drugs. It was also deemed to have a psychological value and a preventive function, particularly among young people and others at risk of becoming dependent on drugs or considering using drugs. These reasons remain valid. The link between drugs and organised crime also means that there is a need for a continued restrictive drugs policy, including criminal liability for drug use.

The seriousness of a drug offence is primarily determined based on the type and quantity of drugs and the other circumstances surrounding the offence. Those who use drugs are normally fined for minor drug offences. Minor drug offences can also include the pos-

session of a small amount of drugs for personal use. Cases such as possessing a large quantity of drugs, selling drugs or involvement in drugs that are not intended for personal use are usually classified as regular drug offences or, in more serious cases, as serious or very serious drug offences.

For drug offences that are not minor offences, the only punishment is imprisonment. In accordance with the general rules, it is possible – under certain conditions – to replace a prison sentence with another sanction: a conditional sentence, probation or transfer to special care (transfer to LVM care or forensic psychiatric care and, in the case of young offenders, the special juvenile sanctions). Several of these sanctions have scope for elements of care and treatment. A probation order may be combined with orders on measures such as drug abuse care, psychiatric care or other treatment. Such orders are also possible for those who are subject to supervision following release on parole from a prison sentence, and treatment measures may also be carried out within the context of a prison sentence.

There are no opportunities to offer care and support measures to individuals who have been fined within the system of sanctions. This is related to the fact that fines are a less severe sanction than imprisonment, and that sanctions with a care element are only used as an alternative to imprisonment. However, such measures could be offered outside the judicial system. Offers of care and support measures are already made to people with harmful use or dependence, albeit not in a systematic way. There may be a need to create clearer offers of care and support for this group. One such approach relates to traffic, where those suspected of drink-driving or drug-driving are offered help under a model for cooperation to combat the use of alcohol and drugs in traffic. The model involves the police offering suspected drink-drivers the opportunity to make contact with social services or dependency care services.

The inquiry chair shall therefore:

– Propose whether – and, if so, how – care and support measures can be offered in a more systematic way to those convicted of minor drug offences.

– Review how the care elements within the sanctions for drug offences are provided.

The inquiry chair shall not propose changes to criminal law legislation or to the legislation on preliminary investigations and prosecution.

Care and support measures provided by the Swedish Prison and Probation Service and SiS

One of the basic tasks of the Swedish Prison and Probation Service is to enforce sanctions. The Service shall work to prevent relapses into crime, and shall take measures to reduce relapses into addiction, for example. Drug problems are common among the Service's clients. On any given day, there are around 10 000 clients with more or less pronounced drug problems in the Service's prisons, detention centres and probation centres. In recent years, the Service has developed its work with individual enforcement plans, which set out the measures needed by the client to avoid relapsing into crime or addiction, and the preparations that must be made for a life in freedom.

Cooperation between actors is important in order for the Service's clients with harmful use or addiction to receive the right treatment measures during and after enforcement. The Service does not have primary responsibility for care and support, but other authorities do in accordance with the principle of normalisation. However, the Service is expected to take significant responsibility for identifying needs and for establishing contact with the relevant authorities. At the same time, it is sometimes possible to receive care at certain prisons.

Every year, more than a thousand men and women are compulsorily detained under LVM and placed in one of SiS's LVM homes. There are eleven LVM homes with almost 400 places for withdrawal treatment, motivational work or rehabilitation. Clients at LVM homes have many years of drug dependence behind them. This involves abusing alcohol, drugs or medicines, or a mixture of these. The aim of LVM care is to end life-threatening substance abuse and encourage voluntary treatment. The maximum duration of LVM care is six months. Care should be transferred to another form of care outside the institution, known as Section 27 care, as soon as possible. Care can then continue at an open treatment home, in a family home or through participation in an outpatient programme. The average duration of LVM care is just over four months. SiS provides LARO treatment within LVM.

A short stay at an LVM home does not break a long period of substance abuse. Long-term substance abuse requires long-term treatment and support. During the placement period, SiS works together with the client's network and the social service responsible for the placement to ensure that the measures at the LVM home are followed by advanced measures after discharge.

All clients in LVM care are offered a SiS LVM investigation. This investigation forms the basis for planning future care. Mapping addiction and criminality, as well as mental, medical and social conditions, increases the chances of identifying the right measures for each individual client. The results of the investigation are submitted to social services. The client is also informed of the results.

The inquiry chair shall therefore:

– Identify the care and support measures offered within the framework of SiS and the Swedish Prison and Probation Service's operations, and analyse how these operations relate to the health and social care offered by other providers.

