

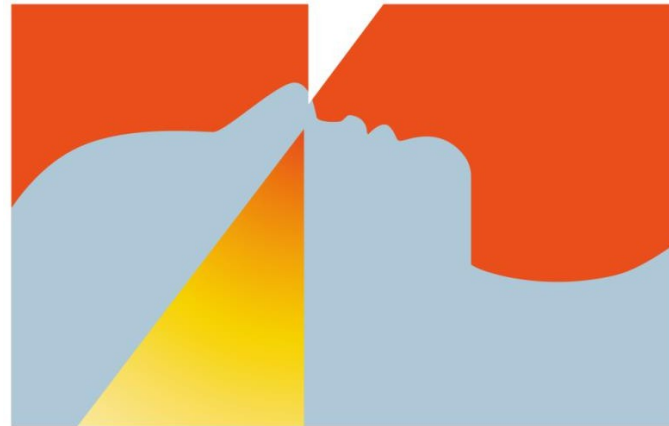
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# NALOKSON



## **Project report for part II of the strategy (2019 - 2023)**

In 2013, SERAF was commissioned to implement and evaluate buddy rescue with naloxone nasal spray as part of the Norwegian Directorate of Health's national strategy to reduce overdose deaths.

This report summarizes the activities of the camera rescue project over the past three years.

For complementary and updated info, please see also [www.nalokson.uio.no](http://www.nalokson.uio.no).



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## 1. Summary 2019 to 2023

In 2014, the health authorities established a national strategy to reduce overdose deaths, partly in collaboration with SERAF, UiO. The first strategy period (2014 to 2018) was extended by 4 years until the end of 2022.

The strategy is based on relatively high overdose figures over several years and consists of various measures. The measures include a) a motivational campaign promoting safer use of heroin; heroin smoking rather than injecting, b) established cooperation between the most vulnerable municipalities in a network for learning and exchange of experience and c) implementation of distribution of the opioid antidote naloxone as a nasal spray to drug users.

Since the start of the strategy, SERAF has been tasked with implementing and evaluating camera rescue with naloxone nasal spray. During the first period (2014 - 2018), the camera rescue project was established in Oslo, Bergen and all network municipalities. In the second strategy period, we significantly expanded our reach so that the spray is now distributed from more than 350 different locations in 108 municipalities across Norway. Preliminary findings show that almost 30,000 nasal sprays have been distributed since the start-up, mainly to people who inject drugs, but also to those who work with the target group, as well as other interested parties who wanted to participate in buddy rescue and collect naloxone.

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## 2. Background

### 2.1. Overdose death

Every year, between 250 and 350 people die from overdoses in Norway, which corresponds to between 70-80 deaths per million inhabitants per year (in the age group 15-64). In comparison, the European average is reported to be significantly lower with approximately 22 annual overdose deaths per million inhabitants (EMMCDA, 2019). In the USA, on the other hand, the reported figure of 217 overdose deaths per million inhabitants in 2017 is approximately 10 times higher than the European average. There are complex reasons why the observed incidence of overdose deaths in Norway is higher than in other parts of Europe. Both the high proportion of syringe users and the concurrent use of opioids and benzodiazepines are usually cited as explanations. After very high mortality at the turn of the millennium with more than 400 deaths (dominated by heroin as the triggering cause of death), a downward trend in overdose deaths has been observed in recent years (Amundsen, 2015). The year 2020 was an exception, with 331 overdose deaths nationwide (Gjersing 2023).

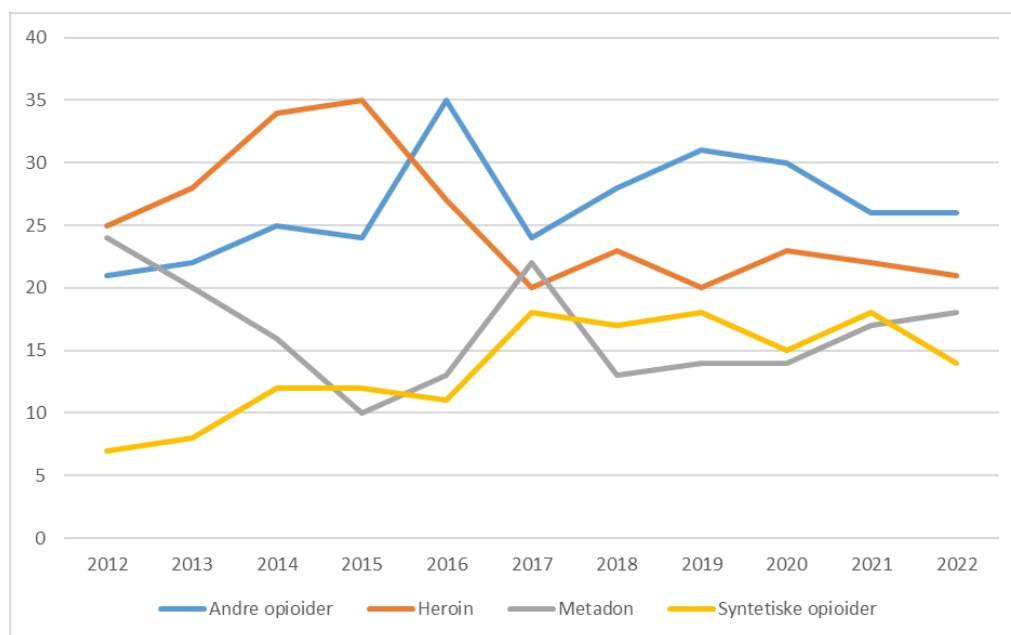
The decline since the 2000s coincides with a significant expansion of drug-assisted rehabilitation (DAR), which is the first choice in the treatment of opiate addiction. Maintenance treatment with methadone or buprenorphine in OMT protects the patient group from premature death, including overdoses (Clausen, Anchersen, & Waal, 2008). Since the turn of the millennium, the number of patients receiving maintenance treatment through OMT in Norway has steadily increased from around 1000 patients to the current approximately 8000 patients receiving maintenance treatment (Nesse et al., 2023).

The increase in OMT services came after the inclusion criteria were expanded, and in recent years this has also included low-threshold OMT, which has become available in several health trusts. Low-threshold OMT followed a harm reduction rationale, with daily dispensing of medication (initially only buprenorphine-naloxone) with no requirement for measures to improve substance abuse control and no requirement for a rehabilitation plan before starting (Gjersing, Waal, & Clausen, 2009). Another important harm reduction measure was established in February 2005 when the user room opened in Oslo (Olsen & Skretting, 2007). Both the user room and low-threshold LAR were evaluated positively, and the measures were continued and expanded to Bergen, and to include both buprenorphine and methadone.



