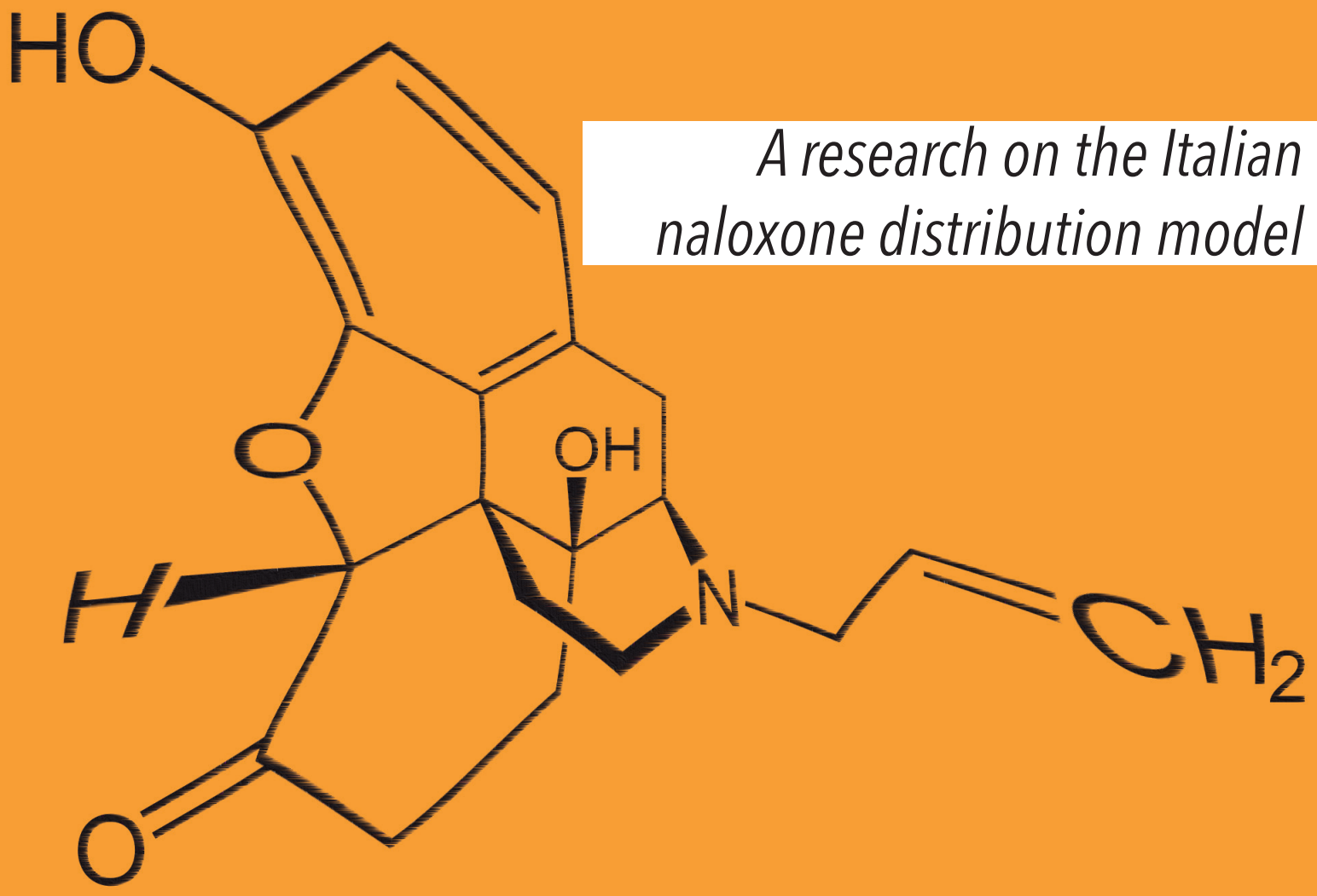
forum droghe

In cooperation with
Eclectica
Addiction Department ASL ex Torino 2
Addiction Department ASL Torino 3
Addiction Department ASL Napoli 1

Preventing opioid overdose deaths



A research on the Italian naloxone distribution model

2016

This research was coordinated by **Forum Droghe** and conducted in partnership with **Eclectica**, who collaborated to the elaboration of the research project, the survey and analysis. Other partners were the **ASL ex Turin 2**, **ASL Turin 3** and **ASL Naples 1** (Local Health Agencies - Addiction Departments), which were all involved in the elaboration of the research project, scientific consultancies in various phases of the project and the activation and guarantee for the survey data.

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Those who actively contributed to the research process were:
ITARDD - the Italian Network for Harm Reduction; **CNCA** - National Coordination for Residential Centers, and the associations **Isola di Arran** and **IndifferenceBusters**.

Susanna Ronconi was responsible for the editing of the research report, in collaboration and consultancy with the research group. Those who participated in the writing up of the report were: **Franca Beccaria**, **Antonella Camposeragna**, **Sara Rolando**, **Paolo Nencini** and **Paolo Jarre**.

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Foreword

This research on the Italian experience of the distribution of naloxone to people who use drugs and in the wider community (Take Home Naloxone-THN) was born from the need to fill a gap of knowledge, information and communications concerning more than twenty years of experience of harm reduction (HR) and risk limitation (RL) correlated to opiate drug use in Italy.

The scientific literature about THN in Italy is scarce and limited to a few local studies and dated, so much so that the more recent international reviews paradoxically rarely include Italy, even if it is one of the few national experiences of THN that is significant in terms of duration, continuity and range of the intervention. An emblematic example is the following: the studies cited indicate 1996 as the year when the first THN intervention began, whereas already in 1991 the first street outreach programs had adopted this method, anticipating what then happened in other countries. It is not the responsibility of international researchers of course for this gap, as they have, and continue to have, difficulty in accessing data and sources regarding the Italian experience.