– Examine whether the possibility of initiating a coordinated individual plan can facilitate SiS's and the Swedish Prison and Probation Service's work with clients with harmful drug use and dependence on drugs, and if necessary submit the necessary legislative proposals, and examine how the care and support authorities can facilitate SiS's and the Swedish Prison and Probation Service's work with these clients.

– Analyse how people's addiction diseases are taken into account when drawing up and implementing enforcement plans and treatment plans within the Swedish Prison and Probation Service and SiS.

– Suggest how collaboration with other actors can be strengthened to ensure that other actors step in with regard to care and support when SiS's or the Swedish Prison and Probation Service's responsibility ceases, so that the care includes analysing collaboration in connection with those who are repeatedly convicted of drug offences or are compulsorily detained chains remain in place. This under LVM.

Cooperation between healthcare services, the Swedish Police Authority and social services, and their cooperation

Substance abuse and dependence services include the responsibilities of healthcare and social services for people of all ages who misuse or are dependent on alcohol, drugs, other addictive substances, medicines, doping substances and gambling. A more detailed description of the responsibilities of healthcare and social services can be found in the section 'How can access to good quality care and support be improved for people with harmful drug use and dependence and harm, and for their families and loved ones?' (p. 8).

Together with other authorities within and outside the justice system, the Swedish Police Authority shall contribute through its actions to the goal of criminal policy: to reduce crime and increase people's security. The work of the Authority contributes towards reducing access to drugs within society.

It is common for police officers to come into contact with people who use drugs. A number of different interventions are carried out in these cases. Social services are often involved, and in serious situations there is a need to seek healthcare. Essentially, the Authority has a law enforcement remit. Social services and healthcare services are responsible for meeting the support and care needs of individuals.

There is a need to strengthen the cooperation between healthcare services, the Swedish Police Authority and social services. Knowledge needs to be increased about the activities of the actors involved and about drugs and drug use, including addiction disease. Inadequate contact links between different actors and unclear responsibilities make it harder to help people with harmful drug use or dependence in the best possible way.

The inquiry chair shall therefore:

– Propose measures to strengthen cooperation between healthcare services, the Swedish Police Authority and social services to ensure that individuals with harmful use or dependence receive adequate assistance.

– Suggest how the level of knowledge about drugs and drug use, including addiction disease, can be strengthened among the Swedish Police Authority, healthcare and support providers, and other relevant actors, and how the level of knowledge about the respon-

sibilities of each service provider can be increased, with the aim of continually improving knowledge.

– Propose ways to strengthen the contact channels between healthcare, the Swedish Police Authority, social services and other actors when the police come into contact with people who use drugs.
– In view of the various actors' different remits, propose measures that contribute towards measures meeting the needs of the individual.

What constitutes a harm-reduction measure and which harm-reduction measures should we have in Sweden?

Measures to reduce the medical and social harm caused by drugs are of great importance from various perspectives. A central principle for harm reduction is the development of pragmatic responses to managing harmful drug use and dependence. This is done through various types of interventions that primarily emphasise reducing the health-related harm of continued drug use. Human rights are an important starting point for harm reduction measures, including everyone's right to enjoy the best possible health. There is no generally accepted definition of harm reduction. The World Health Organization (WHO) describes it as follows: "Harm reduction is a set of policies, programmes, services and actions that aim to reduce the harm to individuals, communities and society related to drugs, including HIV infection."

One important harm reduction measure is the introduction of syringe exchange programmes. In order to improve nationwide access to syringe exchange services for people who inject drugs, an amendment was made in 2016 to the Act (2006:323) on Exchange of Syringes and Needles (Govt Bill 2016/17:15). The National Board of Health and Welfare's follow-up of the legislative change was presented in December 2019, and shows that the availability of syringe exchange services in Sweden has increased. In order to make syringe exchange programmes more accessible, the Government proposes that the principle of residence should be removed from the Act on Exchange of Syringes and Needles, so that those who are not considered to be resident in a particular region can also be given the opportunity to participate in such programmes (Govt Bill 2021/22:129). It is pro-

posed that the legislative change should enter into force on 1 August 2022. The availability of naloxone medicines is another important harm reduction measure. Naloxone reverses the effects of overdoses of opioids such as heroin or methadone, and the availability of this drug has improved. Syringe exchange and naloxone programmes are now available in almost all regions. The number of people infected with hepatitis C as a result of injecting drugs has decreased.

One common treatment intervention for opioid dependence is LARO, a Swedish acronym for medication-assisted treatment for opioid dependence. The National Board of Health and Welfare has issued regulations and general advice on LARO. In March 2020, the Board published knowledge support for this treatment, which is given a high priority in the Board's national guidelines for care and support for substance abuse and dependence.

