Take home naloxone programmes in the EU and Norway

Snapshot 2017

Study carried out on behalf of the EMCDDA

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Summary

People who overdose on opioids generally receive naloxone, a life-saving overdose reversal drug. This treatment has been used by emergency medicine in ambulance as well as hospital settings since the 1970s to reverse the respiratory depression caused by the overdosed opioid. In 1998 the first European take-home naloxone project was initiated in Berlin/ Germany, making the antidote available in places where overdoses are likely to occur. This harm reduction intervention combines a provision of the emergency supply of naloxone to those people who are likely to witness an opioid overdose and have a specific training in overdose emergency, aftercare management as well as instructions about its administration. Since then various THN programmes/ projects were implemented in the EU and Norway with a current increase of new and recently planned initiatives.

The following report gives an overview of the characteristics of the current state of available THN programmes/ projects in the EU and Norway in 2016/2017. It aims at updating and specifying the THN projects presented in the EMCDDA Insights 20 (Strang & McDonald 2016). It specifically focuses on the description of details on the legal/ regulatory aspects and input and how to tackle them, regarding the modes of THN initiatives as well as their performance and cost needs. A collection of links to training material and of some recent scientific papers is also available.

To collect the information presented in this report, a specific template has been developed in cooperation with the EMCDDA. The template contains overall questions on the THN projects and specifies on existing challenges of its implementation: type of medication and application, legal status. Further it includes questions on training components, naloxone distribution, re-fill procedures as well as on the performance and estimated resources. The templates were pre-filled with available information for each THN initiative and sent out to the national experts identified through the EMCDDA Head of Focal Points. In total 16 templates from ten EU countries have been returned.

Chapter 2 gives a historical overview of the THN programme development and update core data from current programmes in the EU and Norway. It further presents ten country profiles, including background materials and links to project reports and training materials. THN programmes/ projects are currently available in Denmark, Estonia, France, Germany (5 Projects), Ireland, Italy, Lithuania, Norway, Spain/ Catalonia, the UK, UK/ Scotland and UK/ Wales. The geographical spread varies from national to regional up to local initiatives, ranging from a total of less than 100 THN-kits distributed up to nearly 30.000 THN-kits.

Chapter 3 gives an overview of the main aspects of THN programme designs, describing types of medication and application and distribution and re-fill procedures. Aspects of the contextual framework and cooperation with partners and costs and funding are outlined. At present the majority of THN initiatives provide injectable naloxone products, some by providing or recommending an off-licence application tool. Currently only France and Denmark dispense a licenced nasal spray. It is expected that the ongoing process of introducing nasal formulation of naloxone in the EU might change this currently predominant application form. Most of the THN

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initiatives are targeting at and training current or former drug users in drug services, with an emphasis on the low threshold setting. Six THN projects are based in prison or upon release from prison. Peer involvement is an essential part in the majority of the initiatives; apart from recruitment they are involved in programme development as well as in trainings.

This **Chapter 3** focuses on the description of THN programme approaches to deal with specific legal and regulatory challenges. Practice has shown that the major challenges to THN programmes/ project rise from legal/ regulatory aspects, due to the fact that naloxone is a prescription only medication (POM) in most of the countries. The report outlines concepts and strategies to tackle these challenges with regard to the prescription of naloxone to non-medically qualified third parties, the distribution of naloxone to third parties and its administration by a not medically qualified person/ layperson in case of a drug emergency.

Chapter 5 summarises the main aspects regarding THN trainings, which generally are a relevant component of THN initiatives. In seven interventions the THN training is part of a general overdose-management training. THN trainings generally often involve physicians or nurses/paramedics as trainers. Apart from drug users, family/partners/close friends are a target group often addressed at THN trainings, followed by outreach workers and staff members at drug agencies.

Chapter 6 refers to a possible framework for monitoring THN programmes/ projects.

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List of Abbreviations

ANSM Agence Nationale de Sécurité du Médicament

ATU Authorization for Temporary Use

BMJ British Medical Journal

CHMP The Committee for Medicinal Products for Human Use

CPR Cardiopulmonary Resuscitation

DKK Danish Crowns
DRD drug-related deaths

e.g. for example

EMA European Medicine Agency

EMCDDA European Monitoring Centre for Drugs and Drug Addiction

et al. and others
EU European Union

FDA Food and Drug Administration

GÖG Gesundheit Österreich GmbH [Health Austria]

h/y hours per year HFP Head of Focal Point

HSE Health Service Executive (Ireland)
HTA Health Technology Assessment
MAA Marketing Authorisation Application

N/A no answer

N-ALIVE trial NALoxone InVEstigation

NGO non-governmental organisation
NIHD National Institute for Health (Estonia)
NSP needle and syringe programme

NTA National Treatment Agency for Substance Misuse, UK

ÖBIG Österreichisches Bundesinstitut für Gesundheitswesen [Austrian Health Institute]

OD overdose

OST opioid substitution treatment
PGD patient group direction
POM prescription only medication
PSD patient specific direction
PWID people who inject drugs

REITOX REITOX European Information Network on Drugs and Drug Addiction (Réseau

Européen d'Information sur les Drogues et les Toxicomanies)

SDF Scottish Drug Forum

SNNP Scottish National Naloxone Programme

SOP standard operating procedure

THN take home naloxone UK United Kingdom

WHO World Health Organization

WG Welsh Government

XADC Catalan Drug Abuse Care Centres Network

Country Codes:

Member States of the European Union (EU) and other countries have been assigned a two-letter country code, always written in capital letters, and often used as an abbreviation in statistical analyses, tables, figures or maps.

European Unio	n (EU)			
Belgium	(BE)	Greece (EL)	Lithuania (LT)	Portugal (PT)
Bulgaria	(BG)	Spain (ES)	Luxembourg (LU)	Romania (RO)
Czech Republio	(CZ)	France (FR)	Hungary (HU)	Slovenia (SI)
Denmark	(DK)	Croatia (HR)	Malta (MT)	Slovakia (SK)
Germany	(DE)	Italy (IT)	Netherlands (NL)	Finland (FI)
Estonia	(EE)	Cyprus (CY)	Austria (AT)	Sweden (SE)
Ireland	(IE)	Latvia (LV)	Poland (PL)	United Kingdom (UK)

European Free Trade Association (EFTA)

Iceland (IS) Norway (NO) Liechtenstein (LI) Switzerland (CH)



1 Introduction

Naloxone is a life-saving overdose reversal drug that rapidly counteracts the effects of opioids. It has been used in emergency medicine in hospitals and by ambulance personnel since the 1970s to reverse the respiratory depression caused by opioid overdose. Take-home naloxone (THN) programmes are a harm reduction measure that aim preventing opioid-overdose deaths by making the antidote available in places where overdoses are likely to occur. In case of an opioid overdose, naloxone is readily available and can be administered to the overdose victim before the arrival of the ambulance. THN programmes combine the provision of an emergency supply of naloxone to current and former drug users and other people who are likely to witness opioid overdoses and have specific training in overdose prevention, emergency management and instructions about its administration (Strang & McDonald 2016, p.5ff).

Currently THN programmes/ projects exist in ten of the countries monitored by the EMCDDA and policy planners and service providers in other European countries are considering their introduction. This may be accelerated by the introduction of a nasal formulation of the medication in Europe and by changes in the drug situation, indicating increasing opioid overdose risks.

The current report aims at supporting policy and service levels in Europe through presenting information and practical guidance from experts setting up and running such programmes. It provides information on a) models of legal and operational frameworks of take-home naloxone programmes relevant to policy makers, and b) guidance for service providers about different models of take-home naloxone programmes including how to set them up, carry out training, and how to implement and monitor such projects/ programmes.

To systematically collect and update information on all THN projects in the EU and Norway a specific template (see Appendix) was developed and discussed with several experts within the REITOX network and was presented at the Head of Focal Point (HFP) meeting in May 2017. The templates were pre-filled with available information about each THN programme/ project and sent out to national experts identified through EMCDDA HFPs. In total 16 templates from ten EU countries have been returned, but not all of them where fully completed.¹

The following report gives a systematic overview of the characteristics of available take-home naloxone (THN) programmes in Europe and Norway, including a collection of training models and curricula. The focus lies on THN programmes/ projects underway in Europe in 2016 and in the first quarter of 2017 and can be seen as an update to chapter 4 of the EMCDDA Insights 20 (Strang & McDonald 2016).

Thanks to all responding national experts and to the REITOX Focal Points who contributed to the data collection as well as to this report.

Introduction

Missing information from the templates is indicated with N/A in the tables of this report.

2 European Overview

Chapter 2 gives a historical overview of take-home naloxone (THN) programme development (Ch. 2.1) and updates core data from current programmes in the EU and Norway (Ch. 2.2). It further presents ten country profiles, including background materials and links to project reports and training materials (Ch. 2.3).

2.1 Historical Development

The following table presents an overview of the historical development and spread of THN provision generally and specifically focussed on the European countries in regard to recent developments. Table 1 is an update of Table 4.1 in the EMCDDA Insights 20 on *Preventing opioid overdose deaths with take-home naloxone* (Strang & McDonald, 2016).

Table 1: Implementation timeline of take-home naloxone (THN)

Year	Event
1961	First patent is filed for naloxone
1971	United States: FDA licenses naloxone as prescription-only medication; naloxone enters clinical practice in Europa in subsequent years
1991	Italy: 1st experimental naloxone distribution intervention started
1992	Notion of THN is mooted at International Harm Reduction Conference (Strang, 1992)
1994	First reported use of intranasal naloxone for overdose reversal (Loimer et al., 1994)
1996	BMJ editorial states "Home based supplies of naloxone would save lives" (Strang et al., 1996) United States: Chicago Recovery Alliance distributes first THN kits Italy: Italy's Health Ministry officially classified naloxone as an over-the-counter medication and obliged pharmacies to carry it in sufficient supplies
1998	Channel Islands: Island of Jersey starts THN distribution Germany: Fixpunkt Berlin starts THN distribution
2001	Spain: Reports of underground THN distribution in Barcelona United States: New Mexico and San Francisco launch THN programmes First published report of THN distribution (Dettmer et al., 2001) United Kingdom: Introduction of first mainland THN scheme (south London)
2002	Chicago programme reports first lives saved in BMJ (Bigg, 2002)
2005	United States: intranasal naloxone is distributed as part of THN kits in Massachusetts United Kingdom: Legal status of naloxone changed to permit emergency administration of naloxone by any member of the general public (Schedule 7 of the Medicines Act)
2006	United Kingdom: National Treatment Agency for Substance Misuse (NTA) funds THN training initiative for users and carers in 16 pilot sites
2007	United Kingdom: Scotland and Wales establish THN pilots
2008	United Kingdom: Medical Research Council funds N-ALIVE trial Spain: Formal THN programme launched in Barcelona
2009	Wales: THN pilot project/trail in 4 community-based locations: Newport, Cardiff, Swansea, North Wales Ireland: HSE naloxone demonstration project started
2010	Denmark: THN pilot project starts

2011	United Kingdom: Scottish Lord Advocate issues new guidelines United Kingdom: Scotland and Wales launch national THN programmes Australia: First THN programme is introduced in Canberra
2012	Scotland: naloxone peer education initiative established and nasal pilot started in Highland Wales: first evaluation of national naloxone programme (Bennett and Holloway) UNODC Resolution 55/7 states "Opioid overdose treatment, including the provision of opioid receptor antagonists such as naloxone, is part of a comprehensive approach to services for drug users"
2013	Denmark: THN programme starts (intranasal) Estonia: THN distribution launched in Harju and East-Viru countries
2014	Norway: THN programme starts (intranasal) Germany: THN pilot programme in Frankfurt established (until 2015) WHO releases new guidelines, stating "People likely to witness an opioid overdose should have access to naloxone and be instructed in its administration" (WHO, 2014) EMCDDA hosts meeting "Take home naloxone to reduce fatalities: scaling up a participatory intervention across Europe"
2015	Ireland: THN demonstration project starts in Dublin, Waterford/South East, Limerick, Cork EMCDDA publishes systematic review, stating "There is evidence that educational and training interventions with provision of THN decreases overdose-related mortality" (EMCDDA, 2015) United Kingdom: Injecting naloxone can be supplied by drug treatment services without prescription to any individual needing access for saving a life in an emergency Estonia: THN programme starts in prison setting France: the Commission on narcotics and psychotropic substances voted in favour of the nasal route of administration for naloxone by drug users and third parties
2016	EMCDDA publishes Insights on Preventing opioid overdose deaths with take-home naloxone (Strang & McDonald, 2016) France: national THN cohort study (intranasal) Germany: THN programme in Cologne (treatment setting), North Rhine-Westphalia (low-threshold setting) and Munich starts Lithuania: THN programme is introduced in Vilnius
2017	France: French Regulatory Agency ANSM approves marketing authorisation for naloxone hydrochloride nasal spray for the emergency treatment of opioid overdose EU: Motion for a European Parliament resolution to follow the WHO recommendations and promote the reasonable availability of treatment such as naloxone September: Mundipharma receives CHMP positive opinion for Nyxoid® (intranasal naloxone spray) a final decision for pan-EU marketing authorisation is expected in Q4 2017

Source: Strang & McDonald, 2016, p.75; updated by GÖG/ÖBIG

2.2 Overview of existing THN Programmes/ Projects in the EU including Norway

In this report, THN interventions are split in two types: 'THN programmes' are defined as interventions implemented as regular service offer and on a continuous basis, whereas 'THN projects' are pilot studies or trials and have a limitation in time. In some cases, THN interventions started as a project or trial and turned into regular THN programmes in a second step. Currently 9 out of 16 reported THN interventions (see list in Table 2) in the EU and Norway are defined as regular programmes, 6 do have a project status and Italy is neither of both due to naloxone's legal status as an "over the counter" medication.