This shortfall has diverse reasons, the first of which is political in nature. As was stated in the first chapter of this report, the politics of HR in Italy " are done but not mentioned", as a popular saying in Italy goes. As far as the practices go- the interventions and the services, which are spread out in an unequal manner through the regions of this country - they cannot be crosschecked with a clear national policy direction that recognizes HR effectively as one of the operative pillars and a transversal approach in the national drug strategy. The research on HR and therefore on THN pay for this lack of a clear policy direction in terms of inattention and a lack of investment. There are of course also reasons relating to insufficient resources, investment limitations and cuts that place services in difficulty and bring health workers- who are the first observers and experts of this intervention- to neglect monitoring and evaluation of outcomes in favour of front-line work. Further, there is a certain weakness in the otherwise active movement of advocacy for HR, which in Italy has a strong alliance between health workers, associations and PWUDs, but that still today have little impact on orientating policy decisions. Nonetheless, certain gaps in HR research have been closed in recent years by precisely this network, despite scarce or no resources at all.

The lack of studies regarding the evidence and results of THN also has diverse negative consequences. The first among these is the increased difficulty to obtain political support for the practices of HR, in a kind of vicious circle. As important as this, it translates into a lack of knowledge and analysis about the interventions, which are necessary for those very same health workers, in order to adjust objectives, strategies and work methodologies to increase results and suitability.

The idea for this research began a few years ago precisely from the need to evaluate, innovate and develop THN interventions in Italy. It was necessary to identify the strong and the weak points and to accept the challenge of the new drug scene and the relative reorganization of the interventions. The research project had a particular decisive push in the past two years, when some of the researchers- who promoted and conducted this study- began to receive questions on the Italian model of THN from different parts of the world. These were from researchers, health workers or PWUDs who were beginning to organize for a global campaign of advocacy to extend the THN practice to many countries where it is not allowed or where it is not accessible. This is one objective that we strongly share, a campaign which we will join, and one we think we are able to contribute to based on experience. We therefore acted on this "push", finding the necessary support in two private sponsors and in our own (limited) resources.

This is therefore a research that looks in two different directions: one is national- to contribute to the development, the up-dating and the definitive accrediting of THN in Italy. The other is international: to provide the THN campaign with information and knowledge. It is a quanta-qualitative research that involved two groups of protagonists- health workers and PWUDs . We are aware of the importance of developing a systematic data base and we plan to continue to work on this, with new alliances and inviting renewed attention from those institutions that should, as their mission, be occupied with this. Nevertheless, we also

know how much qualitative research can contribute to knowledge when what we are dealing with is human behaviour, organizations, empowerment and health.

This research is a new chapter of that push "from the grass-roots", needed to fill the missing gap in knowledge that definitely has need of more actors (above all institutional) and more resources. Knowing the importance of involving more stakeholders, Forum Droghe (an association for advocacy, training and research on HR and on drug policy reform) has promoted an alliance with a research body (Eclectica), and three Public Addiction Departments (ASL 2, and ASL 3 in Turin and ASL 1 in Naples) which are among the most active regarding HR. It has also involved a wide network of workers in this work: associations, private and public services and individuals who use drugs (among these are ITARDD, the Italian network for HR; CNCA, National Coordination for Residential communities, and for PWUDs, Isola di Arran and IndifferenceBusters)

This alliance is emblematic of the positive face of HR in Italy and its potential.

Susanna Ronconi – Forum Droghe

Acknowledgements.
We wish to thank all the managers, health system workers, professionals and peers, from the public and private sectors and their networks, who have collaborated not only by responding to the questionnaires and participating in the focus groups, but also by making the data regarding their interventions, accessible. We also wish to thank the individuals who use drugs and their associations, who provided valuable contributions of their experiences, reflections and evaluations. Without their adhesion and willingness, this research would not have been possible.

Abbreviations and Acronyms

ART	Antiretroviral Treatment
ASL	Azienda Sanitaria Locale (Local Health Department)
DPA	Dipartimento Politiche Antidroga (National Drug Agency)
EMCDDA	European Monitoring Centre on Drugs and Drug Addiction
HR	Harm Reduction
IM	intramuscolar
IV	intravenous
LEA /ELA	Livelli Essenziali di Assistenza (Essential Levels of Health Assistence)
MNE	Mobile needle exchange
OD	overdose
OST	Opioid Substitution Treatment
PDU	Problematic Drug Use
PWUD	People Who Use Drug
RL	Risks Limitation
SBS	Servizi a Bassa Soglia (Low Threshold Services)
SerD	Servizio Dipendenze (Public Addiction Service, also PAS)
THN	Take Home Naloxone
WHO	World Health Organization

The research report.

Structure

This report illustrates the results of the research conducted during 2016 with drug services workers and people who use drugs, regarding the Italian system of naloxone distribution (Take Home Naloxone-THN). The objectives were to evaluate the strong and weak points of the system and to identify perspectives for innovation and improved efficacy and applicability of the operative models.

Chapter 1 illustrates the rational, the objectives of the study and the methodology and instruments used for the inquiry.

Chapter 2 places the Italian model of THN in context, with data regarding opiate use and correlated overdoses and trends. It also looks at the service systems and the interventions for drug addiction and their interventions for preventing opiate overdose and death from overdose. The second part of this chapter provides a more in-depth analysis of the Italian THN system, identifying significant factors - such as the legislative framework and the pharmacological characteristics of naloxone along with the cost to the public health system. It also illustrates data on activity and process and their trends within the Harm Reduction services who distribute naloxone.

Chapter 3 provides the results of the research in this area, both for health system workers and for drug users. The results of the on-line questionnaires and the in-depth focus groups are respectively described, in two sections following the same structure. A discussion paragraph of the results and conclusions are provided for both groups.