Opioids dominate as a cause and account for more than 80% of all drug-induced deaths in Norway each year. According to FHI, the trend in overdose deaths in Norway is changing, with heroin-related deaths showing a downward trend (Gjersing 2023). Although there is some variation over time, this trend is clear for the years after 2015 (see **Figure 1**). At the same time, we see an increase in the proportion of deaths related to strong painkillers, which may seem to coincide with the fact that from 2016 GPs were given the option of prescribing strong painkillers (*Dolcontin*, etc.) for chronic non-malignant pain conditions. Among many patients in OMT, mixed use of prescribed A and B preparations is relatively common. A recent study found that almost half of the women who died in OMT in 2019 had been prescribed an opioid medication (Eide et al., 2023). In the buddy rescue project, the main target group is people who mainly inject heroin, because this is a group that often both experiences overdoses themselves and witnesses overdoses. It is conceivable that the decline in heroin-related deaths is a result of efforts to target this group. At the same time, the consistently high death rate leaves room for the following interpretation: could it be that the rate is driven up by pain patients, or other groups that we do not reach as well?

**Figure 1:** Based on data from FHI. The figure shows the reduction in the proportion of heroin-related deaths (orange). Contrasted with tablets such as *dolcontin* (other opioids - blue) and second-line treatment such as fentanyl (synthetic opioids - yellow).





After the COVID-19 pandemic hit in mid-March 2020, significant infection control measures were added. Demands for social distancing and prioritization of infection control in all health services were at times at the expense of normal operations in the project. Both before and during the pandemic, we have directed naloxone distribution mainly to people who inject heroin regularly. In the years to come, it will be crucial to involve target groups beyond injecting heroin users. For example, injecting amphetamine users who have low opioid tolerance and therefore a high risk of dying if the drug is contaminated with opioids, or if heroin is used sporadically. In addition, measures should be targeted at patients who are prescribed strong opioids by their GP and their relatives.

## 2.2. Antidote as harm reduction

In 2014, camera rescue with the opioid antidote naloxone was incorporated as a new harm reduction measure in the Directorate of Health's strategy to reduce overdose deaths. In this context, SERAF was commissioned to implement training in the use of the nasal spray, as well as to scientifically evaluate the effect of the measure. After an approved drug (with marketing authorization) became available in May 2018 (see **Figure 2a**), we have used this type of drug in our project, at the same time as naloxone also became available on prescription for regular C-drug prescriptions.

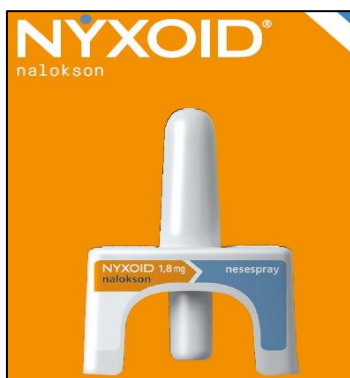
In this report, we describe the period between May 2018 and October 2023, because it is during this period that we have distributed registered sprays (*Nyxoid* and *Ventizolve*) for camera rescue (see **Figure 2**).

**Fig 2a:**

*Nyxoid* is a single-dose spray that contains 1.8 mg naloxone and was developed in collaboration with the Norwegian

**Fig 2b:**

*that Ventizolve* became available from June 2020. The spray contains 1.26 mg naloxone and was developed in collaboration with the Norwegian market in May 2018.





For both drugs, two single-dose sprays are distributed in Norway as a "kit" in case one spray does not provide sufficient effect.

At the same time as registration, a prescription with reimbursement via the blue prescription scheme was introduced. This reimbursement scheme allowed all doctors to prescribe nasal sprays to those who need or want them. At the same time, SERAF continues to deliver sprays to established distribution points in the same way as before as part of the naloxone project (with funding from the Norwegian Directorate of Health). The cost of a registered nasal spray kit (which now contains two doses/sprays) is a maximum of NOK 474.50 (incl. VAT).

### **3. Methodology**

#### *3.1. Project design and purpose*

The purpose of buddy rescue by means of distribution of naloxone nasal spray and first aid training is to reduce the number of fatal and non-fatal overdoses (OD). The measure has been evaluated continuously since 2014 by SERAF using a research-based approach that includes questionnaires, follow-up surveys and register linkages. Both implementation and evaluation of the project were initially limited to the pilot cities of Oslo and Bergen, but were quickly expanded to other cities/municipalities. One of the main goals was to achieve sufficient coverage of naloxone per capita based on an estimated need for annual distribution of 1500 - 2000 naloxone sprays in the project cities. Another important outcome measure is the development in OD mortality, which is monitored through both annual FHI reports from the Cause of Death Registry (DÅR) and cross-linking of our cohort with DÅR.

From the outset, the project was designed in two parts, with an emphasis on both implementation and data collection. In order to make the distribution happen in many places at the same time, SERAF has established coordinating municipal units in Oslo, Bergen and Trondheim. The coordinators know the field well, are linked to existing low-threshold services, promote the project and play a key role in distribution and data collection. The implementation strategy is considered to have been successful as we reached high distribution figures early in the project. The success was based on the coordination of systematic training, broad information, participation in and organization of conferences and the offer of free delivery of nasal spray to all units that showed interest in becoming a distribution site





(Madah-Amiri D, Clausen T & Lobmaier P, 2016). In the long term, SERAF's ambition and strategy is to



the project is anchored both locally and regionally to ensure that it can be run as part of ordinary practice in the municipalities.

### 3.2. Project team and structure

The staff of the camera rescue project consists of researchers from UiO, coordinating municipal units, administration and a doctoral student affiliated with SERAF (UiO). The coordinators are located in Oslo, Bergen and Trondheim and have regional responsibility for Southern and Eastern Norway, the Western region and the Central/Northern region.

In Oslo, the coordinator's position is now linked to Kompetansesenter Rus (Korus) Oslo, while coordination in Trondheim has been assigned to the local Overdoseteamet. In Bergen, the coordinator position was gradually increased from 50 to 100% and is linked to the municipal service MO Gyldenpris. Project coordination with local anchoring and regional tasks has been essential for the project to develop and establish itself in new municipalities (see **Figure 3**). Project coordinators are crucial for expanding and being able to offer naloxone training in both selected pilot municipalities and eventually all places with an interest in buddy rescue and overdose prevention work.