In general, THN programmes or projects are linked to a national or regional policy for prevention of drug-related deaths. Exceptions are the German projects as well as the one in Lithua-

Chapter 2 / European Overview

nia/Vilnius. The first THN interventions started in Berlin and in the Channel Island of Jersey in 1998. As Table 2 indicates, most of the current THN interventions were started during the past five years, including five very recent initiatives which began in the course of 2016.

Looking at the geographical spread of the reported THN intervention, a nearly balanced distribution between national, regional and local THN projects can be seen. Most of the THN interventions are city-based. A broad distribution throughout the country currently takes place in the UK, in Scotland and Wales. Italy, where naloxone is an over-the counter medication, it could potentially reach a broader target group.

Table 2 also indicates that there is a great variety among the THN interventions when it comes to size, indicated by the number of THN-kits distributed, as well as the number of people trained.

There is evidence on the effectiveness of naloxone distribution as part of THN programmes/ projects including overdose education as well as ongoing research in the form of pilot studies, e.g. in France on intranasal application of the medication. The evidence has been reviewed by the EMCDDA in 2015 (Minozzi. Amato & Davoli, 2015) and implementation issues been described in an EMCDDA *Insights* publication (Strang & McDonald 2016). WHO has issued recommendations (WHO 2014) focus on the evidence regarding two naloxone-related key questions: naloxone distribution and formulation and dose of naloxone. A list of further reading is enclosed in the Annex.

Table 2: Overview on existing THN programmes/ projects in the EU and Norway (status: June 2017)

Country	Geographical coverage	Geographic scope	Type of THN intervention	Starting year of intervention	Total number of THN-kits distributed since beginning	Number of THN- kits distributed in last 12 months	Total number of people trained since beginning	Number of people trained in last 12 months
France	national		pilot project/ trial	2016	600	600	900	900
Italy	national		Available in pharmacies without prescription	1991	N/A			
Norway	national	National strategy includes 13 cities, with at least one distribution site per city	pilot project/ trail	2014	4500	1770	2500	1000
UK	national		regular programme	2005/2015	N/A			
UK	national	Scotland	regular programme	2011	29309	8146	Training not mandatory	Training not mandatory
UK	national	Wales Started in 2009 as pilot project/ trail in 4 community-based locations: Newport, Cardiff, Swansea, North Wales; national in 2011	regular programme	2009	10552	3186	6154	2171
Estonia	regional	Harjumaa – Tallinn ; East-Virumaa – Jõhvi; Kohtla-Järve; Narva; Sillamäe ; Tartumaa – Tartu (prison only)	regular programme	2013	1764	433	1770	424
Germany	regional	Bavaria/ Munich	regular programme	2016	68	42	114	53
Germany	regional	North Rhine-Westphalia: Bochum, Wuppertal, Dortmund, Düsseldorf Aachen (planned for 2017)	regular programme	2016	80	80	80	80
Ireland	regional	Demonstration project: Dublin; Waterford/ South East; Limerick; Cork: Further expanded to: Tipperary, Galway, Kerry; National coverage is planned	pilot project/ trial	2015	1200	600	840	200
Germany	regional	Berlin	regular programme (since 2003) pilot project (1998 - 2002)	1998	N/A			
Spain	regional	Catalonia	regular programme	2009	3776	642	6516	875
Denmark	local	Copenhagen; Aarhus; Odense; Svendborg; Kolding; Esberj NGO based in Copenhagen but working all over the country	pilot project/ trial	2010	865	175	865	175
Germany	local	Frankfurt	pilot project/ trial	2014	60	N/A	60	N/A
Germany	local	Cologne	regular programme	2016	55	N/A	55	N/A
Lithuania	local	Vilnius	pilot project/ trial	2016	200	200	200	200

Source: GÖG/ÖBIG

2.3 Country profiles

2.3.1 Denmark

The Danish Naloxone project is based on a small pilot project in Copenhagen 2010 – 2012. The following project (2013 – 2015) was positively evaluated. Based on these results, the parties under the social reserve agreement decided in 2015 to set aside a total of DKK 8 million for the period 2016 – 2018 for training in the treatment of ODs using naloxone and the handout of naloxone to those who had been trained.

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Project reports, evaluations and scientific papers

Thiesen, Henrik et al. (2013): Forsøg med distribuering af Naloxon til stofafhængige til forebyggelse af opioid-overdosisdødsfald. Kopenhagen.

http://www.hjemlosesundhed.dk/?download=Overdosisrapport_2013.pdf (3.8.2017)

Thiesen, Henrik: *RED LIVE*. http://www.hjemlosesundhed.dk/?download=REDLIV_rapport-2016.pdf (3.8.2017)

Saelan, Henrik (2014): The Danish Naxolone Scheme.

http://www.emcdda.europa.eu/attachements.cfm/att_232498_EN_9.%20Henrik%20Saelan%2 0The%20Danish%20Naloxone%20Scheme.pdf (3.8.2017)

Training material

RED LIV: http://www.hjemlosesundhed.dk/?download=REDLIV_rapport-2016.pdf (for trainers and helpers, p118-146; 3.8.2017)

2.3.2 Estonia

In September 2013, the THN programme was launched in Estonia by the National Institute for Health Development (NIHD). The programme trains PWID and potential bystanders in recognising an overdose and administer naloxone to the person who have overdosed, as well as in overdose management and CPR until the arrival of the ambulance.

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Project reports, evaluations and scientific papers

Abel-Ollo K.; Kurbatova A.; (2014): *Take home naloxone pilot program in Estonia*. http://www.emcdda.europa.eu/attachements.cfm/att_233175_EN_Katri%20Abel%20Ollo_Take%20home%20naloxone%20pilot%20programme%20in%20Estonia.pdf (3.8.2017)

Männisalu A; Nikitina N; Võrno T; Reile R; (2015): Naloksooniprogramm üledoosidest põhjustatud surmade ennetamiseks. Tartu.

2.3.3 France

The THN intervention in France was established as a cohort study on intranasal administration of naloxone. In 2016 naloxone for nasal use was granted a cohort temporary authorisation for use (ATU). The project aims at making nasal naloxone available to people at risk of an opioid overdose as well as getting market authorization for the product approved. Only physicians practising in a treatment centre for addiction, in emergencies departments or in medical units in prisons may include patients in the cohort ATU. The pilot study aims at the evaluation of effectiveness of intranasal naloxone and results may also provide some quantification of the impact. In July 2017 the ANSM approved of marketing authorisation for naloxone nasal spray in France (Nalscue®).

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Project reports, evaluations and scientific papers

http://ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/ATU-de-cohorte-en-cours/Liste-des-ATU-de-cohorte-en-cours/NALSCUE-0-9-mg-0-1ml-solution-pour-pulverisation-nasale-en-recipient-unidose (3.8.2017)

 $\frac{http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Spray-nasal-de-naloxone-Nalscue-actualisation-du-point-d-information-de-decembre-2016-Point-d-information}{$

Training material

Protocole d'utilisation therapeutique et de recueil d'informations:

http://ansm.sante.fr/var/ansm_site/storage/original/application/2b98cf8dc3a0f7c4f815c1 dd8c5f56a1.pdf (engl. Protocol for therapeutic use and information; 3.8.2017)

2.3.4 Germany

The first THN programmes started at city level in Berlin in 1998. Frankfurt initiated a 2 year THN pilot-project in 2014, which did not get further funding in 2016. This programme is planned to start again in 2017. In 2016 a small-scale THN programme in Cologne was launched in treatment setting and in addition with a low-threshold focus in selected cities in North Rhine-Westphalia. In the same year an initiative in Munich/ Bavaria started with a THN programme. Bavaria is planning to implement a bigger model project by the end of 2017, which at least should include Munich as well as Nuremberg. In Berlin a concept for a research and pilot project on the issuing of naloxone prior to prison release has been developed. This project has not yet been established. All of the German projects are run independently and are mostly implemented in the low-threshold setting.

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Project reports, evaluations and scientific papers

Case report THN programme Munich: www.condrobs.de/kontaktladen-limit (3.8.2017)

Fixpunkt e.V. First aid course and use of Naloxone by drug users.

http://www.emcdda.europa.eu/attachements.cfm/att_232496_EN_6.%20Kerstin%20Dettmer %20DE%20First%20aid%20courses%20and%20use%20of%20Naloxone.pdf (3.8.2017)

Dettmer, K.; Knorr, B. (2016): Drogennotfalltraining und Naloxonvergabe vor der Haftentlassung. Eine modellhafte Intervention. Deutsche AIDS-Hilfe e.V., Berlin

Training material

akzept e.V. Leben Retten mit Naloxon; http://www.akzept.org/uploads2013/NaloxonBroschuere1605.pdf (3.8.2017)

Jesse, Marco. NALOXON. Ein Leitfaden zur Naloxonvergabe an Opiatkonsument*innen im Rahmen niedrigschwelliger Drogenarbeit. akzept e.V.;

http://www.akzept.org/uploads1516/NaloxonJESnrw17.pdf (3.8.2017)

2.3.6 Ireland

The HSE Naloxone Demonstration Project is both a response to the WHO recommendations and also to Action 40 of the National Drugs Strategy (2009–2016) aimed at tackling the harm caused by the misuse of drugs. This was also a key action of the 2015 HSE Primary Care, Social Inclusion operational plan.

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addiction/naloxone/

web: www.drugs.ie/resources/naloxone/

Project reports, evaluations and scientific papers

Clarke, Ann; Eustace, Anne (2016): *Evaluation of the HSE naloxone demonstration project*. Dublin: Health Service Executive; http://www.drugsandalcohol.ie/26037/ (3.8.2017)

Klimas, J. et al. (2016): *Primary Care – A key route for distribution of naloxone in the community.* International Journal of Drug Policy 38: 1–3; http://www.ijdp.org/article/S0955–3959(16)30303–6/fulltext (3.8.2017)

Training material

http://www.drugs.ie/resources/naloxone/ (3.8.2017)

2.3.6 Italy

Naloxone in Italy is an over-the counter drug since 1996, which means it is sold in pharmacies without needing a medical prescription (SOP). This guarantees its accessibility for any citizen. In 1991 an experimental naloxone distribution started at local level. At present 57 harm reduction

services nationwide distribute naloxone to drug users. There are some regions with no THN intervention due to the lack of a harm reduction service.

Contact N/A

Project reports, evaluations and scientific papers

Beccaria, Franca et al. (2016): *Preventing opioid overdose deaths. A research on the Italian naloxone distribution model.* Forum droghe.

http://idpc.net/publications/2017/02/preventing-opioid-overdose-deaths-research-on-the-italian-naloxone-distribution-model (3.8.2017)

Fitzgerald, Caitlin (2017): *The Success of Italy's Community–Based Approach to Naloxone*. In Talking Drugs http://www.eatg.org/news/the-success-of-italys-community-based-approach-to-naloxone/ (3.8.2017)

Ministry of Health (2000): Linee guida sulla riduzione del danno. Genova:

http://www.emcdda.europa.eu/attachements.cfm/att_231450_EN_IT01_Harm%20Reduction %20Guidelines.pdf (3.8.2017)

Open Society Foundations: Learning from Italy's Lead on Naloxone.

https://www.opensocietyfoundations.org/voices/learning-italy-s-lead-naloxone (3.8.2017)

2.3.7 Lithuania

In 2016 the Vilnius Centre for Addictive Disorders started a THN initiative, giving naloxone ampoules to opioid users who have fulfilled a training before. Drug, Tabacco and Alcohol Control Department is recently preparing an action plan for making naloxone available for PWID (also in prison setting) as well as their family members.