Chapter 4 illustrates the general conclusions and elaborates the recommendations, which are articulated in three areas: operative, policy and research. These are differentiated into general and generalizable recommendations and those specific to the Italian context.

The attached Appendix includes a bibliography of the tests cited, the on-line questionnaires for both drug users and workers and a brief curriculum vitae of the members of the research group.

Abstract

In Italy, the trend for deaths from overdose (OD) has been in constant decline since 1997. Deaths from opiate overdose follow this trend, with 470 deaths in 1999, 280 in 2005 and 101 in 2015. The trend for opiate use, particularly heroin, is also declining, with a prevalence of 8.1 per 1000 in 2004 and 5.2 per 1000 in 2014. Nonetheless, 100 deaths a year continue to be an emergency. There are cities and regions that are more exposed and a slight increase in heroin use in the last two years, also among young people aged 15-19 years, has been noted. The prevention of deaths from opiate OD continues therefore to be a issue of extreme attention for addiction services, as is major attention towards new users and their patterns of drug use.

From 1991 in Italy, the distribution of naloxone (Take Home Naloxone, THN) to people who use drugs (PWUDs) and their family and friendship networks, has been implemented. Today the OD prevention strategy- which in the Italian model is based mainly on the network of Harm Reduction (HR) services- is promoted alongside treatment with substitute drugs (OST), as far as OD prevention is concerned, with the aim of reducing risks. OST and THN are the two “pillars” for OD prevention and for prevention of death by opiate OD that characterize Italian policies. Within this framework, THN is inserted into public policy and in the interventions of public services and accredited private services, while the role of private sales and those from pharmacies remain residual. Factors facilitating this development of “public health “ with THN in Italy, are above all the regulatory framework which establishes that naloxone is an over-the-counter drug, accessible and able to be used by all citizens, at a modest cost (above all for public health), and the pharmacological characteristics of naloxone that make it a “safe” drug.

The strong points in the Italian model of THN- which today is distributed from 57 HR services- are many: the enhancing of competencies and of the network of PWUDs. They are identified as those, who in the majority of cases assist in an OD and represent a strategic resource for first aid interventions; professional consultancy from HR staff, who accompany the consignment of naloxone with information and training

interventions as well as specific advice on correct use; the assumption of a health promotion viewpoint, recognizing the intervention skills of non-health workers, with the possibility of widening and activating a broad network of diverse professions. The Italian experience identifies how THN practices work together to increase awareness of risks, skills for intervention and self-efficacy among PWUDs, in a respectable process of social learning, and for PWUDs over the years, who have learnt to keep naloxone on them and use it in an emergency.

The Italian model has also come up against some weak points, above all the limited coverage, on a national level, of HR interventions which for THN programs are strategic. There are regions which are completely uncovered. There is an underutilization of the treatment system as a potential network for THN as well as a lack of HR services that could efficiently integrate and enhance THN programs, such as drug consumption rooms (DCR) or drug-checking. There is also a total lack of HR interventions in prisons.

The Italian model- described, analyzed and evaluated in this research by socio/health workers and PWUDs- highlights the success of THN, above all when it is centered on the PWUDs network. The basic lack of risks or side effects is testimony to its feasibility and sustainability. At the same time this study identifies challenges and necessary innovations for greater suitability and efficiency in the interventions. These challenges are valuable not only for the Italian model but can also be proposed as "lessons learnt", which could be useful in different contexts. They renew specific objectives for the diverse areas involved: one area is implementation- with great diffusion of the THN network points; an improvement in the interventions in natural drug use settings and the ideation of innovative modes for communication and distribution, specifically regarding new targets (young poly-drug users above all, who have a very low perception of OD risk and few skills), plus accelerating the introduction of intranasal naloxone; multiplying the occasions for training of PWUDs and the support and incentives for peer support; the activation and synergy with new social actors and professionals on the ground and with other health services and addiction services, towards a continuum of interventions. A second area is policies, with a commitment to sustaining HR without ambiguity, as one of the pillars of the national drug strategies, providing clear guidelines and economic coverage; a third one, research, by improving the OD monitoring system, a more in-depth knowledge of drug use patterns, of consumer strategies, and the influences of contexts; monitoring and evaluating interventions, with the aim of promoting efficiency, efficacy and feasibility.

An articulated and reasoned list of final recommendations is proposed as the basis for a national and international discussion and debate.

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1. The Research

1.1 Rationale and Objectives

Preventing fatal opioid overdoses has been, since the 1980s, one of the major priorities of drug policies in the world. In Europe it has been one of the goals – the other being the reduction of HIV infections – which have radically changed global drug strategies and introduced the drug related harm reduction (HR) approach. From the mid-80's, different models of prevention of fatal overdoses were introduced all over Europe, also thanks to the implementation of low threshold services and outreach interventions, which made it possible to reach the hidden population of intravenous (IV) users, unknown to health and drug services. These outreach/low threshold models have shown their efficacy against fatal overdoses, as the European Monitoring Centre on Drugs and Drug Addiction (EMCDDA) data show, and their development and improvement in many member states is still a cornerstone of national drug policy: overdoses are still one of the major causes of death among young people in Europe.

Growing attention is paid to a specific prevention model, Take Home Naloxone (THN), nowadays adopted in a very limited number of states, based on drug users' easy access to naloxone- a lifesaving drug for opiate overdose- and on the empowerment of users' and social networks' skills as a strategic source in fighting overdose risks.
In the last few years in particular, campaigns have been implemented in many countries advocating the sale of naloxone in pharmacies as an over-the-counter drug and making it fully available in drug services and low threshold facilities, for distribution to drug users by all kinds of professionals, not only medical staff[1] .
All over Europe and in many other countries in the world, coalitions of drug users, drug professionals and NGOs are campaigning for THN systems. The EMCDDA itself has published a study to promote and support this practice[2] and the WHO has published guidelines regarding this[3]. Furthermore the availability of intranasal naloxone would increase the possibility for greater distribution and access.
An intensive advocacy action is urgent and necessary, as presently the number of countries where naloxone is an over-the-counter drug is very limited. Consequently, the possibility to implement an effective and widespread prevention strategy, based on the development of drug users' abilities and social networks, is very limited too.