**Figure 3:** The timeline illustrates the extension to 2022. There is no longer room in the graphic for participating municipalities in 2023





The coordinators also provide a direct line of communication to staff and users participating in the project. The structure with specially designated project coordinators has contributed significantly to a general increase in knowledge about overdose prevention among those working in low-threshold, voluntary, specialist health services, the police and security guards. This knowledge boost was considered important because overdose situations are rare events that require training and knowledge maintenance. The coordinators from the project who are close to the participating distribution points could in this way more easily receive feedback on what works and what changes and adaptations should be made. At the same time, it is also very important to increase engagement and knowledge about naloxone in prisons and the specialist health service "TSB", so that user groups who are in life situations where they may be particularly at risk of overdose death are offered and educated about naloxone. This structure has enabled the naloxone project to be dynamic and constantly evolving.

### 3.3. *The e-course as a further development of the training*

A staff training course was previously created and this course was a prerequisite for being able to distribute naloxone to the end user. The course was held by one of our key trainers (the various coordinators and the PhD fellow) and took around two hours to complete.

The course was delivered as classroom training in direct contact with the employees, supported by PowerPoint. The main topics of the course included the following:

- 1) The background to companion rescue in overdose
- 2) The mechanisms of an overdose
- 3) The effects of naloxone
- 4) Signs of an overdose
- 5) How to act in an overdose situation
- 6) Storage and collection of project information
- 7) Composition and distribution of naloxone
- 8) Opportunities to implement naloxone distribution at each site

From spring 2020, we replaced classroom teaching with our online learning platform for training new coaches. The coincidence in time with the Covid-19 outbreak was coincidental. This e-course



is available via the project website (<https://www.nalokson.uio.no/om/e-kurs/>) and is a great resource saver for the coordinators.

All the learning points from the classroom training were integrated into interactive modules that end with a short knowledge test. From April 2021 to November 2023, 4260 people have enrolled in the e-learning program, of which 82% have completed the training. The e-course is currently being evaluated in terms of knowledge increase and whether it leads to the initiation of naloxone distribution. The same knowledge measures were also investigated in a prison population and were the basis for a master's thesis published in 2017 and subsequently published (Pettersen & Madah-Amiri, 2017).

During the COVID-19 lockdown of society, the e-course became a very important service, precisely because electronic teaching could meet the health authorities' requirements for social distancing. Thus, the possibility of automated, electronic training has ensured project operations, even in the pandemic situation, while the coordinators can still offer classroom teaching as needed.

After the e-course, participants receive a ninja diploma confirming that they have completed the training and are thus able to both use and dispense naloxone nasal spray.

#### 3.4. *Data collection*

Since September 2018, all data collection related to naloxone distribution is done electronically to make it easier to collect information. Participation in the research part is still consent-based with the possibility to withdraw from the project at any time. It is voluntary to provide a social security number for later registry linkage. The use of electronic data collection excludes logical errors that could occur when using paper forms. All information is stored directly and securely in UiO's "service for sensitive data - TSD". The storage is encrypted and only project staff have access to the data. All data must be de-identified (incl. deletion of personal numbers) by 2030 at the latest.

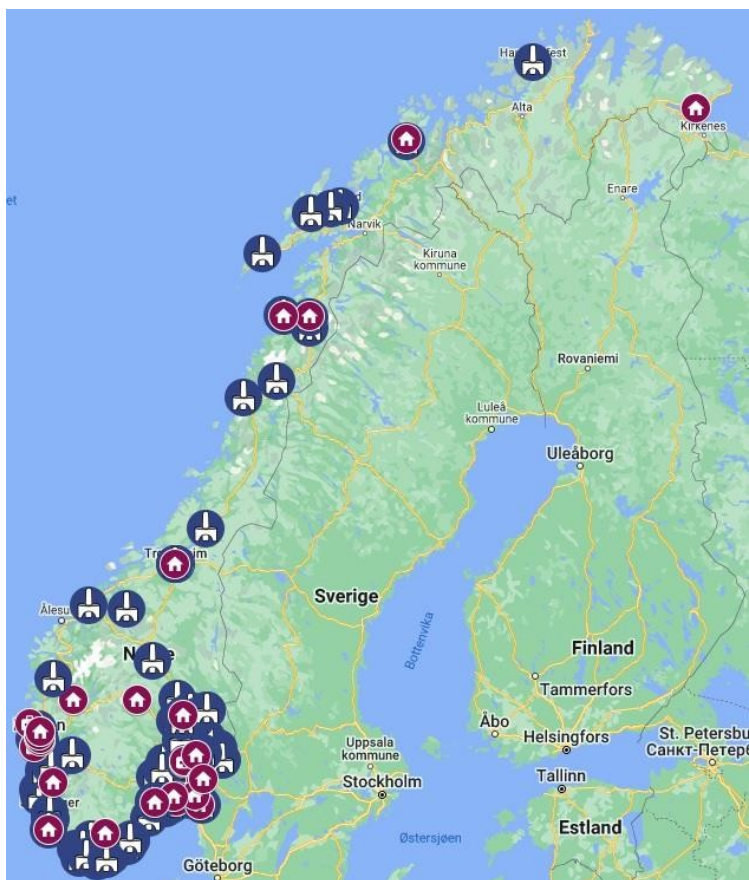


## 4. Findings

### 4.1. Distribution points and collaboration

In 2023, there were more than 350 sites distributing naloxone in Norway (see **Figure 4**). The distribution sites are diverse and include prisons, hospital wards, emergency rooms, low-threshold initiatives, various outreach work and various places that offer shelter. All the locations listed on the website have had the opportunity to distribute naloxone, but it is the low-threshold services that have distributed the most.