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2.3.8 Norway

In 2014 the Norwegian Minister for Health launched a national OD-prevention campaign based on the OD-prevention strategy 2014 – 2017, including THN distribution. This strategy aims at reducing the numbers of annual overdose deaths. THN programmes exist in 13 cities with at least one distribution side per city. Further sites are planned. The THN programme is based on an off-label use of injectable naloxone. The kit does not contain a needle, and only intranasal application is possible.

Contact Norwegian Centre for Addiction Research

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Project reports, evaluations and scientific papers

Clausen, Thomas (2014): *Naloxone Nasal Spray in Nor-way*.http://www.emcdda.europa.eu/attachements.cfm/att_232500_EN_11.%20Clausen%20Norway%20Naloxone%20nasasl%20spray.pdf (3.8.2017)

Clausen, Thomas (2017): The Norwegian experience with naloxone distribution as part of a national overdose prevention strategy. (3.8.2017)

Madah-Amiri, D.; Clausen, T.; Lobmaier, P. (2016): *Utilizing a train-the-trainer model for multi-site naloxone distribution programs*. Drug Alcohol Depend, 163, 153–156. doi:10.1016/j.drugalcdep.2016.04.007 (3.8.2017)

Madah-Amiri, D.; Clausen, T.; Lobmaier, P. (2017): *Rapid widespread distribution of intranasal naloxone for overdose prevention*. Drug Alcohol Depend, 173, 17–23. doi:10.1016/j.drugalcdep.2016.12.013 (3.8.2017)

Madah-Amiri, D.; Clausen, T.; Myrmel, L.; Brattebo, G.; Lobmaier, P. (2016): *Circumstances* surrounding non-fatal opioid overdoses attended by ambulance services. Drug Alcohol Rev. doi:10.1111/dar.12451 (3.8.2017)

Tylleskar, I.; Skulberg, A.K.; Nilsen, T. et al. (2017): *Pharmacokinetics of a new, nasal formulation of naloxone*. In: European Journal of Clinical Pharmacology (2017) 73: 555–562. https://doi.org/10.1007/s00228-016-2191-1 (3.8.2017)

Training material

https://www.youtube.com/watch?v=HlvpqT7o74U (3.8.2017)

2.3.9 Spain

In 2008, the Public Health Agency of Barcelona and the Public Health Agency of Catalonia launched a formal take-home naloxone programme. The Catalonian take-home naloxone programme was embedded in the Catalan Drug Abuse Care Centres Network (XADC). People who injected drugs received a financial incentive to attend training. The THN programme includes 64 drug-treatment centres, 17 therapeutic communities, 10 detox units and 13 drug-consumption rooms.

Contact Ministerio de Sanidad, Servicios Sociales e Igualdad

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Project reports, evaluations and scientific papers

Arribas-Ibar E.; Sánchez-Niunò A.; Majó X.; Domingo-Salvany, A.; Brugal, M.T. (2014): *Couverage of overdose prevention programs for opiate users and injectors: a cross-sectional study.*Harm Reduction Journal 11, p.33

Espelt, Alber; et al. (2015): *Implementation of Systematic Programs of Overdose Training at Drug Treatment and Prevention Centres in Catalonia, 2008–2013.*

http://drogues.gencat.cat/web/.content/minisite/drogues/noticies/actualitat/arxiu/Espelt-et-al_2015.pdf (3.8.2017)

Major X.; Carvaja S.; et al. (2014): *Involving the network of drug abuse care centres of Catalonia in a take-home naloxone programme*.

http://www.med.uio.no/klinmed/forskning/sentre/seraf/aktuelt/arrangementer/konferanser/konferanser-2015/overdosekonferansen-2015/majo---involving-the-network-of-drug-abuse-care-centres-of-catalonia-in-a-take-home-naloxone-programme.pdf (3.8.2017)

Sarasa-Renedoa; Ana et al. (2014): Overdose prevention in injecting opioid users: The role of substance abuse treatment and training programs.

http://scielo.isciii.es/pdf/gs/v28n2/original7.pdf (3.8.2017)

Training material

Majo, Xavier; et al. (2019): *Manual per educar en prevenció I assistència a les sobredosis*.

Barcelona.

http://drogues.gencat.cat/web/.content/minisite/drogues/professionals/guies_i_manuals/arxius/manual_per_educar_en_prevencio_i_assistencia_a_les_sobredosis.pdf (3.8.2017)

2.3. 10 a UK

Naloxone has been available as a prescription-only medicine in the UK since the 1970s. It could only be prescribed to a named patient or supplied to an individual by means of a patient specific direction (PSD) or a patient group direction (PGD).

Since a change in the law in 2005 naloxone can be used lawfully by anyone for the purpose of saving life in an emergency. This means that not only qualified medical professionals can administer injectable medicines. With the agreement of someone to whom naloxone can be supplied, it could also be provided to family members, carers, peers and friends.

Since a change in the law in 2015, injectable naloxone can be supplied by drug treatment services across the UK, without prescription, to any individual (not organisations) needing access to naloxone for saving a life in an emergency. Drug services are loosely defined to include specialist treatment services and their outreach workers, needle and syringe programmes including community pharmacies, community pharmacies providing supervised OST, and others. As a result of the change in legislation, the provision of naloxone at a local level has expanded, especially in England where 90% of the local authorities now support it (LGA 2017). The majority of provision is by drug services to their service users and Public Health England is supporting a more widespread provision to other groups.

Project reports, evaluations and scientific papers

LGA (2017): Naloxone survey 2017. London: Local Government Association; https://www.local.gov.uk/naloxone-survey-2017 (3.8.2017)

Training and information material

Public Health England (2017), *Widening the availability of naloxone, Guidance*.

www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone (UK)

http://www.nta.nhs.uk/uploads/phetake-homenaloxoneforopioidoverdoseaug2017.pdf (3.8.2017)

http://www.exchangesupplies.org/shopdisp_prenoxad_naloxone_prefilled_syringe.php (21.11.2017

2.3. 10 b UK/ Scotland

The Scottish National Naloxone Programme (SNNP) has been introducted in 2011. The programme involves THN distribution in the community as well as in prisons (upon release). Community-based services can issue take-home naloxone to the person at risk of opioid overdose, to family members and peers (with documented consent of the person at risk) and to agency staff. The Scottish government funds the programme centrally. In Scotland a legal exemption from the Lord Advocate applies to supply naloxone to services who work with those at risk of OD. A naloxone peer education initiative was established in 2012 with the aim of involving hard-to reach user groups. Due to the changes to the regulations in 2015, the next step is to pilot a naloxone peer supply model. This initiative will be the first of its kind in the UK and is due to be progressed during 2017. Since 2012 UK/ Scotland is conducting also a pilot project in Highland with intranasal naloxone, which involves an intranasal device attached to the

pre-filled syringe. The service is provided for drug users and their families as part of NHS Highland's Harm Reduction Service.²

Contact SDF Scottish Drug Forum

web: http://www.sdf.org.uk/what-we-do/reducing-harm/take-home-naloxone/

Project reports, evaluations and scientific papers

- Bird, S. M.; McAuley, A.; Perry, S.; Hunter, C. (2016): Effectiveness of Scotland's National Naloxone Programme for reducing opioid–related deaths: a before (2006–10) versus after (2011–13) comparison. Addiction, 111: 883–891. doi: 10.1111/add.13265. http://onlinelibrary.wiley.com/doi/10.1111/add.13265/full (3.8.2017)
- Bird, S. M; et al. (2017): Prison-based prescriptions aid Scotland's National Naloxone Programme. In: The Lancet, Volume 389, Issue 10073, 1005 1006. http://thelancet.com/journals/lancet/article/PIIS0140-6736(17)30656-6/fulltext
- Horsburgh, K.; and McAuley, A. (2017): Scotland's national naloxone program: The prison experience. Drug and Alcohol Review, doi: 10.1111/dar.12542. https://www.ncbi.nlm.nih.gov/pubmed/28397322 (3.8.2017)
- Kings College London: N-ALIVE Randomised trial of take-home Naloxone to prevent heroin overdose deaths post-prison release. https://www.kcl.ac.uk/ioppn/depts/addictions/research/drugs/N-ALIVE.aspx (3.8.2017)
- McAuley, Andrew; et al. (2012): From evidence to policy: The Scottish national naloxone programme. In: Drugs: Education, Prevention and Policy. 19/4: 309–319. http://dx.doi.org/10.3109/09687637.2012.682232 (3.8.2017)
- McAuley, Andrew; et al. (2016): Engagement in a National Naloxone Programme among people who inject drugs. In: Drug and Alcohol Dependence, 162: 236–240. http://www.sciencedirect.com/science/article/pii/S037687161600106X (3.8.2017)
- National Services Scotland (2016): *National Naloxone Programme Scotland Monitoring Report* 2015/16. https://www.isdscotland.org/Health-Topics/Drugs-and-Alcohol-Misuse/Publications/2016-10-25/2016-10-25-Naloxone-Report.pdf?77830141783 (3.8.2017)
- Strang, John (2014): *The N-ALIVE randomised prison-release naloxone trial: testing pre- provision of naloxone to prevent heroin overdose deaths.* National Addiction Centre, London.

http://www.nhshighland.scot.nhs.uk/News/Pages/IntranasalNaloxonebeingintroducedinHighland.aspx (21.11.2017)

 $http://www.emcdda.europa.eu/attachements.cfm/att_232494_EN_4.\%20John\%20Strang\%20\\ Naloxone-NALIVE-EMCDDA-oct2014-min-PDF.pdf (3.8.2017)$

Watt, Glenys; et al. (2014): SERVICE EVALUATION OF SCOTLAND'S NATIONAL TAKE-HOME NALOXONE PROGRAMME. Scottish Government Social Research. http://www.gov.scot/Resource/0045/00451251.pdf (3.8.2017)

Training material

http://www.sdf.org.uk/what-we-do/reducing-harm/take-home-naloxone/ (3.8.2017)

2.3.10 c UK/ Wales

In July 2009 the THN pilot-project was launched by the Welsh Government (WG) in selected areas of Wales. The key aim of the project was to reduce drug-related deaths in Wales. Full national implementation of THN projects throughout Wales was approved by the WG in May 2011. On 1 October, 2015, new national regulations came into force, which allowed the widening of the availability of naloxone.

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Project reports, evaluations and scientific papers

Bennett, Trevor; Holloway, Katy (2011): Evaluation of the Take Home Naloxone Demonstration Project. Welsh Assembly Government Social Research. http://gov.wales/statistics-and-research/evaluation-take-home-naloxone-demonstration-project/?skip=1&lang=en (3.8.2017)

Morgan, Gareth; Smith, Josie (2015): *Harm Reduction Database Wales: Take Home Naloxone 2014–15*. Public Health Wales, Cardiff.

https://www2.nphs.wales.nhs.uk/SubstanceMisuseDocs.nsf/Public/1D876D9A88E4BAB0802 57EB5003AD902/\$file/HRD%20Wales%20-%20Take%20Home%20Naloxone%202014-15%20FINAL.pdf?OpenElement (3.8.2017)

Morgan, Gareth; Smith, Josie (2016): *Harm Reduction Database Wales: Take Home Naloxone 2015–16.* Public Health Wales, Cardiff.

 $\frac{https://www2.nphs.wales.nhs.uk/SubstanceMisuseDocs.nsf/Public/73A04023C6B9BD95802}{57EE50049E202/\$file/FINAL%20Naloxone%20HRD%20report%202015-16.pdf?OpenElement}(3.8.2017)$

3 Legal and Regulatory Contexts

Practice has shown that main challenges in establishing THN interventions where similar within countries and refer mainly to legal and regulatory aspects regarding the

- » prescription of naloxone to not medically qualified third parties
- » distribution of naloxone to third parties
- » administration of naloxone by a not medically qualified person/ layperson in case of a drug emergency. This challenge mainly occurs in terms of injecting application.