In Europe, Italy has played a leading role in fatal overdose prevention: since the end of the eighties, naloxone has been available in pharmacies as an over-the-counter drug; since the early nineties, it has also been available in many Italian HR facilities (street/outreach units in particular, and drop in centres) and widely distributed to drug users in a "peer to peer" network along with providing information about its correct use and peer education for first aid interventions.
Today there are 57 HR services throughout the country, some with a continuity of more than 20 years, that have been involved in distributing naloxone to thousands of opiate users, in providing "street first aid training" and information, in promoting peer support networks and solidarity attitudes for mutual aid and in increasing awareness in drug users' families and citizens. The HR and outreach staff – both medical and social professionals– have been able to save hundreds of lives, thanks to interventions on the drug scenes. Italian professionals have been monitoring their interventions and have carried out evaluation studies at a local level, with positive results in terms of efficacy. Nevertheless, a thorough national evaluation study has never been undertaken to analyse THN processes, methodologies, sustainability and outcomes. The

1http://www.eurohrn.eu/index.php/overdoe-campaign;
http://www.eurohrn.eu/images/stories/pdf/publications/models of community report.pdf
http://www.eurohrn.eu/images/stories/pdf/publications/study report euroHRNII.pdf:
http://www.opensocietyfoundations.org/publications/stopping-overdose; http://www.naloxoneinfo.org

2 In EMCDDA (2015) Preventing opioid overdose death with Take home Naloxone in http://www.emcdda.eurpoa.eu/publications/insights/take-home-naloxone

3 WHO (2014) Community management of opioid overdose, in www.who.int

current international advocacy movement for naloxone availability is requiring more information and knowledge from Italian professionals and users on the "Italian model", in particular the European and international networks and NGOs. The 20-plus years of Italian experience is seen as a source of learning and competencies, useful for everyone who will promote, support and implement such a strategy, and could be an evidence based support to the advocacy campaign.

This current research has the general aim of providing information about the "Italian model" of naloxone distribution in terms of approach, operative models, methods and tools for the intervention and analysis of both the strong and weak points of this model. In particular the objectives are:

- to provide information and analyses of the context factors and the system that has facilitated the adoption of the THN model in Italy
- to provide data on HR interventions at a national level regarding access to naloxone (2000-2015)
- to compile an assessment study of the operative THN model by adopting a double perspective: that of health and social workers and that of people who use drugs (PWUDs), also highlighting agreements/disagreements between these perspectives
- to analyse the intervention models, methodologies, work tools and organizational models, to highlight factors of success and weak points.
- to identify, based on the research results, best practices also with a prospective of up-dating the Italian model
- to identify, based on the research results, some recommendations useful for reproducing the THN model in other contexts.

1.2 Methodology

The research adopted a quant-qualitative method (mixed method) and worked using two tools: on-line questionnaire and focus groups.

1.2.1 On-line Questionnaires

a) Research aimed at health service workers

The questionnaire (Attachment 1) given to workers in the public and private services for dependencies, was constructed using SurveyMonkey© software for on-line surveys and sent to potential respondents using a mailing list (which included the Addiction Departments in 30 major Italian cities). This list was constructed ad hoc by the working group with the main intention of contacting services who distribute naloxone. It also used the web site www.itardd.com of the Italian Harm Reduction (HR) Network that unites workers, associations, Third Sector organizations and users (PWUDs). The request to compile the questionnaire was accompanied by a brief letter that summarized the aim of the research and indicated the average time needed for compilation (10-15mins). A request was made that the questionnaire be answered by a person in charge of the service operations and /or health and social workers (professionals and peers) who had direct knowledge of the practice of distributing naloxone and an "historical" perspective. In cases where the organizations were composed of more than one service (for example Public Addiction Services- SerD, drop-ins and mobile needle exchanges-MNE) more than one worker and up to a maximum of three workers were invited to complete the questionnaire per service.

The questionnaire was sent, via web and via mail, on the 20th April 2016. Two recalls were made, the first on the 19th May and the second on the 16th June, with an extension to the expiry date, given that many of the attained responses were incomplete. At the end of collecting the responses, the data set attained (144 replies) was organized and the incomplete questionnaires were eliminated. Those with at least 50% of the questions answered were retained. It is noted that a very high number of respondents abandoned the compilation almost immediately, and then began again at a later time as the presence of double IP addresses suggested. Others, less numerous, replied to the research questions but did not complete the data relating to the respondent or the service. Finally, a small number of respondents interrupted the compilation half-way through the questionnaire.

Following this procedure, a final sample of 63 questionnaires were obtained, of which 44 were from

services that distribute or had distributed naloxone in the past to PWUDs. This is a satisfactory result if one considers the in last published Annual Report to Parliament on the state of drugs and drug addiction in Italy 2016 (data up until 31/12/15), 57 HR services declared they distributed naloxone.
The data received was processed using the S.P.S.S. Software version 20.

b) Research aimed at people who use drugs (PWUDs)