**Figure 4:** Map section from nalokson.uio.no showing all distribution points in Norway as of 2023.

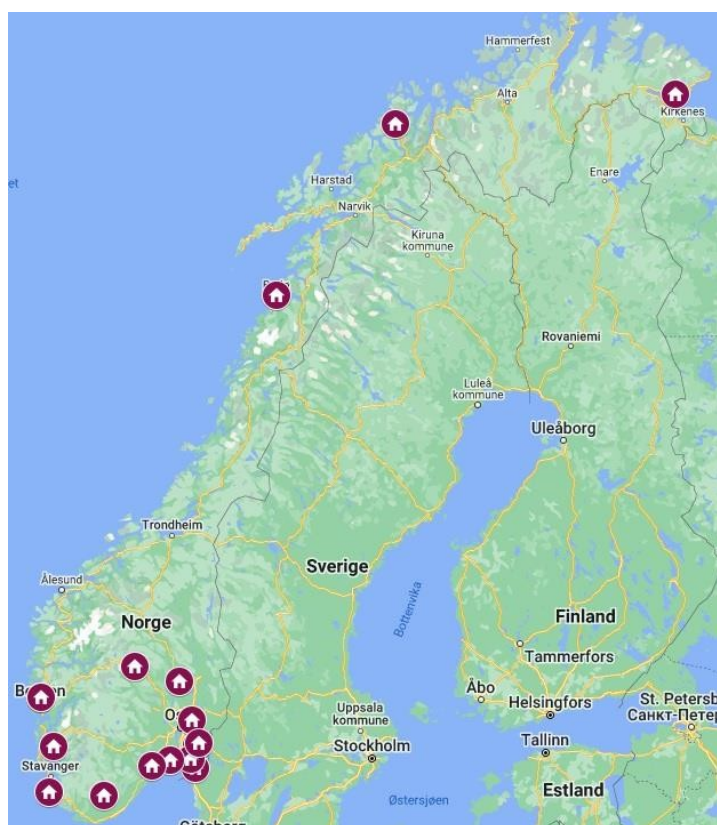


In order to implement user training over the years, a number of relevant actors in the country have shown interest in and willingness to provide premises, time and staff. In the initial phase of the project, the main focus has been on establishing cooperation with existing low-threshold services that already reach out to disadvantaged users. In recent years, we have increasingly provided broad information to districts in Oslo, smaller municipalities and less specialized initiatives such as home care services, security companies and the police.



Across municipal boundaries (and far to the east), 37 prisons are also distributing naloxone kits (see **Figure 5**). Establishing good cooperation and routines for training in prisons has presented challenges and taken time. However, the collaboration with the Norwegian Correctional Service's Education Center (KRUS) and their overdose project has become a very important alliance in our efforts to reduce overdose deaths after release. Post-release overdose mortality was particularly highlighted by another SERAF project (Bukten et al., 2017), which showed a high risk of overdose death shortly after release from Norwegian prisons. Naloxone distribution on release from prison is currently an important part of KRUS's project and is included as one of the main measures in 37 prisons. The collaboration is considered important and will continue to be a focus area in the future. The probation offices in Oslo, Vestfold, Telemark, Buskerud and Bergen are already part of the buddy rescue program and offer naloxone distribution.

**Figure 5:** Map section showing prisons in Norway that distribute naloxone.



During the project period, a number of police districts have participated in training courses and have had nasal sprays deployed in their patrol cars. The police in Bergen, Oslo, Trondheim, Drammen, Larvik, Tønsberg, Arendal, Øst police district, Stavanger, Sandes, Møre og Romsdal (as well as several regions in the West) and Alta (Nordland police district)



have all had sprays deployed in their patrol cars.



#### 4.2. *Distribution and use in 2023*

Since its inception, naloxone distribution has been both a harm reduction measure and a research project. This means that participation in the research part is voluntary, which means that stakeholders are provided with spray after training regardless of consent. It also means that there is a difference between the number of sprays purchased, distributed to distribution points and registered in the database. Based on figures from naloxone orders, inventory and registered distributions, we can estimate that about half of the ordered sprays are registered as part of the research project. At the same time, stock levels are low and we assume that at least 75% of ordered naloxone has been distributed.

For example, as of August 2023, 9143 naloxone nasal spray kits have been delivered to pharmacies throughout Norway (of which 87% were *Ventizolve*), while a total of 7013 kits were delivered throughout 2021. These figures are based on wholesale sales and therefore also include sprays delivered outside the project. Compared to wholesale sales, the number of sprays ordered for the project was somewhat lower in 2021 with 6204 boxes. As of October 2023, orders for the project are clearly higher than previously (9548 naloxone kits, cf. **Table 1**) and so far more comparable with wholesale sales than in 2021. There is generally a clear preference for the Norwegian-produced *Ventizolve*, and the proportion of *Nyxoid* fell further in 2023 compared with 2021 (1056 for the whole of 2021 and 499 for 2023 as of October).

**Table 1:** Number and type of sprays ordered for project from pharmacies in 2023 (to mid-October), whole country.

<i>Type, as of Oct. 2023</i>	<i>Vest</i>	<i>Middle</i>	<i>South-East</i>	<i>Sum</i>
<i>Nyxoid</i>	25	0	474	499
<i>Ventizolve</i>	2527	1100	5458	9085
<i>Total</i>	2552	1100	5932	<b>9584</b>

Naloxone distribution has increased every year since the project started (see **Figure 6**). From 2017, we saw a greater proportion of sprays registered as refills compared to initial training. This was interpreted as a clear indication that we are reaching the target group: users who actually need the spray. Although refill spray accounts for the majority of registered naloxone in recent years, we also see that approximately 500 to 1200 new individuals are added each year. The decline in distribution in 2021 is probably due to the Covid-19 pandemic and