This Chapter therefore focuses on the description of THN programme approaches to deal with specific legal and regulatory challenges regarding the prescription (Ch. 3.1), the distribution (Ch. 3.2) and the administration (Ch. 3.3) of naloxone. Chapter 3.4 gives an overview of the remaining challenges and recent developments.

3.1 Legal challenges in terms of prescription

Generally naloxone is a prescription-only medication (POM) in 9 out of 10 EU countries, where THN interventions exist. In **Italy** naloxone is classified as an over-the-counter medication and can be distributed in any pharmacy to anyone, but specific advertising is forbidden. An additional regulatory challenge refers to the fact that mainly injectable naloxone products have a market authorization in the EU. It is only a recent development that a nasal formulation got the market authorization in France (see chapter 2.4).

In the framework of THN interventions no prescription for naloxone is needed in the UK, in Scotland, Wales as well as in France and Norway.

Since a change in the law in 2015 drug treatment centres in the **United Kingdom**, also in **Scotland and Wales** act as intermediate institutions and therefore can give out naloxone to an individual by means of a patient specific direction or a patient group direction without prescription. Drug services are loosely defined to include specialist treatment services as well as outreach work, NSP interventions and community pharmacies providing supervised OST and others. Naloxone remains a POM, so it cannot be sold over the counter. This law also only refers to injectable naloxone. If nasal naloxone preparation is granted a licence, it won't automatically be covered by this law.

To overcome legal challenges in terms of prescription **Norway** legally implemented a waiver of need for individual naloxone prescription. An important prerequisite has been the limited time frame of the THN project and a restriction to those cities participating in the national strategy to reduce ODs. In addition to this there is the intention to get regulatory approval of a nasal application tool.

The THN intervention in **France** was established as a cohort study on intranasal administration of naloxone. For being able to start the THN programme the Commission on narcotics and psychotropic substances voted in favour of a nasal route of naloxone administration. Intranasal naloxone has been exempted from the list of poisonous substances and therefore dispensing it does not require a medical prescription. Limitations refer to the target group, as only physicians practising in a CSAPA³ setting, in certain addiction medicine or emergency departments and in prison treatment units may include patients in the cohort study. Supply is exclusively reserved for pharmacies dispensing to those treatment centres mentioned above. The recent market authorisation for intranasal naloxone (Nalscue®) could change the general legal approach to THN programmes in France.

In those countries, where the prescription is still a key factor in THN programmes/ projects, the prescribing doctors need to fulfil certain defined formal and/ or safety standards.

In **Estonia** there is an agreement that the prescription needs to be formally correct, which means personalised and documented according to current legislation. Under these conditions naloxone can be prescribed to drug users and potential bystanders.

Until recently the regulatory framework in **Denmark** demanded a direct personal supervision by prescribing doctors of every delivery of naloxone. After a re-evaluation by medical authorities the prescribing doctor now has to set up a detailed set of rules of prescribing regulations. All legal responsibility still stays with the prescribing doctors. But under the condition of setting up a safe environment the prescribing doctors can delegate prescription to *1st THN trainers*. They do not have to be medically qualified in this framework but need to be directly trained by the doctor. The prescriber also has to supervise use, which is set up by online registration of the individual helper and by reporting at re-fills, which is relevant also in terms of the evaluation of the programme.

In **Germany** opiate dependence is a required indication for naloxone prescription. The legal situation is not entirely clear for the prescribing doctor in existing THN programmes/ projects. There is a special duty to inform the patients on administration, (side) effects and a strict documentation is recommended. A private prescription for naloxone is also possible, in that case costs are not covered by the health insurance.

An amendment to the Prescription Regulations in **Ireland** was made in October 2015, to enhance distribution and access to naloxone to opioid users. This amendment may serve to enable exemption from prescription control of a medical product, e. g. in a specific establishment by a person who has a certified and accredited training. A registration of those who successfully completed the THN training could be maintained. Currently it cannot be held safely in stock by families or service providers for use in the event of an emergency.

3

Centres de soins, d'accompagnement et de prévention en addictologie

In **Spain**/ **Catalonia** naloxone is provided to professionals working in some harm reduction centres and drug consumption rooms for supply to people who use opioids. Medico-legal concerns inhibited the authorisation of a THN pilot-study.

3.2 Legal challenges in terms of distribution to a layperson

When setting up the legal framework for a THN programme/ project, the distribution of naloxone to laypersons is an essential aspect. Supplying naloxone also to families, friends and other potential bystanders is possible in Denmark, where it is connected with the broad interpretation of the prescription rules. In Estonia also the possible distribution to layperson is regulated by the prescription mode. In Estonia, Norway, UK, Scotland and Wales the exemptions in prescribing naloxone in the framework of THN programmes additionally lowers the barriers due to the distribution to a layperson.

Legal challenges in terms of the distribution to a layperson can also be related to the fact that the medication has only be available as an injectable drug until July 2017. To facilitate a broad distribution of THN, Denmark therefore decided to include a nasal naloxone-product in their programme.

As naloxone in Germany is distributed in pharmacies only, there is no chance to include this target group in the THN projects. In Spain/ Catalonia the situation is similar, as naloxone provision is only possible in harm reduction centres directly to opioid users. In Lithuania the distribution to a layperson is not allowed, a limitation that is now tackled through a new legal initiative introduced by the Drug Control Department under the Government of the Republic of Lithuania.

3.3 Legal challenges in terms of administration by a layperson

The administration of naloxone by a non-medically trained bystander is mainly allowed in those countries, where the aspect of distribution to a layperson is regulated. Limitation exists in Lithuania, where the administration of naloxone is only allowed with consultation provided by emergency management agencies over the phone. In case of an overdose emergency the purpose of saving life in some countries legally justify the administration of naloxone by a non-medically trained person. Duty to rescue-laws⁴ or Good Samaritan laws⁵ provide legal protection for those administering naloxone in case of an emergency.

4

Duty to rescue refers to the duty of a person to rescue another personwho is in a dangerous situation. The rescuer must

3.4 Remaining Challenges and Recent Developments

Remaining legal/ regulatory challenges for THN programmes/ project mainly refer to the provision of THN-kits to those in need. It has been mentioned that the POM status of naloxone limits not only the client but also family access. The fact that THN training and distribution often needs medically qualified staff is described as a barrier to increase THN distribution. A proper and lawful maintenance, also in terms of storage and expiration date seems to be a challenging factor for existing THN programmes/ projects. Although the market authorisation for intranasal naloxone is generally seen as a facilitator for THN programmes/ projects, it also raises the concern, that this market authorisation might increase the prices for THN-units.

With regard to legal/ regulatory aspects of THN interventions recent developments in the EU refer to the intranasal application of naloxone. A highly concentrated nasal formulation (by the company Indivior, tradename Nalscue®) received market authorisation in France in July 2017, after it had been used on a trial basis before (see Ch. 2.2).

In November 2016, the company Munipharma submitted a Marketing Authorisation Application (MAA) to the European Medicine Agency (EMA) for an intranasal naloxone spray (tradename Nyxoid®). In September 2017 the Committee for Medicinal Products for Human Use (CHMP) of the EMA has issued a positive opinion for this intranasal naloxone. If approved, this will be the first intranasal formulation of naloxone to receive a pan-EU approval. A final decision is expected in Q4 2017.6

In February 2017, the company Adapt filed a Marketing Authorisation Application (MAA) for an intranasal naloxone spray (tradename Narcan®) in Europe, which had been licensed by the US FDA in January 2017.

generally act with reasonable care. Liabilities from rescuers in case of injuries caused are in some circumstances limited or removed. The rescuers furthermore need not endanger themselves in the rescue situation.

Good Samaritan laws offer legal protection to people who - on a voluntary basis - give reasonable assistance in an emergency situation to an injured person.

http://www.biospace.com/News/mundipharma-receives-chmp-positive-opinion-for/469507/source=MoreNews (21.9.2017)

4 Modes of THN Programmes/Projects

This Chapter gives an overview of the main aspects of the THN programme design, describing types of medication and application (Ch. 4.1) and distribution and re-fill procedures (Ch. 4.2). Aspects of the contextual framework and cooperation with partners (Ch. 4.3) and costs and funding (Ch. 4.4) are outlined as well.

4.1 Medication used and Type of Application

The medication distributed in THN programmes is strongly connected to its marketing authorization. Table 3 gives an overview of medication used in combination with the type of application. Except for France and recently also Denmark all THN programmes/ projects are based on injectable products. 9 THN interventions use Prenoxad®7, which comes in a pre-filled and ready to use syringe with needle. Norway combines Prenoxad® with a nasal atomization device (MAD300), for which they received market authorization. Apart from that, THN interventions mainly use other naloxone products, which are distributed in ampoules together with syringes within a THN-kit8. Some German THN projects distribute ampoules/ syringes as well as an off-licence nasal application tool within the THN-kit, with the recommendation of nasal application.

Apart from the medication itself and the application tool in nearly all countries first aid instructions, an emergency telephone number or an ABC are part of the THN-kit. Denmark, Norway and the THN project in Germany/ Munich also add official THN-documents to the kit, e.g. a THN training certificate, copy of prescription, carriers or data card. Paraphernalia to prevent infectious diseases, e.g. sterile cloth, injecting paraphernalia, gloves are part of the THN-kits in Germany and Spain/ Catalonia. The Danish kit includes a re-fill questionnaire.

Prenoxad Injection is a pre-filled syringe containing 0.91mg/ml naloxone hydrochloride solution for injection in a pre-filled syringe. It is produced in the UK and sold under certain conditions in the UK by an online provider in a pack, which contains one 2mL prefilled syringe with 2 needles.

THN-kit is defined as the entire package or unit given out to the potential user. This kit not only contains the medication including application tool but could also contain additional paraphernelia as described.

Table 3: Medication and application tool provided in THN-kit

	Medication				Application tool provided in THN-kit					
	Prenoxad®	Narcan®	Naloxone– ratiopharm®	Naloxone WZF	Naloxone generic	Nalscue®	Pre-filled syringe with needle	Ready to use nasal spray	Off-licence nasal application tool	Ampoule and syringe set
1 Denmark	х	x				×	x	x		
2 Estonia	х						х			
3 France						x		х		
4a Germany/ Berlin	х									
4b Germany/ Frankfurt	x								×	х
4c Germany/ Cologne			x						х	х
4d Germany Munich			x						x	x
4e Germany/ North Rhine-Westphalia			×						х	х
5 Ireland	x						х			
6 Italy ¹										х
7 Lithuania				х						x
8 Norway	x								х	
9 Spain/ Catalonia					x					x
10 a UK national	х						х			
10 b UK/ Scotland ²	х						х			
10 c UK/ Wales	x						х			

¹ List of available naloxone products: https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/cerca-per-principio-attivo?princ_att=Naloxone_(10.10.2017)
<a href="https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/cerca-per-principio-attivo?princ_att=Naloxone_(10.10.2017)]
<a href="https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-principio-attivo.gov.it/bancadatifarmaci/cerca-per-pr

Source: GÖG/ÖBIG

Table 4: List of THN medication available in the EU

Trade name	Naloxone HCl concentration/ mL	Application	Doses per package		
Generic naloxone	lmg/lmL	injectable	Content varies between products		
Prenoxad® (2mL in pre-filled syringes)	lmg/lmL	injectable	1 syringe per package 5 doses of 0.4mL per syringe		
Nalscue®	0.9mg/0.1mL	nasal spray	2 one-dose applicators per package (each nostril)		
Narcan®	4mg/0.1mL	nasal spray	1 nasal spray per package (one nostril)		

Source: EMCDDA

4.2 Distribution and re-fill Procedures

The target group for THN intervention are people at risk of an overdose as well as potential bystanders. To reach current drug users THN distribution on–site in a low–threshold setting is an important intervention and therefore well implemented. On–site THN distribution at outpatient or inpatient treatment centres, in OST–programmes as well as in the prison setting aim at reaching former drug users, who are at risk of starting to use drugs again. The distribution in pharmacies can be seen as an indicator to facilitate the distribution of THN to those in need, as shown in Table 5, it is hardly implemented.