The questionnaire aimed at PWUDs (Attachment 2) includes the following areas: demographic characteristics of the PWUDs (age, gender, geographic residential area); actual use of opiates (mode, frequency, years of use), previous experience of opiate overdose- personal and of others (where they assisted); knowledge of naloxone and its use. For this question a reduced version of the Opioid Overdose Knowledge Scale was used[4].
The questionnaire was self-administered and the compilations were available in two modes: paper and on-line. For the on-line compilations, the platform SurveyMonkey© was employed, which provides a high guarantee of protecting sensitive data and privacy, using the protocols of the SSL network and employing the data protection of Norton and TRUSTe.
The questionnaires were anonymous. Even though the data was returned in an aggregated manner, nevertheless permission was requested, conforming with the intent of the DL 30 June 20013, n.196 (Italian Law on Privacy).
The requirements for eligibility for the sample were the following: being of age (18 years and over) and having used opiates outside of those medically prescribed, both intravenously and via other modes of administration, at least 10 times in the past year (the 12 months previous to the data compilation). For opiates is was intended: heroin, morphine, opium, methadone -assumed outside of a treatment regime.
The recruitment of the sample occurred via the internet (network sites and willing associations) as well as drop-ins, day centers, MNEs, and SerDs -who provided logistical and organizational support necessary for the compilation (access to a computer, internet connection, even distributing the paper version of the questionnaire). Some SerDs and HR services also spread information about the research so that people could choose autonomously to participate, providing a link to respond to the questionnaire. This link was sponsored by the Forum Droghe site: www.fuoriluogo.it and by www.sostanzeinfo.it (an information, advice and drug-use self-management site managed by the Florence Local Council).
Collaboration was also requested from the Italian Network for harm reduction (ITARDD), the National Coordination for Residential Communities (CNCA) and from Forum Droghe for the diffusion of the research. There was a 7 week period for administering the questionnaire: from 13th May until the 27th June 2016.
The statistics utilized were the Z test for the discreet variables and the median test, using a index of significance p^ 05, while the student T-test was used for continuous variables.
The SPSS software version 19 IBM was used to analyze the data.

1.2.2 Focus Groups

Four focus groups were conducted, two with health and social workers and two with PWUDs. The focus groups were managed according to a semi-structured outline aimed at getting in-depth information about the more significant themes that emerged from the questionnaires, according to the opportunities offered by qualitative research.

With respect to the health and social workers involved in THN programs, one group was held in Naples and the other in Turin. They involved public and private workers in the drug field from services that are the most active in distributing naloxone in different regions. 18 health workers participated overall, coming from the private social sector (9)- cooperatives, associations and foundations that manage low-threshold services, and from public services- local council (1) and above all the SerDs (7) which also include the drop-in services, and the MNEs. The cities represented are: Brescia, Collegno (TO), Florence, Latina, Milan,

4 In EMCDDA (2015) Preventing opioid overdose death with Take home Naloxone, cit

Naples, Perugia, Prato, Reggio Emilia, Rome, Settimo Torinese (TO), Turin, Venice.

The recruitment of the workers occurred via direct contact with the researchers, according to criteria of including representatives from different geographic areas, cities of different dimensions, public sector and private sector and diverse professions.

The focus groups were facilitated by a researcher using a predisposed outline. The outline for conducting the group included the following areas:

- strong points and weak points of the Italian model of THN
- results obtained
- analysis of the intervention over time, trends and future scenarios
- THN and the Italian drug policy, critical aspects and perspectives
- objectives and concrete proposals for the development of THN in Italy

In reference to the focus groups for PWUDs, the participants came from Turin (and surrounding areas) and from Naples. There were a total of 13 people, 8 from Turin and 5 from Naples, including 2 women. The ages ranged from 27 to 56 years, with a median age of 45 years. Of the 13 participants, 5 had had at least one opiate OD in their lives (3 from Turin and 2 from Naples); 8 had given aid to someone else (5 in Turin, 3 in Naples) and only 2 participants (who do not use intravenously), had not had a personal experience nor had the occasion to assist in an OD or help someone.

Given the objective of getting more in-depth knowledge about the Italian model of THN from the viewpoint of PWUDs, two places were chosen- Turin and Naples- where it was considered possible to recruit PWUDs who had direct experience of access to this service. These two cities are in fact among those where HR interventions have been the most continuous (active for 20 years or more) and present a minor reduction in dedicated resources with respect to the national average. Furthermore, the contacts in the local SerDs and HR services guaranteed major efficiency in distributing the questionnaire to PWUDs, which is why the respondents in these cities were numerically greater than in the rest of Italy.

The enlisting of PWUDs was done via direct contact on behalf of the researchers, with members of PWUDs associations, and through the activation of workers in low-threshold services in both cities. In Turin the focus group was held in the offices of the association “Isola di Arran”, a peer association. In Naples it was held in the offices of the SerD. All participants were offered a gadget for their participation.

The focus groups were facilitated by a researcher using the predetermined outline. This outline included the following areas:

- perception of the factors for OD risk
- competencies around OD and experience in using THN and relative opinions
- competencies among young PWUDs and generational relationships
- system of distributing THN: opinions on the efficacy of the HR services, perspectives and developments
- obstacles for improving the diffusion of THN
- advocacy, lessons learnt and a message to the international movement for access to THN

Analysis.

The focus groups were registered and transcribed and the texts were then analyzed according to the methods proposed by Grounded Theory[5]: a reading according to an inductive approach that from narratives, events and opinions arrives at a construction of concepts and interpretative categories.

5 Glaser B, Strauss A. The Discovery of Grounded Theory. Chicago: Alcan; 1967; Glaser B. Theoretical Sensitivity. San Francisco: Sociology Press; 1978

The texts were broken down into significant units, sections of which were then coded. Through a selection process of codes and a second integration according to criteria of affinity of meanings, the process of constructing more general concepts proceeded. Once the concepts were selected then interpretive categories were established. These categories constructed in this way and based on the data, consented to the formulation of an interpretation of the results.