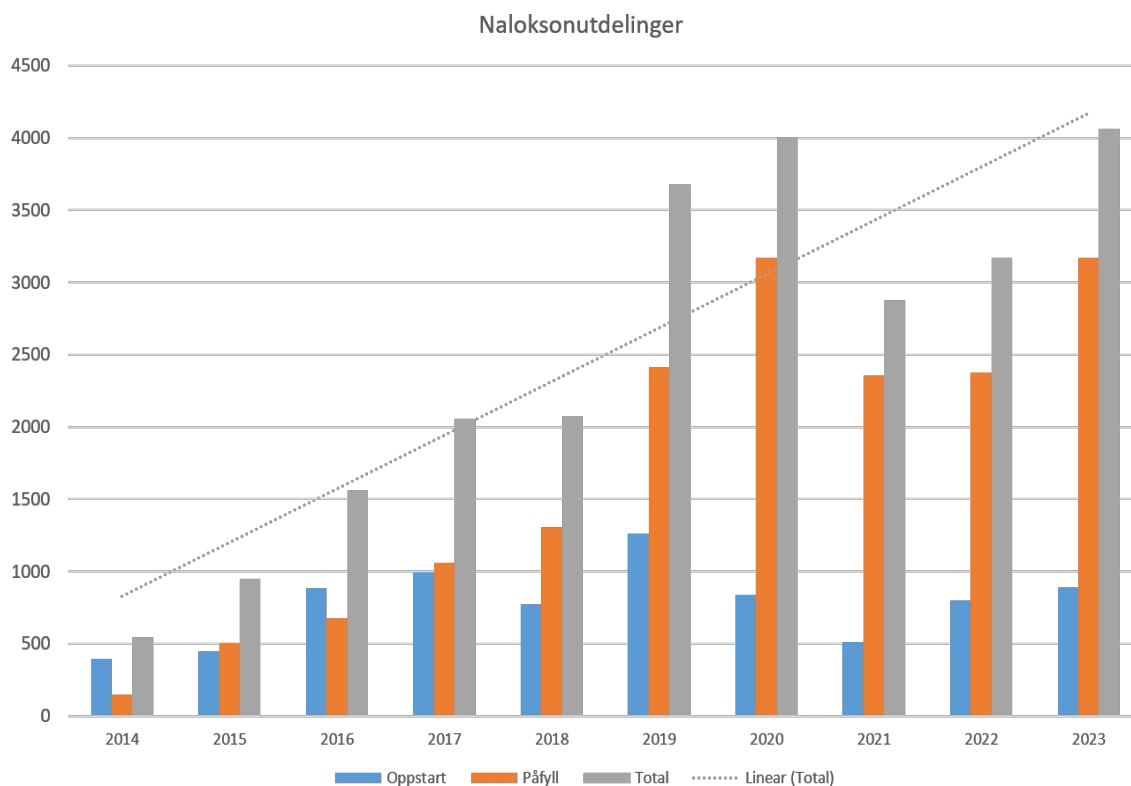




demands for social distancing etc. (McDonald et al. 2022).



**Figure 6.** Annual naloxone distribution 2014 to 2023.



Throughout much of the Covid19 pandemic (2021/22), the number of registered sprays (i.e. registered in the database with consent) is significantly lower than the number ordered. This is due to prioritization of distribution over research activity while society was shut down. At the same time, we have reason to assume that the proportion of people who needed spray in an overdose situation and reported this back was fairly stable during the pandemic. The proportion of spray used for overdose reversal was roughly the same before, during and after the pandemic (see also **Table 2**).

From the start of the project in June 2014 until 2021, naloxone use was reported 1282 times (56% of refill sprays). In these incidents, a survival rate of 94% was also reported (Ericson, et al. 2022).



**Table 2:** Registered spray distributions in Norway from 2019 through November 2023 with proportion (%) used in overdose and outcome.

Year	Registered distributed	Used in OD (% distributed)	Survived (% used in OD)	Don't know / deficiencies	Dead*
2023	4301	1102 (26 %)	873 (79 %)	213 (19 %)	16
2022	3172	942 (30 %)	750 (80 %)	181 (19 %)	11
2021	2855	683 (24 %)	556 (81 %)	123 (18 %)	4
2020	4004	1011 (25 %)	877 (87 %)	126 (12 %)	8
2019	3680	934 (25 %)	826 (88 %)	98 (10 %)	10

\* registered deaths without causal relationship. Camera rescue was given regardless of time of death.

Previous studies conducted in the USA have found that at least 100 sprays per 100,000 inhabitants are needed to achieve an effect on overdose mortality (Walley et al. 2013). In our project, several municipalities achieve the same distribution rate: in Bergen, Oslo, Haugesund, Sandefjord, Stavanger and Tønsberg, more than 100 sprays per 100,000 inhabitants were distributed for many years.

In our ongoing research, we are investigating how high distribution rates affect OD mortality locally.

#### 4.3. Ongoing research

Although the national overdose death figures are relatively stable, accidental overdose deaths involving heroin appear to show a downward trend in recent years. At the time of writing, a study is being conducted on accidental overdoses caused by heroin, focusing on geographical areas with high naloxone distribution rates. Figure 7 shows the downward trend of unintentional heroin overdoses in Vestland and Oslo county for the years following naloxone implementation.

The following research questions are also investigated:

- Evaluation of knowledge increase and degree of initiation of distribution among employees who complete e-courses (submitted for peer review).
- Descriptive analysis of the first seven years of distribution of naloxone kits in Norway, with investigation of "empowerment" as a motivational factor (manuscript

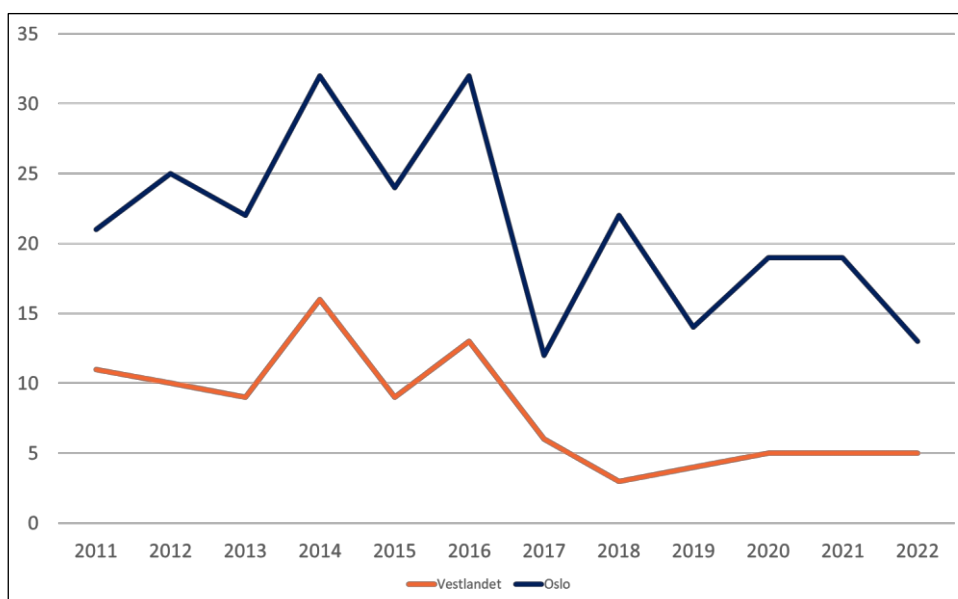


to be prepared).



- Survey of participants and deaths between 2015 and 2022 as reported in the cause of death register (submitted for peer review).
- Interrupted-time-series (ITS) analysis to measure the effect of naloxone distribution on overdose management through eight years (cf. **Figure 7**) (manuscript is being prepared).

**Figure 7:** Heroin overdoses (number) in Oslo and Western Norway before and after naloxone implementation in 2014/15.



#### 4.4. *Research conducted*

Since 2014, SERAF has published several research articles based on a number of elements of the naloxone project. These include a survey of participants who return to collect new naloxone kits, with a particular focus on those who return frequently and those who actually use their knowledge for overdose management. **Table 3** shows this and other publications and their main findings.