Table 5: Distribution sites for THN

Sort	Country/ city	On-site at low threshold agencies	On-site at outpatient treatment centres	On-site at impatient treatment centres	To clients of OST pro- grammes	In prison setting/ on release	On pharma- cies on prescrip- tion	In pharma- cies
1	Denmark	х	х		x	х		
2	Estonia	х			x	х		
3	France		х	х	х	х		
4a	Germany/ Berlin	х						
4b	Germany/ Frankfurt						х	
4c	Germany/ Cologne	х		х				
4d	Germany/ Munich	х						
4e	Germany/ North Rhine-Westphalia	х						
5	Ireland	х	х					
6	Italy	х	х	х				x
7	Lithuania			х				
8	Norway	х	х	х	x	х		
9	Spain/ Catalonia	х	х	х	х			
10a	UK national	х	х	х	x			x
10b	UK/ Scotland				х	х	х	х
10c	UK/ Wales	x	x	x	x	x		
	Total amount of specific distribution site	12	8	8	8	6	2	3

Source: GÖG/ÖBIG

Most of the programmes provide a structured **procedure** (interview or questionnaire) when clients return for a **re-fill**. A debriefing in case of a client's return for re-fill is mandatory in nine THN programmes.⁹ Questions mainly cover aspects like the reason for the re-fill, the description of

⁹

the drug emergency/ situation, involvement of ambulance and the outcome of emergency. Some projects ask for the place of the emergency, the substance causing overdose, the given dosage of naloxone or specific information on the victim.

Post-training monitoring is sometimes a challenge in terms of reaching the THN-kit recipients. A systematic follow-up with all THN-kit recipients is implemented in Denmark, Estonia, France, Germany/ Munich and Spain/ Catalonia. UK/ Wales has a national data system, which alerts, when naloxone replenishment and training update is required for the original recipients. In Estonia a re-training course is mandatory every 3 years.

4.3 Contextual Preparation of THN Programmes/ Projects

At the survey among existing THN programmes/ projects underlines the importance of cooperation during the THN programme development as well as continuous cooperation. Table 6 gives a detailed overview on cooperation-partners and their specific role as far it was described in the templates.

Apart from this cooperation peer-involvement is a crucial aspect in THN programmes/ projects. Peers are generally essential for the recruitment. In eight THN programmes peers do play an active role as co-trainers, for example to train pharmacists (UK/ Scotland). User advocacy groups were involved in the THN programme development in Norway, Ireland and UK/ Wales and in the development of the specific service delivery model in Estonia.

Looking at the lessons learned from collaborations three main fields of recommendations can be identified:

I. Stakeholders involvement and cooperation networks

- » Cooperation and open communication partnerships generally are supportive when establishing a THN programme
- » Continue to draw in the full suite of stakeholders, especially those who doubt the project
- » Governmental support as well as the inclusion of THN in a national strategy (on DRD) is an important facilitator
- » Cooperation with relevant (health-related) authorities is essential, especially when it comes to legal aspects and limitations and legal/regulatory solutions
- » Cooperation with existing local healthcare facilities and NGOs, as well as the inclusion of family members is supportive
- » Setting up a good and ongoing cooperation with the police is helpful

II. Communication strategy

- » Mapping barriers and opponents, providing arguments in advance
- » Raising awareness of political and administrational level in advance
- » Raising awareness of the importance of naloxone within a wider network of NGOs and community networks

- » Strengthen the presence and involvement of service user networks and organisations within the communication about naloxone
- » Agreement/ compromise on pilot-project can be seen as a first step; adopt a more measured and strategic approach in the first step
- » Continue open conversation and thought sharing to bring forward the quality of the product and the process
- » When THN programme is already established, the publicity about THN should be more widely distributed to include others than drug agencies as well as the general public

III. Facility add-ons

- » THN programmes provide positive experience for staff at drug-treatment centres to interact with their patients as well as their families
- » Naloxone as a prescription drug also gives the opportunity to interact systematically with
- » Training sessions make a suitable situation for discussing other health issues then ODs
- » Appointments for THN trainings can be challenging
- » Work out a recruitment strategy including motivating aspects for users to participate in the THN training
- » Being flexible and adopting to specific user's situations (e. g. length of THN training)

Table 6: Partners involved in THN programme development and ongoing cooperation

Partner	programmes involving this partner (sort number)	Cooperation in THN programme development	Ongoing cooperation
Treatment/ harm reduction service provider	12 1,2,3, 4c,4d,4e,5, 6,8, 10b,10c	 » Development of training programme as well as service delivery model (2) » Focus groups with staff (8) 	 Invited to participate in advance training to have a local trainer (1) Treatment centre includes patients in cohort study (3) On-site trainings, overdose trainings (4e) Involvement of non-drug services, e.g. homeless service, family support networks (5) Emergency rooms (6)
Police	10 1,2,4b,4c,4 d,4e,5,9, 10b,10c	 » Agreement of procedure when person is detained with naloxone or after administering naloxone (2) » Release information (4b, 4c, 4e) 	 Information on THN project, on THN trainings, on THN-kits (1, 4d,5) Regular coordination with the police to assure that the THN-kits are not confiscated (9) Still a challenge (10b)
Government	10 1,2,4c, 4d,4e,5, 8,9,10b, 10c	 » Health sector (e.g. Ministry of Health, Health Service Executive, Health Committee of the parliament, Department of Health) (1, 5, 8) » Involvement in programme development as well as in development in service delivery model (2) » Release information (4c, 4e) 	 » Due to funding and monitoring (2,4d) » THN programme is coordinated by govermental agency (9)
Local phamacies	8 1,2,4b, 4c,4d,5, 10b,10c		Provision (contractual supply) of naloxone to project stakeholders or service delivery locations (1, 2, 4d) Information on THN project (4c) Institute of Pharmacy and pharmaceutical society accredited training (5)
Ambulance services	6 1,2,5,8, 10b,10c	» Defining need für THN programme (2)	» Information on THN project (1, 5) » Distribution of information leaflet (5) » Counselling and validation of CRP (cardiopulmonary resuscitation) and overdose management training (8) » Data exchange (2)
Medical Chamber	4 2,4c,5,8	» Agreement on procurement procedure and import of unlicenced medicine (2) » Written statement on handling naloxone to opioid users (4d)	
University	5 1,2,4b, 8,10c		Project evaluation (1) HTA on effectiveness of THN programme (2)
Legal advisory body	5 3,4d,4e, 5,10c	 » Informed (4c) » Health Products Regulatory Authority/ Agency for Medicines and Health Products Safety (3) 	
Local community	4 1,5,8, 10b,10c	» Local governments (1)» Task force (5)	» Staff and users from local facilities (8)
Others	6 1,3,4d,5,8, 10c	» NGO (1)» Public Health Institute (10c)	 » Physician for prescription (4d) » Naloxone Quality Advisory Group (5) » Pharmaceutical company/ industry 3,8)

Source: GÖG/ÖBIG

4.4 Costs and Funding

The estimated cost per THN-kit shows a huge variety between €3 in Lithuania, where the generic substance, in vials, is used, and € 78 in Denmark, where each kit contains two Nalscue nasal atomizers. The average price seems to be around € 25 per THN-kit. For a better understanding, the price/ THN-kit is outlined in relation to the medication and additional content per THN-kit in Table 7.

Table 7: Estimated price and content of THN-kit

Sort	Country	Estimated	Medication	Medication	Medication	Medication	Additional content of
num– ber		price per THN-kit	Prenoxad® (pre-filled syringe)	Nalscue® (nasal atomizer)	Naloxone- rati- opharm	Generic naloxone	THN-kit
1	Denmark	€ 781	×	×		×	First aid instructions THN-documents Re-fill questionnaire
2	Estonia	€ 23	×				First aid instructions
3	France	€ 0 (€ 100)²		×			First aid instructions
4a	Germa- ny/ Berlin	N/A	x				N/A
4b	Germa- ny/ Frankfurt	€ 20	х				First aid instructions Paraphernalia
4c	Germa- ny/ Cologne	€ 20			x		N/A
4d	Germa- ny/ Munich	€ 33			x		First aid instructions THN-documents Paraphernalia
4e	Germa- ny/ North Rhine- Westpha- lia	€ 20			х		First aid instructions Paraphernalia
5	Ireland	€ 29	х				
6	Italy	N/A				х	
7 8	Lithuania Norway	€ 3				х	First aid instructions Off-licence nasal application tool
		€ 40	х				(MAD300) First aid instructions THN-documents
9	Spain/ Catalonia	€ 5,60				х	First aid instructions Paraphernalia
10a	UK	N/A	х				N/A
10b	UK/ Scotland	N/A	х				
10c	UK/ Wales	€ 13,50	×				First aid instructions

 $^{^1}$ this price is for Nalscue® only, price for Prenoxed® and generic naloxone used in THN programme is not known. 2 the first 9000 kits are given free by the laboratory. After this it will be sold for 100€/kit to the THN programme.

Source: GÖG/ÖBIG

Figures for investment in human resources to implement the programme and for funding are outlined in Table 7. Due to a lack of information provided in the templates the cost per trained person can hardly be estimated. Entries vary between € 400 in Germany/ Munich, € 60 in Ireland and € 8 in Lithuania. One cost factor could definitely be the mandatory involvement of physicians or medically trained staff in the training.

Table 8:
Performance and resource needs (latest available 12-month reporting period)

Country	Set up programme and development of training curriculum/material Staff needed	Implement and monitor THN programme Staff needed	Source of funding of THN programme	Source of funding of THN training (if separate)	Estimated costs per person trained
Denmark	 » health professionals: 1700 h/y » physicians: 400 h/y » agency staff: 40 h/y » for coordinating unit only 	 staff: 1900 h/y update of training material: 37 h/y post-training monitoring: 100 h/y administration: 40 h/y drafting final report 	 integrated part of the general budget of the facility specific national funding local governments release staff to project 	specific national funding	N/A
Estonia	 » physicians: 0,1/year » agency staff: 0,1/year » administration: 0,5/year » programme was mainly developed by the staff of the NIHD 	 staff: 0,2/year update of training material: 80 h/y administration: 0,1/year monitoring the programme is ongoing work 	» integrated part of the general budget of the facility (fully governmental funded)		N/A
France	» 275 physicians and 275 pharmacists have been trained		» specific national funding» pharmaceutical industry	pharmaceutical industry	N/A
Germany/ Berlin	N/A	N/A	N/A	N/A	N/A
Germany/ Frankfurt	N/A	N/A	» funded from own resources		N/A
Germany/ Cologne	N/A	N/A	N/A	N/A	N/A
Germany/ Munich	» agency staff: 150 h/y» administration: 50 h/y	staff: 150 h/ypost-training monitoring: 50 h/yadministration: 30 h/y	 » specific regional or local funding » funding needs to be applied annually 		€ 400
Germany/ North Rhine- Westpha- lia	» administration: 50 h/y» peers 150 h/y	 staff: 100 h/y post-training monitoring: 10 h/y administration: 50 h/y 	 » specific regional or local funding » self-care fund of health insurance funds 		N/A
Ireland	» physicians» agency staff» administration		» specific national funding		60€
Italy	N/A	N/A	» specific regional or local funding	N/A	N/A
Lithuania	» harm reduction worker 40 h/y	» staff: 48 h/y » update of training material: 10 h/y	» integrated part of the general budget of the facility		8€

Chapter 4 / Modes of THN Programmes/Projects

Norway	 » health professionals: 100% » physicians: 40% » administration: 160% (100% is full time position) 		 integrated part of the general budget of the facility specific national funding 		N/A
Spain/ Catalo-	N/A	I - 1	 integrated part of the general budget of the facility specific regional or local funding 		N/A
nia					
UK	N/A	N/A	N/A	N/A	N/A
UK/	N/A	N/A	» specific national funding		N/A
Scotland					
UK/	» health professionals: 120 h/y	» staff: 180 h/y	» specific national funding		N/A
Wales	» physicians: 30 h/y	» update of training material: 20 h/y			
	» administration: 200 h/y	» post-training monitoring: 60 h/y			
	» resources for development of	» administration: 60 h/y			
	curriculum in 2009/2010: 350 h/y	» other: 320 h/y			

5 THN Training

This chapter summarise main aspects regarding THN trainings, which generally are a relevant component of THN initiatives. Ch. 5.1 focuses on the main target groups on recruitment issues and trainers, whereas the setting, duration and content of THN training is described in Ch. 5.2.

5.1 Target Groups, Recruitment and Trainers

Current or former drug users are the main target group in all listed THN programmes/ projects. Figure 1 shows that partners, family members and close friends are the second largest group of trainees, followed by outreach workers and staff at drug agencies. The recruitment to THN trainings is achieved mainly by face-to-face contacts, also peers play a major role in recruitment. Flyers and the use of specific media is used in 7 THN programmes/ projects.