1.2.2 Activity Data

The research included data gathered regarding the processes inherent to the activities of some of the HR services that have distributed naloxone with the most continuity and for the longest time. This data was integrated with that obtained from the on-line questionnaires for the health and social workers. This monitoring was proposed to 20 services, of which 10 provided sufficiently complete answers. The data covered a time period from 2000 until 2015 (relevant data for the 1990's was not available in electronic format). Of the 10 services who replied, 5 gave data for the total period 200-2015, while 1 service provided data from 2001; 1 from 2006; 1 from 2007; 1 from 2009 and 1 from 2011.
The data includes: number of vials of naloxone distributed each year (10 services responded); number of contacts (all of the services offered) per year (10 services); number of clients (physical people) (6 services), number of counselling sessions on THN (6 services); number of informative THN materials distributed (4 services); number of first aid interventions by health or social workers of that service (5 services); number of group training courses on THN (3 services) and the number of first aid interventions reported/ done by clients of the service (2 services).

2. The THN model in the Italian system[6]

2.1 The background (1). Opiates drug use in Italy and cases of overdose

2.1.1 Trends in heroin use and other opiates

In order to have a picture of opiate use in Italy, the available sources are data on seizures, which give limited indications as to what quantity of drugs are available on the market, and the prevalence estimates by problematic users (PDUs). These key indicators are among *the five indicators used by the EMCDDA to provide estimates which are comparable and scientifically founded, on the prevalence of the more problematic patterns of use, which cannot be realistically measured by research*[7]. PDUs are considered habitual intravenous users of opiates and cocaine, who in the Italian context coincide mostly with intravenous users of opiates.

The estimates of prevalence use the treatment multiplier method, based on data of people in treatment to which are added data coming from other official sources. The prevalence is calculated on the general population aged between 15 and 64 years.
The estimates indicate a reason decline in users of opiates in Italy, going from a rate of 7.7% (range 7.4-8.0) estimated in 1996 (corresponding to 299.000 persons), to 8.1 (range 7.8-8.3) in 2004 (approximately 312.000), to 5.2 (range 4.5-5.7) for the last estimate available (approximately 203.000 people) relative to 2014.

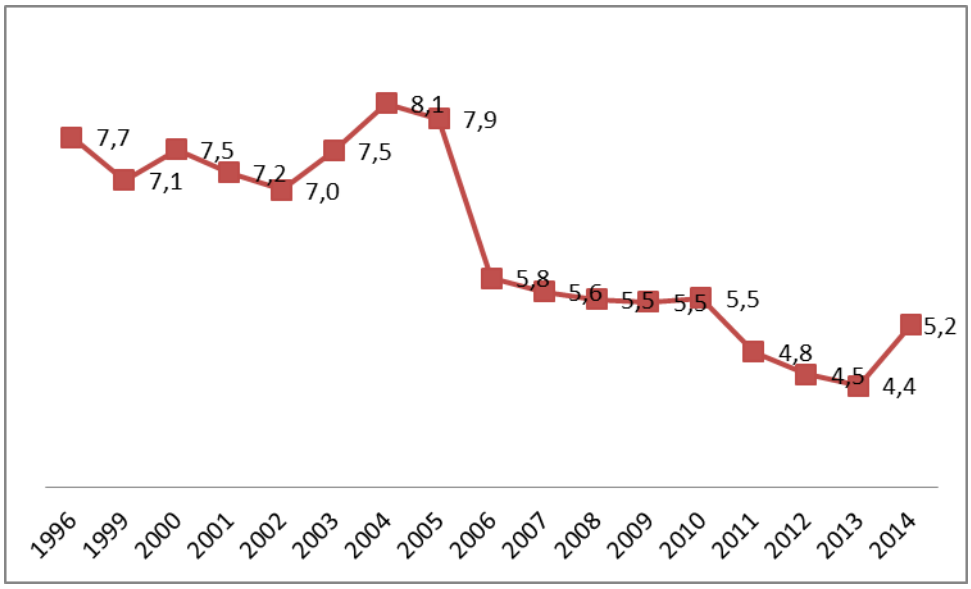

Fig. 2.1 Rate of prevalence PDU per 1000 inhabitants (15-64 years), Italy. Elaboration of data published by EMCDDA Statistical Bulletin(years 2004-2015)

Compared to other countries in Europe, Italy is among the 5 countries with the highest rate of PUDs, as reported in the last European Drug Report[8] published by EMCDDA.

[6] By Susanna Ronconi and Antonella Camposeragna, with the contribution of Paolo Jarre and Paolo Nencini

7 EMCDDA (2004), Guidelines for the prevalence of problem drug use (PDU) key indicator at national level http://www.emcdda.europa.eu/html.cfm/index65519EN.html