The Public Health Agency proposes continuing to develop syringe exchange programmes and expanding low-threshold mobile services in its report on proposals for action to prevent drug use and the medical and social harm associated with drugs. Low-threshold activities involve 'lowering the threshold' – in other words, there is higher tolerance for people who participate in these activities still having an active addiction. This differs from the drug-free approach as a condition for participation in measures.

An international perspective suggests that different countries are carrying out different measures to reduce the medical and social harm caused by drug use. There is a broad consensus within the EU on the importance of reducing harm, not least the spread of contagious diseases, and measures to reduce overdose-related morbidity and mortality. LARO treatment and syringe exchange services are the most common harm reduction measures, alongside naloxone programmes (see the section 'How will Sweden's drugs policy contribute towards fewer deaths from drug poisoning?', p. 19). Further examples of measures include outreach work, health promotion measures and education.

Recently, there have been new opportunities to improve access to and the effectiveness of harm reduction measures, in particular through the development of information technology and mobile applications. New ways of offering harm reduction measures include the use of new e-health solutions to deliver short-term measures or support for recovery or rehabilitation. There may be a need to learn

from other countries about effective measures to reduce the medical and social harm caused by drug use.

The inquiry chair shall therefore:

- Define what should be deemed to constitute harm reduction measures in Sweden, in order to create a common definition that can serve as a common starting point for knowledge-based work within the field in Sweden.
- Explore how existing harm reduction measures, including medication-assisted treatment for opioid dependence (LARO) and syringe exchange services, can be developed and implemented more widely and become more equitable, gender equal and accessible nationwide.
- Propose how low-threshold activities can be more widely introduced, developed and monitored in Sweden.
- Provide an international overview of available harm reduction measures and current developments within the field and, if necessary, submit proposals for new measures that should be taken in Sweden to reduce the medical and social harm of drug use.

How will Sweden's drugs policy contribute towards fewer deaths from drug poisoning?

The number of deaths due to drug poisoning in Sweden is high. These deaths often affect vulnerable people, and they also cause suffering for families and loved ones. In 2018 and 2019 there was a reduction, mainly due to fewer deaths caused by fentanyl analogues. In 2020, 822 people died from these causes – a decrease of 8 per cent compared to the previous year. The aim is to reduce the number of deaths continuously.

In recent years, several national measures have been taken to reduce the number of deaths due to drug poisoning. The Government has promoted the expansion of naloxone programmes and syringe exchange services. Funding has been added to the Public Health Agency's administrative appropriation for faster classification of new psychoactive substances. The National Board of Health and Welfare has been commissioned by the Government to draw up knowledge support for medication-assisted treatment of opioid depen-

dence. In June 2021, the Board presented the Government's remit to map emergency departments' procedures for dealing with drug-related overdoses. In June 2021, the Public Health Agency was tasked with implementing a national warning system to prevent drug-related deaths. However, it is clear that further measures are needed to reduce the number of deaths due to drug poisoning. The Riksdag has announced that the Government should commission an analysis of the outcome of measures carried out internationally to reduce drug-related deaths (Committee Report 2021/22:SoU10 point 9, Riksdag Comm. 2021/22:150).

Naloxone reverses the effects of overdoses of opioids such as heroin or methadone. The National Board of Health and Welfare's national guidelines for care and support in connection with substance use and dependence include a recommendation that healthcare services should offer naloxone and education to people with opioid dependence and risk of overdose. Several efforts have been made in recent years to increase access to naloxone, but more can still be done. In June 2021, the Board was therefore tasked by the Government with actively supporting greater access to naloxone, within the framework of the current regulations. Access to naloxone could be further improved if naloxone were to be prescribed in such a way that additional professional groups could administer the drug to people who have taken an overdose. Through more teams having and administering naloxone, quick and effective life-saving action can be carried out. In 2018, the Swedish Medical Products Agency and the National Board of Health and Welfare assessed that proposals to allow key groups outside healthcare to have and administer naloxone medicines to another person need to be investigated following a specific procedure. They noted that such a proposal would necessitate comprehensive considerations on issues such as constitutional rights, and that any statutory amendments they would entail would probably have to be made largely at legislative and regulatory levels. In addition, it is important that issues relating to working environment, responsibility and competence are investigated in relation to the relevant actors' remits and conditions.

The inquiry chair shall therefore:

– Carry out an analysis of the outcomes of efforts taken internationally to reduce drug-related deaths.

– Propose a national programme to reduce the number of deaths due to drug poisoning.
– Analyse whether professional groups other than health professionals – and, if so, which ones – should be able to administer naloxone for opioid overdoses, and if necessary submit legislative proposals on how this should be regulated.

What are the experiences from other countries on generic classification of new psychoactive substances?