Figure 1:

Target groups in THN programmes/ projects apart from current or former drug users

Source: GÖG/ÖBIG

Ten THN initiatives involve physicians as **trainers**. Those trainings without a physician involved either do include other medically trained staff (e.g. UK/ Scotland) or use social workers as trainers and split the THN training from the prescription of naloxone (e.g. some German projects). France is the only THN project, where only physicians can train. Another crucial trainer group are drug workers, who are involved in 11 trainings. Nurses/ paramedics are part of eight

^[1] DK, EE, FR, DE/ Munich, IE, IT, NO, ES/ Catalonia, UK, UK/ Scotland, UK/ Wales

^[2] DK. EE. DE/ Cologne, DE/ Munich, IE. IT. NO. UK, UK/ Scotland, UK/ Wales

^[3] DK, EE, DE/ Munich, IE, NO, UK, UK/ Scotland, UK/ Wales

^[4] DK, IE, NO, UK/ Scotland, UK, UK/ Wales

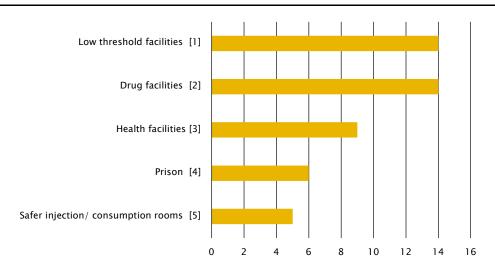
^[5] DK, NO, UK/ Scotland, UK/ Wales

trainings and eight trainings work with peer-educators. In some THN programmes/ projects also accredited pharmacists (Ireland, UK Scotland), shelter staff (Denmark), social workers (Denmark, Lithuania), social educators (Denmark) and criminal justice professionals (UK Wales) can act as trainers.

5.2 Setting, Duration and Content of THN Training

Generally a previous training is mandatory in 13 THN programmes/ projects. No training is required in Italy, UK and UK/ Scotland. THN trainings mainly take place in low threshold facilities and drug facilities. There are nine THN interventions, which train participants in health facilities and six trainings are implemented in prison setting. THN-trainers takes also place in safer injection/ consumption rooms (see Figure 2). No information is available on the implementation setting of UK THN interventions, except from Scotland and Wales.

Figure 2: Implementation setting of THN training



- [1] DK, EE, FR, DE/ Berlin, DE/ Frankfurt, DE/ Cologne, DE/ Munich, DE/ North Rhine-Westphalia , IE, IT, NO, ES/ Catalonia, UK/ Scotland, UK/ Wales
- [2] DK, EE, FR, DE/ Berlin, DE/ Frankfurt, DE/ Cologne, DE/ Munich, DE/ North Rhine-Westphalia, IE, IT, NO, ES/ Catalonia, UK/ Scotland, UK/ Wales
- [3] DK, EE, FR, IE, IT, LT, NO, UK/ Scotland, UK/ Wales
- [4] EE, FR, IE, NO, UK/ Scotland, UK/ Wales
- $\hbox{[5] DK, DE/ Berlin, DE/ Frankfurt, DE/ North Rhine-Westphalia , ES/ Catalonia}\\$

Source: GÖG/ÖBIG

The THN training format varies regarding duration and the number of sessions. In low threshold or waiting settings brief trainings up to 15 minutes are appropriate. 8 THN interventions use this often spontaneous format. Structured teaching sessions define standard trainings, which are provided in eight THN programmes/ projects. This more in depth format consists mostly of one session with 1 to 1.5 hours of teaching. Two THN interventions report sessions up to 3 to 4

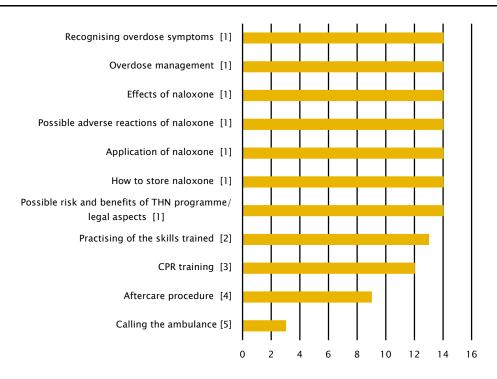
hours of teaching per session. In one case the training is free to adapt the training and shorten the group training to 30 minutes depending on the respective needs. Advanced THN trainings are implemented in three programmes, with diverse formats and up to 8 to 16 hours of training. Besides some THN programmes also offer train-the-trainer formats for staff members for instance.

In seven interventions the THN training is part of a general overdose-management training and 6 THN programmes/ projects also provide a kind of mandatory or optional refresh session or follow-up training. Looking at the **training framework** nine THN interventions hand over a certificate of training completion. In five trainings there is a test of knowledge after training and also in 5 programmes a training pack is distributed to participants or supervision for trainers is provided. Only 3 THN programmes/ projects give out incentives for participants.

The issue of overdose symptoms and management is the main **content** as well as specific information on the medication itself (storage, application) and its effects and side-effects (possible adverse reaction). Most of the trainings also train by actually practising the skills. Legal aspects and possible risks and benefits of the THN programme are focussed on in most of the trainings. Aspects of aftercare procedures, calling the ambulance are less often trained (see Figure 3). No specific information on the content of THN trainings is available for the programmes in Germany/ Berlin and UK.

Training manual/ guidelines are available in 14 THN initiatives, only Italy and Lithuania have not listed a specific THN training manual. In Chapter 1 available web links are listed in the country profiles.

Figure 3: Content of THN training



- [1] DK, EE, FR, DE/ Frankfurt, DE/ Cologne, DE Munich, DE/ North Rhine-Westphalia , IE, IT, LT, NO, ES/ Catalonia, UK/ Scotland, UK/ Wales
- [2] DK, EE, DE/ Frankfurt, DE/ Cologne, DE/ Munich, DE/ North Rhine-Westphalia , IE, IT, LT, NO, ES/ Catalonia, UK/ Scotland, UK/ Wales
- [3] DK, EE, DE/ Frankfurt, DE/ Cologne, DE/ Munich, DE/ North Rhine-Westphalia , IT, LT, NO, ES/ Catalonia, UK/ Scotland, UK/ Wales
- [4] DK, FR, IE, IT, LT, NO, ES/ Catalonia, UK/ Scotland, UK/ Wales
- [5] EE, DE/ Munich, IE

Source: GÖG/ÖBIG

6 Monitoring Framework

Considering the experiences of data collection with the THN template used for this survey, the following questions seem to be appropriate to define a core data set to future monitor existing THN initiatives. Questions from Table 9 and Table 10 could give an annual overview of existing THN initiatives including their performance. Collecting information from Table 11 could help to monitor the recent developments regarding naloxone medication and market authorisations of nasal products. Table 12 and 13 include more stable indicators on THN training and distribution components. Here, updates could be less than annually.

Table 9: Indicators to monitor general information on the THN intervention

No.	Indicator	Format
1.1	Country	
1.2	Geographical coverage	National
		Regional
		Local
1.3	Type of intervention	Regular programme
		Pilot project/ trial
		Other, please specify
1.4	Starting year of intervention	уууу

Source: GÖG/ÖBIG

Table 10: Indicators to monitor performance and resources of THN interventions

No.	Indicator	Format
5.1	Reporting period	mm.yyyy to mm.yyyy
5.2	Contents and price per THN-kit (end consumer)	€/ THN-kit
5.3	Total number of people trained (past 12 months)	
5.4	Total number of kits distributed (past 12 months)	
5.5	Number of reported administrations (past 12 months)	

Source: GÖG/ÖBIG

To monitor the number of reported (successful) administrations (see Table 10, 5.5) the collection of this specific information needs to be connected either to the re-fill procedure (e.g. question-naire when clients return for re-fill) or to the general monitoring of the THN programme (e.g. enrollment in THN programme to manage mandatory follow-up training or expiry date of naloxone product). Question 2.3.4 in the template (see Appendix) recommends possible contents in connection with the monitoring of (successful) administrations.

Table 11: Indicators to monitor information on medication and THN-kit

No.	Indicator	Format
2.1	Name of naloxone product	Prenoxad®
		Narcan®
		Nalscue®
		Other, please specify
2.2	Application tool provided in THN-kit	Pre-filled syringe with needle
		Ready to use nasal spray
		Off-licence application tool
		Ampoule and syringe
2.3	Is medical prescription required?	Yes/ no

Source: GÖG/ÖBIG

Table 12: Indicators to monitor THN intervention training component

No.	Indicator	Format
3.1	Implementation setting of training	Drug facility
		Health facility
		Prison
		Low threshold facility
		Other, please specify
3.2	Trainees	Drug users (current/ former)
		Partner, family members and close friends
		Other carers, e.g. hostel staff
		Other potential bystanders (e.g. police, firemen, prison guides)
		Other, please specify
3.3	Trainers	Physician
		Nurse
		Paramedic
		Other health professional
		Drug worker
		Service user/ peer
		Other, please specify

Source: GÖG/ÖBIG

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Table 13: Indicators to monitor THN distribution and post-training monitoring

No.	Indicator	Format
4.1	Distribution procedure of THN	On-site at low threshold agencies
		On-site at outpatient treatment centres
		On-site at inpatient treatment centres
		To clients of OST-programmes
		In prison setting/ on release
		In pharmacies on prescription
		In pharmacies
		Other, please specify
4.2	Is naloxone given out only to trained people?	yes/ no
4.3	Post-training monitoring	No
		Interview/ Questionnaire when client returns for re-fill
		Systematic follow-up with all THN recipients
		Systematic follow-up with a random subsample of THN recipients
		Independent evaluation/ cohort study
•		Other, please specify

Source: GÖG/ÖBIG

References

- EMCDDA (2015), *Preventing fatal overdoses: a systematic review of the effectiveness of take-home naloxone*, EMCDDA papers, Publication Office of the European Union, Luxembourg.
- Bennett, G. A. and Higgins, D. S. (1999), 'Accidental overdose among injecting drug users in Dorset, UK', Addiction 94, pp. 1179–1189.
- Bigg, D. (2002), 'Data on take home naloxone are unclear but not condemnatory', *BMJ* 324(7338), p. 678.
- Dettmer, K., Saunders, B. and Strang, J. (2001), 'Take home naloxone and the prevention of deaths from opiate overdose: two pilot schemes', *BMJ* 322(7291), pp. 895-896.
- Kumar, Th. & Rosenberg H. (2017), Five things to know about: Take-home naloxone. CMAJ 2017 September 18;189:E1192.doi:10.1503/cmaj.170600
- Loimer, N., Hofmann, P. and Chaudhry, H. R. (1994), 'Nasal administration of naloxone is as effective as the intravenous route in opiate addicts', *International Journal of the Addictions* 29, pp. 819-827.
- Strang, J. (1992), 'Harm reduction: defining the concept, exploring the boundaries, and identifying operational possibilities', paper presented at the Third International Harm Reduction Conference, Melbourne.
- Strang, J., Darke, S., Hall, W., Farrell, M. and Ali, R. (1996), 'Heroin overdose: the case for take-home naloxone', *BMJ* 312(7044), p. 1435.
- Strang, J. & McDonald, R. (2016), *Preventing opioid overdose deaths with take-home naloxone*, European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) Insights 20, Publication Office of the European Union, Luxembourg.
- WHO (2014), *Community management of opioid overdose.* World Health Organization, (http://apps.who.int/iris/bitstream/10665/137462/1/9789241548816_eng.pdf?ua=1&ua=1).

Take home naloxone programmes in the

Appendix



TAKE-HOME NALOXONE: Snapshot Europe 2016

Template for data-collection among countries where THN programmes are in place in 2016 with the aim to develop a

Quick reference guide on how to set up THN programmes (interactive, webbased)

Gesundheit Österreich GmbH

Naloxone is a life-saving overdose reversal drug that rapidly counteracts the effects of opioids. It has been used in emergency medicine in hospitals and by ambulance personnel since the 1970s to reverse the respiratory depression caused by opioid overdose.

Take-home naloxone (THN) programmes are a harm reduction measures that aims at preventing opioid-overdose deaths by making the antidote available in places where overdoses are likely to occur. In the event of an opioid overdose, naloxone is readily available and can be administered to the overdose victim before the arrival of the ambulance. THN-programmes combine the provision of an emergency supply of naloxone to current and former drug users and others likely to witness opioid overdoses with a specific training in overdose prevention, emergency management and with instructions about its administration (EMCDDA 2016, p.5ff).