8 http://www.emcdda.europa.eu/system/files/publications/2637/TDAT16001ITN.pdf

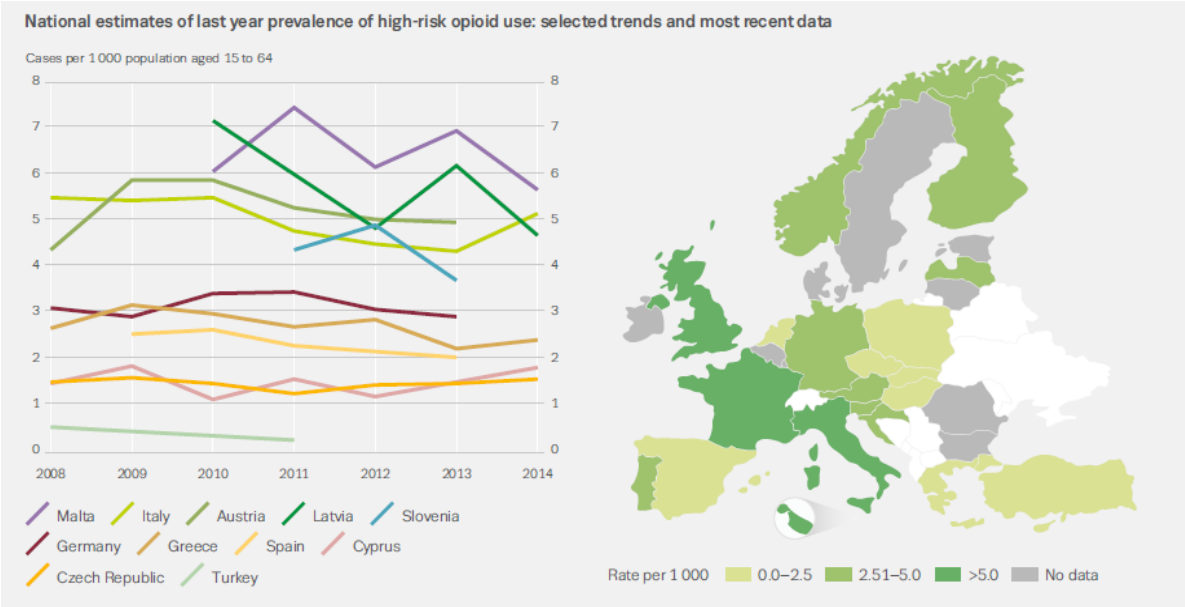

Fig. 2.2 From the EMCCDA Drug Report 2016 pag.50

The official data for opiate users in treatment, provided by the National Information System for Addiction (SIND)[9], of the Ministry for Health, demonstrates a consistent decline starting in 2010 of people in treatment for opiate addiction, with an inversion in this tendency in 2015[10].

Fig. 2.3 People in treatment in Public Addiction Services and people in treatment for opiates (as a primary or secondary drug), Italy. Elaboration of data Annual Report to Parliament, years 2000-2016

Over time the percentage of heroin consumers among the total people in treatment is declining, going from over 85% in the first part of 2000 to 70.1% in 2015, while there is an increase in people who use cocaine in treatment.

9 Source: DAP – Annual report to Parliament on the state of Drug Addiction in Italy, years 2000-2015 http://www.politicheantidroga.gov.it/attivita/pubblicazioni/relazioni-al-parlamento.aspx

10 data relating to the years 2014-2015 have been collected in different ways with respect to preceding years (2008-2013), therefore an underestimate is possible in that the coverage of the SIND is not equal to 100%. In the preceding years, to avoid he problem of total coverage, adjustments to this were made. (cfr Relazione annuale al Parlamento sullo stato delle Tossicodipendenze in Italia2015, http://www.politicheantidroga.gov.it/media/752325/parte%20iii.pdfpg 389)

The data reported by the EMCDDA[11] and provided by the National Focal Point (DPA-National Drug Agency) reported for 2014 that the proportion of opiate users (as their first choice of drug) who were accessing treatment for the first time (incident cases) dropped to 41%. According to SIND, people in treatment for opiate addiction getting substitute drugs therapy (OST) numbered 75.964, of which 90% received methadone(68.385) and the rest were receiving buprenorphine.

With respect to the use of opiates (heroin) in the younger population (study on Italian students aged 15-19 years[12])a net decrease was registered from the years 2000-2009, with use in the last year going from 2.8% to 1%. Nevertheless, between 2010 and 2014, there was an inversion of this tendency, with an increase from 1% to 1.3%. The same trend was seen for frequent use (10 or more times in the last month), with an increase of 0.2% to 0.6-0.7%. Around one-third of students who had used heroin in the past year declared to have used it occasionally (5 times in a year) and about 50% had used it more frequently (20 or more times in a year).

In conclusion, if opiate use in Italy registers overall a decrease over time, it nevertheless remains a significant phenomenon, and the last two years register a variable trend, with a increment, though limited, refers to the younger generation.

1.1.2 Drug-related deaths

Cases of death from OD, regarding all drugs, are declining overall in Italy, a trend confirmed by diverse models and data collection agencies[13].
The episodes of OD are gathered in Italy by a Special Register (RS) of mortality by the Central Directive for the Anti-drug Services (DCSA) for the Ministry of Home Affairs. They collect data of episodes where the Police Force were involved based on circumstantial evidence (unequivocal signs of intoxication from psychotropic drugs). Based on data provided by DCSA, from 1999- the year when 1002 cases of death from OD by psychotropic drugs were registered (all drugs) - there has been a decrease in this phenomena up until 2013, registering 517 deaths annually. From 2004 to 2007 the situation was stable, with a discreet variation between 551 and 653 deaths. In the following years a new decline was observed that reached a minimum of deaths at 365. There was a slight increase in 2012 (393 deaths) and then a drop to the minimum registered in 2015 of 305 deaths.

Mortality from acute intoxication of drugs, as reported in figure 4. demonstrates a trend in net decline over the past 20 years. The drug-related death rate correlated with the adult population (15-64 years) regarding 2014 is 8.0 deaths per million inhabitants. This is notably lower than the European mean (19.2 deaths per million[14]), as reported by EMCDDA in the last European Drug Report.

11 http://www.emcdda.europa.eu/data/stats2016

12 CNR - National Council for Research and ISS – Ministry of Health, ESPAD STUDY 2015 (The European School Survey Project on Alcohol and Other Drugs), in DAP - Annual Report to Parliament on the state of drug addiction in Italy, 2016 http://www.politicheantidroga.gov.it/attivita/pubblicazioni/relazioni-al-parlamento.aspx

13 General Death Registry (RGM) - ISTAT; Special Registry (RS)64 - a DCSA Ministry of Home Affairs, reference to deaths directly attributed to drug use where the Police Force intervened.