**Table 3:** SERAF publications from the naloxone project.

Publication	Conclusions
McDonald R, Eide D, et al. <b>A rapid assessment of take-home naloxone provision during COVID-19 in Europe.</b> <i>Int J Drug Policy.</i> 2022 Sep;107:103787. doi: 10.1016/j.drugpo.2022.103787. Epub 2022 Jul 1; PMID: 35849935; PMCID: PMC9247228.	Through programme innovation supported by public guidelines, many European THN programs managed to ensure stable or even increased THN provision during the pandemic, despite social distancing and stay-at-home orders affecting client mobility.
Eide, D., Lobmaier, P. & Clausen, T. <b>Who is using take-home naloxone? An examination of supersavers.</b> <i>Harm Reduct J</i> 19, 65 (2022). <a href="https://doi.org/10.1186/s12954-022-00647-z">https://doi.org/10.1186/s12954-022-00647-z</a>	THN programs should continue to emphasize and prioritize THN for people actively using drugs, particularly those who have witnessed overdoses previously.
Ericson, Ø.B., Eide, D., Lobmaier, P. <i>et al.</i> <b>Staff preferences towards electronic data collection from a national take-home naloxone program: a cross-sectional study.</b> <i>Subst Abuse Treat Prev Policy</i> 17, 13 (2022). <a href="https://doi.org/10.1186/s13011-022-00440-y">https://doi.org/10.1186/s13011-022-00440-y</a>	The shift towards electronic data collection was necessary for the feasibility of the Norwegian national THN program. This study found that staff not only tolerated the shift, but in most cases preferred this organizational change.
Ericson ØB, Eide D, Lobmaier P, Clausen T. Risks and overdose responses: <b>Participant characteristics from the first seven years of a national take-home naloxone program.</b> <i>Drug Alcohol Depend.</i> 2022 Nov 1;240:109645. doi: 10.1016/j.drugalcdep.2022.109645. Epub 2022 Sep 27. PMID: 36191532.	People who use drugs are a suitable target group for THN programs, as they seem to be willing and capable to reverse overdoses effectively. Given their personal risk factors for overdosing, recipients will likely also benefit from overdose prevention education.
McDonald R, Parkin S, Eide D, Neale J, Clausen T, Metrebian N, Carter B, Strang J. <b>Rethinking 'carriage' of take-home naloxone.</b> <i>Int J Drug Policy.</i> 2021 Sep;95:103253. doi: 10.1016/j.drugpo.2021.103253. Epub 2021 Apr 11. PMID: 33848942.	We present an argument for the need to improve research methods in the case of THN "carriage" and propose a multidimensional measurement structure that takes into account.
Madah-Amiri D, Gjersing L, Clausen T. <b>Naloxone distribution and possession following a large-scale naloxone program.</b> <i>Addiction.</i> 2019 Jan;114(1):92-100. doi: 10.1111/add.14425. Epub 2018 Sep 14. PMID: 30129078; PMCID: PMC6585734.	A large-scale naloxone program in seven Norwegian cities with a cumulative distribution rate of 495 per 100 000 population indicated good saturation in a sample of high-risk individuals, with program duration in each city as an important indicator for naloxone possession and use.
Petterson AG, Madah-Amiri D. <b>Overdose prevention training with naloxone distribution in a prison in Oslo, Norway: a preliminary study.</b> <i>Harm Reduct J.</i> 2017 Nov 21;14(1):74. doi: 10.1186/s12954-017-0200-z. PMID: 29162122; PMCID: PMC5696738.	Given the high risk of overdose that prison inmates face upon release, the need for prevention programs is critical. Naloxone training in the prison setting may be an effective means of improving opioid overdose response knowledge for this particularly vulnerable group. Naloxone training provided in the prison setting may improve the ability of inmates to recognize and manage opioid overdoses after their release; however, further studies on a larger scale are needed.



<p>Madah-Amiri D, Clausen T, Lobmaier P. <b>Rapid widespread distribution of intranasal naloxone for overdose prevention.</b> <i>Drug Alcohol Depend.</i> 2017 Apr 1;173:17-23. doi: 10.1016/j.drugalcdep.2016.12.013. Epub 2017 Jan 28. PMID: 28182982.</p>	<p>A government-supported multisite naloxone initiative appears to achieve rapid, high volume distribution of naloxone to an at-risk population</p>
<p>Madah-Amiri D, Clausen T. <b>The use of public health infrastructure probably the best strategy for national and large-scale naloxone distribution programs.</b> <i>Addiction.</i> 2016 Jul;111(7):1309-10. doi: 10.1111/add.13400. Epub 2016 May 3. PMID: 27145487.</p>	<p>Large-scale THN appear to be effective in reducing OD, but require significant support from policies, trained staff and the local community. The expansion of THN to reach varied at-risk target groups is important, specifically following prison release and hospitalization. We encourage policymakers and public health professionals to initiate THN programs towards all groups likely to benefit, and encourage an acceptable and affordable naloxone device available at as many relevant settings as possible.</p>
<p>Madah-Amiri D, Clausen T, Lobmaier P. <b>Utilizing a train-the-trainer model for multi-site naloxone distribution programs.</b> <i>Drug Alcohol Depend.</i> 2016 Jun 1;163:153-6. doi: 10.1016/j.drugalcdep.2016.04.007. Epub 2016 Apr 14. PMID: 27107847.</p>	<p>Large-scale naloxone distribution programs are likely to continue growing, and will require competent trainers to carry out training sessions. The train-the-trainer model appears to be effective in efficiently training a high volume of trainers, improving trainers' knowledge and intentions to distribute naloxone. Further research is needed to assess the long term effects of the training session, staffs' subsequent involvement following the trainer session, and knowledge transferred to the clients.</p>
<p>Lobmaier, P. P., and Clausen, T. (2016) <b>Radical red tape reduction by government supported nasal naloxone: the Norwegian pilot project is innovative, safe and an important contribution to further development and dissemination of take-home naloxone.</b> <i>Addiction</i>, 111: 586-587. doi: <a href="https://doi.org/10.1111/add.13261">10.1111/add.13261</a>.</p>	<p>We argue that the nasal naloxone formulations already used in a range of settings have distinct advantages, making them favorable alternatives rather than the second-best option, because they reach new users. Ongoing distribution of nasal naloxone saves lives as development takes place. Current nasal naloxone sprays are imperfect, but widespread availability of acceptable naloxone on overdose scenes trump formalities, as clinical evidence is well established.</p>



## 5. Goal achievement

### *Risk reduction as a tool to save comrades*

Overall, we hit both of the project's main objectives with our distribution to active users: The group exposed to OD risk is reached through the talks, in line with harm reduction principle. The training increases knowledge of risk to the user, such as *do not use alone, do not inject - but inhale, do not mix different types of drugs, rather share the dose if in doubt*. In addition, the target group is among those who recognize overdoses in others most often, i.e. they are well suited to practicing buddy rescue with naloxone nasal spray. Many people return to a distribution point for new supplies after they have used nasal spray in an overdose situation.