1. GENERAL INFORMATION on the pro-	gramme (to be filled out for each distinct THN programme)
1.1 Country	
1.2 Name and short description of the THN programme	
1.3 Geographical coverage	national regional local
1.4 If regional or local, please list scope	
1.5 Type of THN intervention	☐ regular programme ☐ pilot project or trial ☐ other, please specify:
1.6 Starting year of the intervention	
1.7 Is the THN programme the result of a national or regional policy for prevention of drug-related deaths?	O yes O no O other, please specify:





1.8 Is the programme targeting overdose risk reduction in a specific setting or situation? Tick all that apply	□ prison □ in-patient detox/rehab/treatment □ substitution treatment □ low-threshold setting □ other, please specify:
2. DESCRIPTION OF PROGRAMME	
2.1 Details on MEDICATION and KIT distribut 2.1.1 Name of naloxone product(s) used in the THN programme Tick all that apply	ted Prenoxad®10 Narcan® other, please specify:
2.1.2 If other medication is injectable naloxone: Concentration	In mg of naloxone hydrochloride per 0.1 mL
2.1.3 If other medication is nasal naloxone: Concentration	In mg of naloxone hydrochloride per 0.1 mL
2.1.4 Type of application(s) of naloxone provided under THN programme Tick all that apply	☐ injecting ☐ nasal ☐ both ☐ other, please specify:
2.1.5 Content of THN-kit Tick all that apply	□ ready to use nasal application tool (Narcan®) □ off-licence nasal application tool □ pre-filled syringe with needles (Prenoxad®) □ ampoule and syringe set □ re-fill questionnaire □ first aid instructions, e.g. emergency telephone number, ABC □ sterile cloth to prevent infection transmission during possible resuscitation □ other injecting paraphernalia such as swab □ other, please specify:
2.1.6 Number of naloxone doses per THN-kit	per THN-kit





2.1.7 If relevant: additional information about new medication in development or being trialed in your country	
2.2 THN Programme Training Component	
2.2. Implementation setting of the training Tick all that apply	☐ drug facilities ☐ health facilities ☐ prison ☐ low-threshold facility ☐ other, please specify:
2.2.2 Method of Recruitment of eligible person for training Tick all that apply	☐ face-to-face ☐ flyer, specific media ☐ peers ☐ other, please specify:
2.2.3 Beneficiary groups of the THN-training Tick all that apply	☐ drug users (current and former) ☐ partner, family members and close friends ☐ other carers, e.g. hostel staff ☐ staff at drug agencies ☐ outreach workers ☐ other potential bystanders: e.g. police, fireman, prison guards ☐ other, please specify:
2.2.4 Trainers Tick all that apply	□ physician □ nurse □ paramedic □ other health professional □ drug worker □ service user □ other, please specify:
2.2.5 Training manual/ guidelines available	C yes / C no





2.2.6 Content of training programme/modules Tick all that apply	☐ recognising overdose symptoms ☐ overdose management ☐ aftercare procedures ☐ cardiopulmonary resuscitation (CPR) training ☐ effects of naloxone ☐ possible adverse reactions of naloxone ☐ possible risks and benefits of THN ☐ application of naloxone ☐ how to store naloxone ☐ how to store naloxone ☐ legal aspects ☐ practicing of the skills trained ☐ other, please specify:			
2.2.7 Training format	☐ brief training in low-threshold or waiting settings (up to 15 min.)			
Tick all that apply				
	number of sessions: hours and			
	advanced training: hours and			
	number of sessions:			
	☐ THN-training is part of a general overdose-management training			
	refresh sessions provided			
	other, please specify:			
2.2.8 Training framework	incentives for participants			
Tick all that apply	☐ training packs distributed to participants ☐ certificate of training completion			
	☐ knowledge test after training			
	provision of follow-up training			
	supervision for trainers provided			
2.3 DISTRIBUTION, RE-FILL PROCEDURES A				
2.3.1 Distribution procedure of THN (indicate where it is available on	on-site at low threshold agencies			
a regular/programmatic basis)	☐ on-site at outpatient treatment centers ☐ on-site at inpatient treatment centers			
Tick all that apply	to clients of OST programmes			
,	☐ in prison setting/on release			
	in pharmacies on prescription			
	other places specific			
	other, please specify:			
2.2.2. Is nalovone only given suit to	O yes , O no			
2.3.2 Is naloxone only given out to trained people	yes / 10			





2.3.3 Debriefing when THN programme clients returns for re-fill	C yes / C no
If yes, mandatory?	C yes / C no
2.3.4 Content of debriefing/ questionaire <i>Tick all that apply</i>	□ reason for re-fill □ description of the drug emergency/ situation □ ambulance involved □ outcome of emergency □ other, please specify:
2.3.5 Post-training monitoring	C yes / C no
If yes, describe: Tick all that apply	☐ interview or questionnaire when THN programme client returns for re-fill ☐ systematic follow-up with all THN recipients ☐ systematic follow-up with a random subsample of THN recipients ☐ independent evaluation, cohort study ☐ other, please specify:
2.4 Description of context of THN program	me development
2.4.1 Co-operation with relevant partners in THN programme development <i>Tick and specify all that apply</i>	□ treatment or harm reduction service providers, please specify: □ ambulance services, please specify: □ police, please specify: □ local pharmacies, please specify: □ Medical Chamber, please specify: □ university, please specify:
	government, please specify:





	☐ legal advisory boo	ly, please specify:		_
	☐ local community,	please specify:		_
	peers, please spec	cify:		
	other, please state	۵٠.		
		<u> </u>		
2.4.2 Please briefly share your experienc-				
es with collaboration main lessons learned, if possible provide examples of good				
practice or tips for others who plan such				
projects				
	<u> </u>			
3. PERFORMANCE AND RESOURCES (late	est available 12-mo	nth reporting pe	eriod/year)_ <i>per type of progi</i>	ramme
3.1 Reporting period	(2000)) to	(2000 1000)	
3.2 Staff resources needed to set up the	(mm.yyyy	, 10	(mm.yyyy)	
THN programme and develop the training	☐ health profession	als:	hours/year	
curriculum/material Tick all that apply	☐ physicians:		hours/year	
	☐ agency staff:		hours/year	
	administration:		hours/year	
	other, please spec	cify:		,
	hour	s/year		
3.3 Staff resources needed to implement	□ staff:	hours/year		
and monitor the THN programme	⊔ Stall.	hours/year		





Tick all that apply	update of training material: hours/year				
	post-training monitoring: hours/year				
	□ administration: hours/year				
	□ other, please specify:				
	hours/year				
3.4 Price take-home THN-kits					
(end consumer, purchasing price at project level)	€/ kit				
3.5 Source of funding of THN programme	☐ integrated part of the general budget of the facility				
(ongoing distribution of naloxone kits)	☐ specific national funding				
Tick all that apply	□ specific regional or local funding				
	☐ pharmaceutical industry				
	other, please specify:				
Source of funding on THN <u>training</u>	\square integrated part of the general budget of the facility				
(if separate)	□ specific national funding				
Tick all that apply	specific regional or local funding				
	☐ pharmaceutical industry ☐ other, please specify:				
3.6 Estimated costs per person trained	€				
3.7 Number of people trained	☐ Total number: past 12 months				
	☐ Total number: since programme started				
If possible, provide breakdown for	☐ drug users (current and former):				
number (past 12 months)	partner, family members and close friends:				
	☐ other carers, e.g. hostel staff:				
	staff at drug agencies:				
	□ outreach workers:				
	other potential bystanders: e.g. police, fireman, prison guards:				
	other:				
3.8 Number of kits distributed	☐ Total number: past 12 months				



	☐ Total number:	since programme started
3.9 Number of re-fills	☐ Total number:	past 12 months
	☐ Total number:	since programme started
4. LEGAL SITUATION regarding THN		
4.1 Is a medical prescription required for naloxone obtained/given out in the framework of take-home naloxone programmes?	C yes C no C In some circumstances, pl	ease explain:
4.2 Are there or have there been any regulatory challenges in regard to the prescription of naloxone to third parties (not medically qualified persons, laypersons) and if so, how were they overcome?		
4.3 Are there or have there been any regulatory challenges in regard to the distribution of naloxone to third parties (not medically trained persons, laypersons) and if so, how were they overcome?		



4.4 Are there or have there been any regulatory challenges due to the administration of naloxone by a not medically qualified person, a layperson, in case of a drug emergency and if so, how were they overcome?	
4.5 Which legal or regulatory challenges/barriers concerning take-home naloxone remain for this programme, if any?	
4.6 How could this THN programme be improved a, for the beneficiaries, and b, in regard to the training component?	





5.1 Please list relevant project reports, independent evaluations and scientific papers (please attach copy, or provide link)	
papers (please attach copy, or provide link)	
5.2 Training material (please attach copy or provide link)	
5.3 Is a contact person available to answer	
information requests? Name:	
E-Mail:	
Website:	

Table A 1: Collection of training material for THN programmes

Country or Institution	Source	Type of material	Title			
Australia	www.copeaustralia.com.au	Guideline/Checklist	COPE_Assembling and Administering Naloxone			
	www.copeaustralia.com.au	Fact Sheet	Fact sheet_Opioid Overdose Response Plan			
	www.copeaustralia.com.au	FAQs	FAQs_About Naloxone			
	www.copeaustralia.com.au	FAQs	FAQs_About Overdose			
	www.copeaustralia.com.au	Information material	Information for users, family and friends			
	www.copeaustralia.com.au	Information material	Information for Health Professionals			
	www.copeaustralia.com.au	Information material	Information for Police			
	www.copeaustralia.com.au	Information material	Overview of COPE			
	www.copeaustralia.com.au	Training Verification	SAMPLE-Verification-of-NaloxoneTraining			
	www.copeaustralia.com.au	Poster	Naloxone poster 1v2generic			
	www.copeaustralia.com.au	Poster	Naloxone poster 2v2generic			
	www.copeaustralia.com.au	Poster	Naloxone poster 3v2ATSI			
	www.copeaustralia.com.au	Poster	Naloxone poster 4v2generic			
	www.copeaustralia.com.au	Poster	Naloxone Poster Health Professionals			
	www.copeaustralia.com.au	Poster	Naloxone Poster Police			
	www.hrvic.org.au	Guideline	Quick Reference Guide to Using Naloxone			
	http://adf.org.au/	Fact Sheet	Naloxone_Fact_Sheet			
Canada	www.healthunit.org	Guideline	Naloxone_Training_Guide			
	www.towardtheheart.com	Training Manual	THN_Training_Manual			
	www.towardtheheart.com	Folder/Handout	THN_Folder_Program_BC			
	www.towardtheheart.com	Videolink	Participant Training Videos_Link			
	www.towardtheheart.com	Forms and Records	Distribution Record			
	www.towardtheheart.com	Forms and Records	Update Site Details Form			
	www.towardtheheart.com	Forms and Records	OD Response Information Form			
	www.towardtheheart.com	Forms and Records	Supply Order Form			
	www.towardtheheart.com	Forms and Records	Training Record			
	www.towardtheheart.com	Poster	I_have_Narcan Naloxone_poster			
	www.towardtheheart.com	Poster	Poster_SAVEME			
	www.towardtheheart.com	Poster	Posters_Wakes-You-Up			
	www.towardtheheart.com	Guideline	Folder_OD_Survival_Guide_English			
	www.towardtheheart.com	Guideline	Folder_OD_Survival_Guide_Chinise			
	www.towardtheheart.com	Guideline	Folder_OD_Survival_Guide_French			