The growing prevalence of new psychoactive substances is a serious problem, and requires an effective system for the rapid classification of substances as narcotics or products that are harmful to health. Generic classification would mean more substances being covered by the legislation more quickly. Generic classification means that the classification is based on the basic chemical structure of the substances. However, such a system is not easy to reconcile with the legal security requirements in cases of drug offences or offences against the Act (1999:42) on the Prohibition of Certain Goods Dangerous to Health. Currently, in order for a substance to be classified as a narcotic, it must be a medicinal product or a product that is dangerous to health, identified as having addictive properties or euphoriant effects, or be easily convertible into such a product. For a substance to be classified as hazardous to health due to its intrinsic properties, it must have been found to pose a danger to human life or health and be used – or suspected of being used – for intoxication purposes or for some other effect.

In its bill 'Classification of new psychoactive substances' (Govt Bill 2017/18:221), the Government considered that a generic classification system should not be introduced in view of the current knowledge base. The Riksdag has announced that the Government should commission an analysis of experiences from countries that have already introduced a system of generic classification of new psychoactive substances (Committee Report 2017/18:SoU7 point 27, Riksdag Comm. 2017/18:354).

The inquiry chair shall therefore:

– Explore the experiences of countries that have introduced the generic classification system for new psychoactive substances.

Monitoring certain aspects of drugs

There is currently no overall picture of the number of people with dependence or harmful drug use. This is because the measures are provided by different authorities and actors, and it is not always clear why a person is seeking care or whether they have active harmful use or addiction. To get a picture of the care and support landscape based on dimensions such as individualisation, accessibility, quality and effect (e.g. reduced mortality), and efficiency, monitoring needs to be improved.

The Government has tasked the Public Health Agency, the Medical Products Agency, the National Board of Forensic Medicine and the National Board of Health and Welfare with compiling, analysing and presenting statistics on deaths due to drug poisoning. This remit includes describing the similarities and differences in registration and reporting practices between Sweden and other Nordic countries, as well as other European countries and internationally, and analysing the significance of these differences. The final report on this remit will be presented on 1 June 2022. Based on the information presented by the various government agencies, there may be grounds for taking actions to develop the national statistical work in this area, in order to create more detailed national monitoring with statistics that are broken down by gender where possible.

The inquiry chair shall therefore:

– Analyse and map the number of people with harmful use of and dependence on drugs in Sweden today, and draw up a system of methods to continuously calculate the number of people in the country with harmful use and dependence. If necessary, the inquiry chair shall draft the necessary legislative proposals.

– Propose a model for appropriate monitoring of addiction and dependence care, which should also include monitoring the use of naloxone medicines and how monitoring will be developed over time.

– Propose how statistics on deaths due to drug poisoning can be developed in order to provide more accurate monitoring. If necessary, the inquiry chair shall draft the necessary legislative proposals.

Impact assessments

The socioeconomic effects of the submitted proposals shall be described and, where possible, quantified. All the public finance effects of the inquiry chair's proposals shall be calculated. If the proposals involve public finance costs, funding proposals shall be submitted. If the proposals affect costs or revenues for municipalities and regions, a calculation of these consequences shall be included in the report. If the proposals in the report affect municipal autonomy, the specific considerations made in accordance with Chapter 14, Section 3 of the Instrument of Government shall be reported. In addition, the inquiry chair shall report on the consequences of the proposals for social services and healthcare, and for the other actors who may be affected by the proposals.

The consequences of the proposals for patients and users shall also be described. In their work, the inquiry chair shall take into account an equality perspective, including equal care as a starting point. Accordingly, the consequence of the proposals shall also be highlighted in terms of socioeconomic and regional equity. The gender impact assessment shall take particular account of the gender equality policy subsidiary objectives of equal health and ending men's violence against women. In addition, the inquiry chair shall specifically report on the consequences of the proposals in relation to the UN Convention on the Rights of the Child.

Contacts and reporting on the remit

Within the framework of the remit, the inquiry chair shall consult with the relevant government agencies, the Swedish Association of Local Authorities and Regions, a selection of municipalities and regions, associations for patients, users and relatives, and professional representatives. The inquiry chair's approach should be outward-looking and inclusive. The inquiry chair shall also stay informed about and take into consideration the work carried out by the Government Offices and relevant authorities that is relevant to the implementation of the remit, and shall initiate a dialogue with the relevant governmental inquiries. The inquiry chair shall keep the Government Offices (the Ministry of Health and Social Affairs) informed of their work on an ongoing basis.

An interim report shall be submitted by 14 October 2022 for the following subsidiary remit:

– Analyse whether professional groups other than health professionals – and, if so, which ones – should be able to administer naloxone for opioid overdoses, and if necessary submit legislative proposals on how this should be regulated.

The remainder of the remit shall be reported on by 29 September 2023.

(Ministry of Health and Social Affairs)