### *Distribution throughout Norway*

The project started in 2014 as a trial in two large cities, with a drug that was not yet marketed. In subsequent years, we have established effective distribution of naloxone and training in overdose prevention by collaborating with existing low-threshold initiatives. It has turned out that there is a constant need for refreshing and restarting the project in municipalities, individual distribution points, prisons, etc. Naloxone distribution is dependent on anchoring in the municipalities and with key people. The coordinators play an important role in maintaining this connection or re-establishing cooperation if things go wrong. To ensure efficient distribution, we have entered into agreements with selected pharmacies that have taken on the task of distributing medicines for us. In 2018, nasal spray also became available in the joint catalog, while project spray still accounts for the majority of distribution, at no cost to the municipality or end user. We now have the opportunity for training and distribution throughout the country. In Bergen, the project has been moved internally to Haukeland Hospital Pharmacy, which means that it is now possible to operate as usual: the person who normally orders medicines for their own department is approved to order naloxone in the pharmacy's ordering system "TønSys". Naloxone is sent from the pharmacy for distribution locally, without an individual prescription. Doctor Lobmaier, who is responsible for the project, in collaboration with the coordinators, reviews the list of orderers once a year and project drugs are invoiced directly to SERAF, as before.

### *E-courses have streamlined training*

As planned, the scope of the project was significantly expanded from Oslo and Bergen to the whole of Norway. We have therefore developed electronic training in overdose prevention and electronic registration of distribution data. This has made the expansion more efficient





and in practice ensured that the project could continue during the pandemic. Classroom training is less in demand and the project coordinators can therefore better focus on expansion to new, more remote areas.



locations. In addition, we can offer complex organizations such as the police and large healthcare companies a more efficient and agile way to train their employees after project participation has been decided.

*Summer campaigns, focus week and commemoration of Overdose Day on August 31* Summer campaigns have been conducted throughout the country for several years, with the aim of maintaining good project operations during the summer months when there are more overdoses, while a number of services have more limited services due to vacation. In addition, two annual focus weeks are held in Oslo and one in Bergen with an extra focus on camera rescue. The camera rescue project has also been a key supporter of the annual commemoration of overdose victims on August 31, which takes place in many of the country's cities and has become a regular meeting point, usually with good media coverage.

#### *Scientific production, knowledge dissemination*

The project has a relatively large amount of data, but there are also challenges related to a lack of routines for regular participant follow-up and relatively general questions that are not very detail-oriented. This approach has been carefully chosen to save both time and resources. Regular follow-up points in this target group usually result in a high dropout rate (>50%), while it is also demanding to work in participants for planned follow-up.

Despite the challenges in the data set, we have been able to facilitate the production of four master's theses, one approved doctoral thesis and one in progress (planned to be submitted by the end of 2023). Two medical students have written project assignments using data from the camera rescue. A number of scientific articles have been published, and at the request of the Norwegian Directorate of Health, all have been made available as "open access". The articles cover several different aspects, including the implementation of the project, the training method, distribution and participant characteristics, as well as an article on non-fatal overdoses (see Table 3).

We have conducted three international conferences in Norway (ThINC - The International Naloxone Conference) in 2015, 2017 and the last one in August 2023 with expert participation from Norway, Sweden, Scotland, England, Australia and the USA.

Through the network created by the overdose strategy, SERAF was also directly involved in the production of an information film about harm-reducing use of heroin: Switch - from injecting to smoking. The film is available on Korus Oslo's website here:

<https://korus.no/v%C3%A5re-fagomr%C3%A5der/switch-tryggere-rusmiddelbruk>



## 6. The way forward

*How has the Naloxone project affected overdoses?*

The central question for the peer review concerns the extent to which the project has had an effect on the number of overdose deaths. The evaluation should therefore be seen in the light of the annual report from the NIPH on the deaths, while the reported overdose victims are not necessarily linked to project participants. So far, there has been no decline in absolute numbers at the national level. Nevertheless, the picture is changing, with a shift from heroin-related deaths to more deaths related to the use of strong painkillers (Gjersing 2023). It is gratifying to observe that the incidence of heroin-related deaths has fallen, because this reduction was the main objective of the national overdose strategy when it started in 2014 and was extended in 2019. However, it is difficult to say with certainty whether this change can be attributed to the buddy rescue, even with data from the cause of death register. Moreover, the analyses will require a sufficiently long observation period. We are currently analyzing register linkage of our participants with the Cause of Death Registry for the period 2015 to 2022. It has been decided to discontinue the collection of social security numbers from January 2024 to simplify spray registration and thereby increase registration in the evaluation project again.

Reports of approximately 80% successful management of overdose with nasal spray are, in our opinion, sufficient evidence that many people who inject drugs have good experiences with companion rescue. This is valuable in itself, as through the project we clearly communicate that everyone can make a difference, especially as we find reports of high prevalence of both self and witnessed overdoses. Naloxone provides a unique opportunity to convey a harm reduction message and provides a clear call for better care of others and oneself. However, attitudinal change takes time, and effects on both indirect and direct outcomes are difficult to measure. It is not a given that attitude-changing work is measurable already, after barely ten years. The subsequent years are therefore important for evaluating whether the project has contributed to an improvement in the form of a stable reduction in the number of heroin-related deaths.

*What are the experiences of those who have participated in the buddy rescue?*

A database has been established based on the cohort of everyone participating in the study. We have several thousand questionnaires that are analyzed to understand the use of nasal sprays. Overall, we see that more than half of the medication dispensed is reported back, and



that they are mostly used



against overdose. It is likely that several sprays have been used but not reported back. We have not set up fixed times for follow-up for reasons of resource use.