		C. Halland	Fills OD Cost of City Dottel
	www.towardtheheart.com	Guideline	Folder_OD_Survival_Guide_Punjabi
	www.towardtheheart.com	Guideline/Checklist	Checklist_OD-awareness_opioids
	www.towardtheheart.com	Folder/Handout	Folder_SAVEME
	www.towardtheheart.com	Guideline/Checklist	SAVEME_Guideline_Checklist
	www.towardtheheart.com	Guideline/Checklist	OD_signssymptoms_Guideline_Checklist
	https://www.albertahealthservices.ca/	Questionnaire	Naloxone Kit User Questionnaire
	https://www.albertahealthservices.ca/	Guideline for Professionals	Nurse_Support_Tool
	https://www.albertahealthservices.ca/	Guideline/Checklist	OD_Symptoms_Poster
	https://www.albertahealthservices.ca/	Information material	THN-emergency-department-setting
	https://www.albertahealthservices.ca/	Information material	THN-getting-started
	https://www.albertahealthservices.ca/	Information material	THN-kit_contents
	https://www.albertahealthservices.ca/	Folder/Handout	THN-kit-brochure
	https://www.albertahealthservices.ca/	Poster	THN-kit-poster1
	https://www.albertahealthservices.ca/	Folder/Handout	THN-naloxone-prescribing-flow-sheet
	https://www.albertahealthservices.ca/	Checklist	THN-participant-knowledge-checklist
	https://www.albertahealthservices.ca/	Presentation for Training	THN-presentation-for-clients
	https://www.albertahealthservices.ca/	Presentation for Training	THN-presentation-for-trainers
	https://www.albertahealthservices.ca/	Information material	THN-rescue-breathing
	https://www.albertahealthservices.ca/	Folder/Handout	THN-save-me_handout
USA	http://www.in.gov/bitterpill/	Training Manual	Healthcare_Provider_Training_Guide
	http://www.in.gov/bitterpill/	Guideline	Naloxone_Nasal_Spray_Patient_Guide
	http://www.in.gov/bitterpill/	Handout	Get_Naloxone_Now_Flyer
Denmark	www.emcdda.europa.eu	Information material	The Danish Naloxone Scheme
Germany	www.condrobs.de	Information material/Pres.	Naloxon_aktuelle Projekte_Vorhaben in DE
	http://www.akzept.org	Information material	Naloxon_Broschüre
	http://www.akzept.org	Folder/Handout	Naloxon_Flyerweb
Ireland	www.drugs.ie	Information material	Evaluation Naloxone Demonstration Project
	www.drugs.ie	Information material	Naloxone_and_Overdose_Frontline_workers_pack
	www.drugs.ie	Poster	Carrying Naloxone Could Save A Life Today
	www.drugs.ie	Poster	Clear and Simple Plan
	www.drugs.ie	Poster	Difference between Life and Death
	www.drugs.ie	Poster	Families have no Choice
	www.drugs.ie	Poster	Familiy Support Worker
	www.drugs.ie	Poster	Fear Amongst Service Users
	www.drugs.ie	Poster	Fionas Mom
	www.drugs.ie	Poster	Get Trained Up
	www.drugs.ie	Poster	I'd never thought I would save a Life

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	www.drugs.ie	Poster	It was a Light Bulb Moment
	www.drugs.ie	Poster	It will fit into your Bag
	www.drugs.ie	Poster	Naloxone is a Life Saver
	www.drugs.ie	Poster	Naloxone is a Life Saver2
	www.drugs.ie	Poster	Opt IN not out
	www.drugs.ie	Poster	This Person would not have survived
UK/London	http://www.kcl.ac.uk/index.aspx	Guideline/Checklist	Emergency_Card
	http://www.kcl.ac.uk/index.aspx	Information material	OOAS_Information
	http://www.kcl.ac.uk/index.aspx	Information material	OOKS_Information
	http://www.kcl.ac.uk/index.aspx	Questionnaire	Opioid-Overdose-Attitudes_Questionnaire
	http://www.kcl.ac.uk/index.aspx	Questionnaire	Opioid-Overdose-Knowledge_Questionnaire
	http://www.kcl.ac.uk/index.aspx	Presentation for Training	Overdose-Training-PowerPoint
	http://www.kcl.ac.uk/index.aspx	Training Manual	TrainingManual-SupportingInformation
UK/Wales	www.emcdda.europa.eu	Information material	Guidance and Training Protocol
	www.naloxonesaveslives.com	Guideline	Naloxone_Things-To-Do
	www.naloxonesaveslives.com	Training Manual	OD-Rescue_Naloxone_Training
	www.naloxonesaveslives.com	Guideline	Responding to an Opiate Overdose
	www.naloxonesaveslives.com	Guideline	Using Naloxone
	www.naloxonesaveslives.com	Information material	What is Naloxone
UK/Scotland	www.harmreduction.org	Guideline/Checklist	Overdose_Prevention_and_Survival
	www.harmreductionworks.org	Folder/Brochure	Staying_Alive_Booklet
	www.injectingadvice.com	Training Manual	Overdose_workshop
	www.naloxone.org.uk	Guideline	Administer_Intra_Muscular_and_Nasal
	www.naloxone.org.uk	Information material	Drug-related Deaths - What You Should Know
	www.naloxone.org.uk	Guideline	How to Help
	www.naloxone.org.uk	Guideline	How to set up a Naloxone kit
	www.naloxone.org.uk	Information material	NALOXONE_LIFESAVER_Information
	www.naloxone.org.uk	Information material	U-turn_Overdose_App
	www.naloxone.org.uk	Guideline	When to Use Naloxone
	www.naloxone.org.uk	Poster	I Saved My Best Friend's Life
	www.naloxone.org.uk	Poster	I Saved My Son's Life
	www.naloxone.org.uk	Poster	map_drawing
	www.naloxone.org.uk	Poster	Naloxone_Lifesaver
	www.naloxone.org.uk	Poster	I Made The Call
	www.naloxone.org.uk	Poster	Naloxone Saved My Life
WHO	http://www.who.int/features/2014/naloxone/en/	Information material	WHO_Community Management of Opioid OD
Open Society Foundation	www.naloxoneinfo.org	Questionnaire	A PrePost Training Questionnaire_EN

Naloxoneinfo (OSI)	www.naloxoneinfo.org	Fact Sheet	About Naloxone_Stopping Overdose_A Fact Sheet
	www.naloxoneinfo.org	Information material	Power in a Bottle-Expanding Naloxone Access
	www.naloxoneinfo.org	Information material	Starting a Naloxone Program_EN
	www.naloxoneinfo.org	Training Manual	Training Tools_A Sample Curriculum_Training
	www.naloxoneinfo.org	Presentation for Training	Training Tools_A Sample PowerPoint Naloxone Training
	www.naloxoneinfo.org	Folder/Handout	Training Tools_Handout- Get the SKOOP
	www.naloxoneinfo.org	Folder/Handout	Training Tools_Handout- If Someone Overdosed
	www.naloxoneinfo.org	Folder/Handout	Training Tools_Handout- Opioid Overdose Prevention and Survival
	www.naloxoneinfo.org	Folder/Handout	Training tools_Handout- Things to do
	www.naloxoneinfo.org	Folder/Handout	Training Tools_Handout- What Does An OD Look Like

Appendix 55

Further Reading

Effectiveness literature/reviews

- Berland, N. et al. (2017), *Opioid overdose prevention training with naloxone, an adjunct to basic life support training for first-year medical students*. Subst Abus 38(2): 123–128. (USA)
- Black, L. et al. (2017), *Poor implementation of naloxone needs to be better understood in order to save lives*. Addiction 112(5): 911–912. https://www.ncbi.nlm.nih.gov/pubmed/28244244. (Canada)
- Coffin, P. O.; Sullivan S. D. (2013), Cost-effectiveness of distributing naloxone to heroin users for lay overdose reversal. Annals of Internal Medicine 158(1): 1-9. http://annals.org/aim/article/1487798/cost-effectiveness-distributing-naloxone-heroin-users-lay-overdose-reversal (USA)
- Das, S.; et al. (2017), Intravenous use of intranasal naloxone: A case of overdose reversal. Subst Abus 38(1): 18–21. http://www.tandfonline.com/doi/full/10.1080/08897077.2016.1267686 (USA)
- Dichtl, A., Stöver, H. (Hrsg.) (2015), *Naloxon Überlebenshilfe im Drogennotfall*. Hochschulverlag, Frankfurt am Main.
- Doyon S.; Aks S.E.; Schaeffer S. (2014), *Expanding Access to Naloxone in the United States*. Journal of Medical Toxicology, 2014,10(4):431-434. doi:10.1007/s13181-014-0432-1. (USA)
- Elzey, M.J., Fudin, J. and Edwards, E.S. (2016), Take-home naloxone treatment for opioid emergencies: a comparison of routes of administration and associated delivery systems. Expert Opinion on Drug Delivery, 2017, Vol. 14, lss. 9, 2017. http://dx.doi.org/10.1080/17425247.2017.1230097
- EMCDDA (2015), *Preventing fatal overdoses: a systematic review of the effectiveness of take-home naloxone*, EMCDDA papers, Publication Office of the European Union, Luxembourg. http://www.emcdda.europa.eu/system/files/publications/932/TDAU14009ENN.web_.pdf_en (Europe)
- Fairbairn, N. et al. (2017), *Naloxone for heroin, prescription opioid, and illicitly made fentanyl overdoses: Challenges and innovations responding to a dynamic epidemic*. Int J Drug Policy. https://www.ncbi.nlm.nih.gov/pubmed/28687187 (USA)
- Ferri, M. (2014), *Overview of studies on the provision of take-home naxolon*, EMCDDA, http://www.emcdda.europa.eu/attachements.cfm/att_232493_EN_3%20MF%20Overview%20 of%20studies%20on%20take%20home%20naloxone.pdf (Europe)

Further Reading 57

- Lewis, Ch.; Vo, H.T.; Fishman, M. (2017), *Intranasal naloxone and related strategies for opioid overdose intervention by nonmedical personnel: a review.* Substance Abuse and rehabilitation 2017:8, 79–95.
- Pinto, M.; Tele, S. et al. (2014), *Preventing Avoidable Deaths: Essentials and Recommendations On Opioid Overdose*. APDES & Akzept. http://www.emcdda.europa.eu/attachements.cfm/att_233169_EN_Marta%20Pinto%20APDES_Preventing%20avoidable%20deaths.pdf (Europe)
- Somerville N.J.; O'Donnell J.; Gladden R.M. et al. (2017), *Characteristics of Fentanyl Overdose Massachusetts*, 2014–2016. MMWR Morb Mortal Wkly Rep 2017;66: 382–386. DOI: http://dx.doi.org/10.15585/mmwr.mm6614a2 (Massachusetts, USA)
- Sondhi, A. et al. (2016), *Stakeholder perceptions and operational barriers in the training and distribution of take-home naloxone within prisons in England*. Harm Reduction Journal 13(1): 5. https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-016-0094-1 (England)
- Vanky, E.; Hellmundt, L.; Bondesson U; Eksborg; S.; Lundeberg, S. (2017), *Pharmacokinetics after a single dose of naloxone administered as a nasal spray in healthy volunteers*. Acta Anaesthesiologica Scandinavica 2017, 61/6: 636–640. http://onlinelibrary.wiley.com/doi/10.1111/aas.12898/abstract;jsessionid=D2EFB4C7939E 53BC7AE45BE19039C587.f04t03 (Sweden)
- Wermeling, D. P. (2015): *Review of naloxone safety for opioid overdose: practical considerations for new technology and expanded public access*. Ther Adv Drug Saf 6(1): 20–31. https://www.ncbi.nlm.nih.gov/pubmed/25642320 (USA)
- Williams, A. V. et al. (2014): Training family members to manage heroin overdose and administer naloxone: randomized trial of effects on knowledge and attitudes. Addiction 109(2): 250–259. https://www.ncbi.nlm.nih.gov/pubmed/24103087 (UK)

Legal Aspects

- Network for Public Health Law (2017), Legal interventions to reduce overdose mortality: Naloxone access and overdose Good Samaritan Law, https://www.networkforphl.org/_asset/qz5pvn/network-naloxone-10-4.pdf (USA)
- Prescription Drug Abuse Policy System:, Good Samaritan Overdose Prevention Laws. http://pdaps.org/datasets/good-samaritan-overdose-laws-1501695153 (USA)

General THN Information Websites

http://www.naloxoneinfo.org/ (OSI)

http://www.who.int/features/2014/naloxone/en/

http://www.emcdda.europa.eu/topics/pods/preventing-overdose-deaths

 $\frac{https://www.isdscotland.org/Health-Topics/Drugs-and-Alcohol-Misuse/Publications/2015-10-27/2015-10-27-Naloxone-Summary.pdf}{27/2015-10-27-Naloxone-Summary.pdf}$

http://www.who.int/substance_abuse/publications/management_opioid_overdose/en/

http://www.emcdda.europa.eu/publications/emcdda-papers/naloxone-effectiveness

http://www.nta.nhs.uk/uploads/phetake-homenalox one for opioid over dose feb 2015 relations and the properties of the

Further Reading 59