### *Transition from project to operation*

The "camera rescue with naloxone" project was organized as part of the national strategy for reducing overdose deaths in both periods: first 2014 to 2017 and then 2019 to 2022 (see **Figure 8**). For SERAF, the main focus was research on the implementation and impact of the intervention, based on digital participant observation, as a field study. The data collected so far confirmed regular distribution from multiple locations and that the goal of reaching high-risk groups has been met to a large extent. For the future, a strategy for a transition from project to regular operation will be laid out, which should be further evaluated also after such transition to municipal operation. Our TSD database will operate with approval until 2030 and there is little reason to stop data collection before that time. It is currently unclear whether there will be a third period of national strategy to reduce overdose deaths. If there is a new strategy, or a new package of measures, it is natural that buddy rescue will continue to be part of it. There is little doubt that there is a need for long-term efforts to reduce overdose deaths, and the continued high death rates confirm this. It should be considered as part of a further overdose strategy that the naloxone project is converted from a centrally managed project to ordinary operations in all municipalities, with, for example, a coordinating function assigned to the regional KORUS, but for a period with the continued possibility of registering data for evaluation, as SERAF has experience with. In an assumed new strategy period from 2024 onwards, consideration should be given to including more target groups for overdose deaths, including groups who die from overdoses from painkillers. This will require a separate distribution strategy and data collection with strategies and language adapted to this target group.

A transition phase will probably be needed for the camera rescue as a regular operation to ensure continued distribution of free spray to distribution points. Bolk prescribing as a regular operation seems to have been resolved at the hospital pharmacy in Bergen with the ordering module "TønSys", which allows for distribution in the same way as other medicines. It remains to be seen whether the pharmacies in Stavanger, Trondheim and Oslo can use the same system, and whether it can be implemented elsewhere. In the project, there is no requirement for a personal prescription and this has facilitated easy access to the spray. This seems to have been a prerequisite for the fairly rapid and extensive distribution that has been developed in Norway during the project periods.



### *New target groups*

In light of the recent increase in the number of deaths caused by prescribed opioids, which also partly affects other groups of opioid users, the naloxone project should be adapted to even better reach both the current target group and new target groups of opioid users. Naloxone distribution without a prescription via pharmacies, GPs, pain clinics and ambulance services are possible and relevant points for overdose prevention interventions. Reaching out to new groups requires a tailored approach targeting both professional helpers and new groups of peer and family rescuers. The process of implementing and reaching out to new groups should be supplemented with a research evaluation to ensure quality assurance and knowledge related to naloxone use among groups with different conditions and characteristics than what has characterized the project so far.

### *Planned research*

- ♠ Register link between the Cause of Death Registry (DÅR) and the cohort with substance abuse experience who provided a social security number (article submitted).

In the long term, a register link with FD trygd and NorPD. This will be done in connection with continued evaluation of NOK delivery to the relevant target group, and possibly new ones.

- ♠ Idea 1: What role does the delivery of naloxone kits play in the release from Norwegian prisons?
- ♠ Idea 2: In order to maintain a public health perspective, which best examines morbidity in connection with repeated overdoses, one can apply for renewed consent for linkage to NPR.



**Figure 8:** Milestones and perspective to 2026

**Strategy I: 2014 to 2018**

- Successful start-up phase with implementation using a pilot municipal network, and establishment of a basis for evaluation
- Coordinator positions based at Oslo Municipality, the Health and OD team in Trondheim and in Bergen at Straxhuset (now MO Gyldenpris)
- The main target group was reached: people who inject opioids
- Infofilm produced, 2 international conferences
- First PhD completed (Desiree Eide, born Madah-Amiri)
- transition from temporary to marketed spray in collaboration with hospital pharmacies
- electronic data collection with online forms

**Strategy II: 2019 to 2023**

- preparations for digitalization, e-health, website
- implementation of digital training and data collection in 2020
- Coordinator position in Oslo added to KORUS
- new PhD candidate (Ø. B. Ericson) with first paper accepted '22, two others submitted
- additional funding to reach new target groups (2022 and 2023)
- The third ThINC conference was held in Oslo 31.8. / 1.9.2023

**Opportunities 2024 to 2026**

- continued focus on the target group of injecting drug users
- SERAF implements planned register links to FD Trygd and the prescription register (NorPD)
- preparing transfer of naloxone distribution project to - coordination via KORUS in regions / MO centers
- contributes to strategies/measures aimed at reducing overdoses among users of strong painkillers
- SERAF evaluates new initiatives in new strategy period



## 7. SERAF's priorities and recommendations

After almost ten years of the Naloxone project as part of the national overdose strategy, SERAF's involvement in naloxone distribution in a large number of municipalities and an increasing number of target groups has been consolidated and is constantly evolving. Distribution on release from prison, among LAR patients and to the police is underway, but still needs time to be established on a sufficient scale.

Today, at the end of 2023, which is the last year of the second strategy period, SERAF sees a need for at least one more new strategy period, so that we can ensure good establishment of initiated activities and to prepare for the transition of the naloxone distribution project to ordinary operations under the auspices of the municipalities.

Our ambition is that during a new strategy period, in collaboration with the municipalities and KORUS, we will ensure a planned transition to naloxone distribution as an ordinary municipal overdose prevention activity. This requires time and resources to plan coordination and time to implement, so that the success of the established work can be retained and continued.

There are several potential challenges associated with such a transfer to normal operations, which should be handled through good preparatory work. As an example, distribution without the need for an individual prescription is now in normal operation at Haukeland Hospital Pharmacy. We have switched to using the "TønSys" interface for distribution of sprays, controlled by the coordinator, project doctor and pharmacist. At the same time, this system ensures batch distribution without the need for individual prescriptions, which is considered an important success factor in the work that has been going on since 2014. At best, "TønSys" can be used in the rest of the country, and this needs further preparatory work.

In further overdose prevention work, SERAF sees a need for continued investment in prevention work and measures aimed at the group that injects opioids. In addition, SERAF sees a need to focus prevention efforts on opioid users where strong painkillers dominate. Both those outside OMT and OMT patients who have increasing access because opioids other than methadone and buprenorphine are now made more readily available in OMT, in line with the new guideline.

In addition to this, it is also a priority task to highlight overdose deaths among women in particular, which to some extent have different characteristics/patterns than overdoses among men. Overdoses among aging substance abuse patients / OMT patients are a "forecasted





future challenge" and this should also increasingly be a focus of further overdose prevention work, in the same way as overdoses among the very youngest can be an important focus area.



In a new strategy period where there are plans for more specified subgroups to be specifically considered for targeted prevention measures, SERAF sees a clear need for accompanying evaluation of new initiatives, to clarify and evaluate the benefits of new measures. SERAF has considerable experience and expertise in such evaluations. SERAF would like to have a clear role in such evaluations also in the future.

SERAF will contribute both in the development of new overdose prevention strategies and proposals for prioritized initiatives, as well as contribute with research and evaluation to build a stronger knowledge base related to the benefits of new targeted measures that will be part of new strategy periods.

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