14 http://www.emcdda.europa.eu/countries/italy#pdu

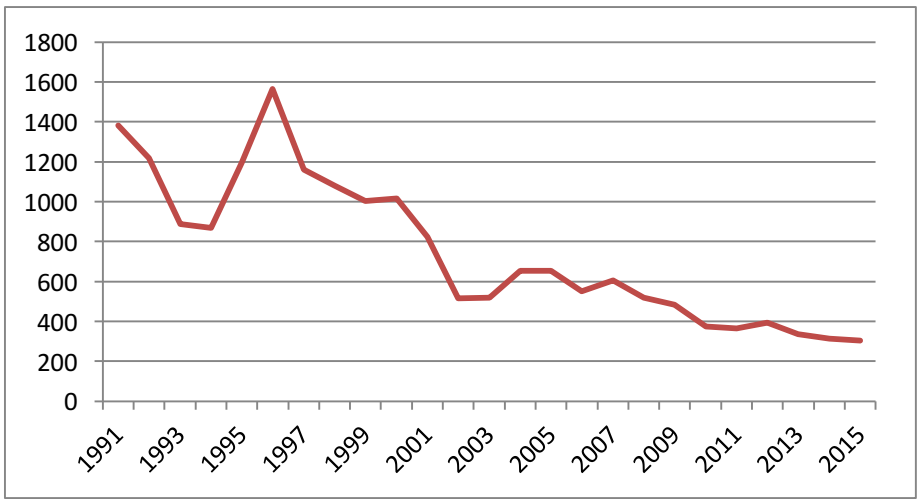

Fig. 2.4 Deaths from overdose by psychotropic drugs over time. Elaboration of data DCSA Ministry of Home Affairs

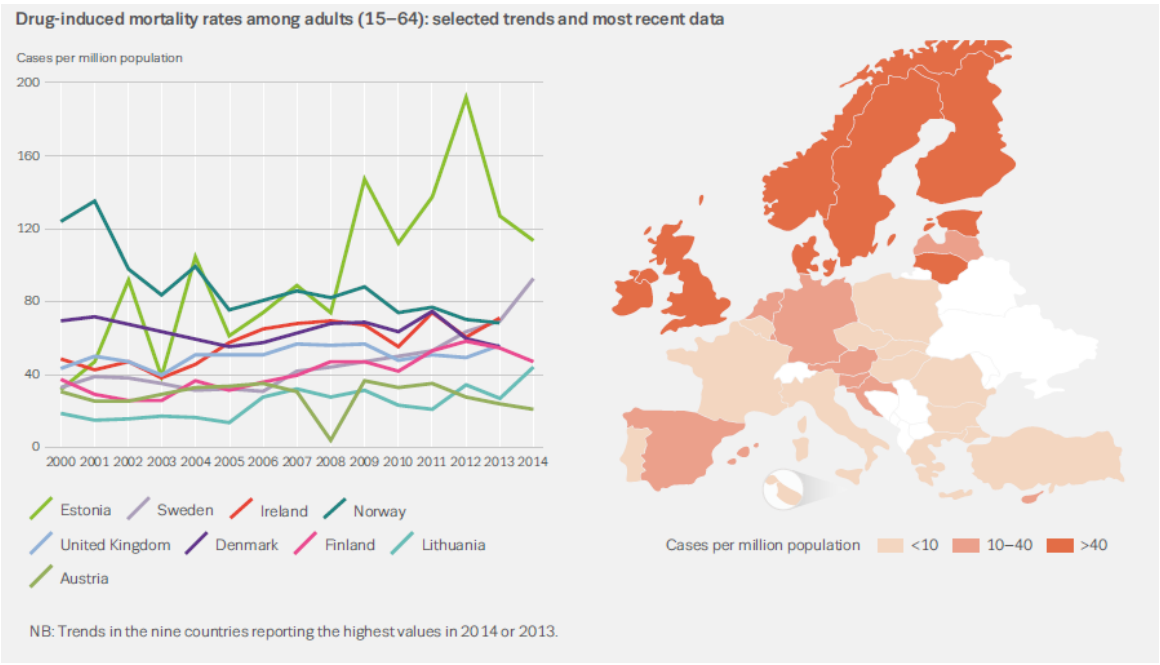

Fig. 2.5 Taken from EMCCDA Drug Report 2016 pag.69

The available data[15], disaggregated at a provincial level for place of death relating to the last year (2015), indicate that deaths occurred in 83 out of 110 provinces and 35% of cases were verified in Bologna (22 cases), Turin (22), Naples (21), Rome (21), Florence (12), and Sassari (12). *"In 93.1% of cases a coincidence was observed between province of residency (including foreigners who live in Italy) and the province where the deceased was found. This leads to hypothesizing on a reduction in drug nomadism, probably connected to the ease of finding drugs in loco if not actually at home"*[16]
At a regional level, the major number of deaths occurred respectively in Emilia Romagna (41), Campania (27), Lazio (33) Tuscany (33) and Piedmont (32).

The certainty that these deaths were due to acute opiate intoxication is confirmed only in cases where the judiciary authority gives a pathologist the authority to undertake verification, such an autopsy, when necessary, and toxicological analysis to support or otherwise the diagnosis.
Deaths from opiate OD have fallen as has the mortality rate for deaths due to psychotropic drugs, following the general trend. From 1999, when 470 deaths attributed to heroin OD were registered, there has been a

15 Idem
16 Idem

decrease in the phenomena, if not linear, arriving at 280 cases in 2005 (the only year that showed a marked inversion in this tendency), to 154 cases in 2010 (a year that had a decrease of -34.7% with respect to the previous year) down to 101 cases in 2015.
For 2015[17], these deaths account for 33% of total fatal OD. This percentage is falling, while those of death by unspecified drugs is rising, to 51.8% of the total (it was 44.5% just one year previous). This figure alludes to the poly-consumption of drugs as to the difficulty in identifying the new molecules that are becoming available on the market.
In general OD that can be attributed to opiates without doubt, range from 30% to 50% of total OD and from 90% to 65% of OD that have been examined toxicologically.

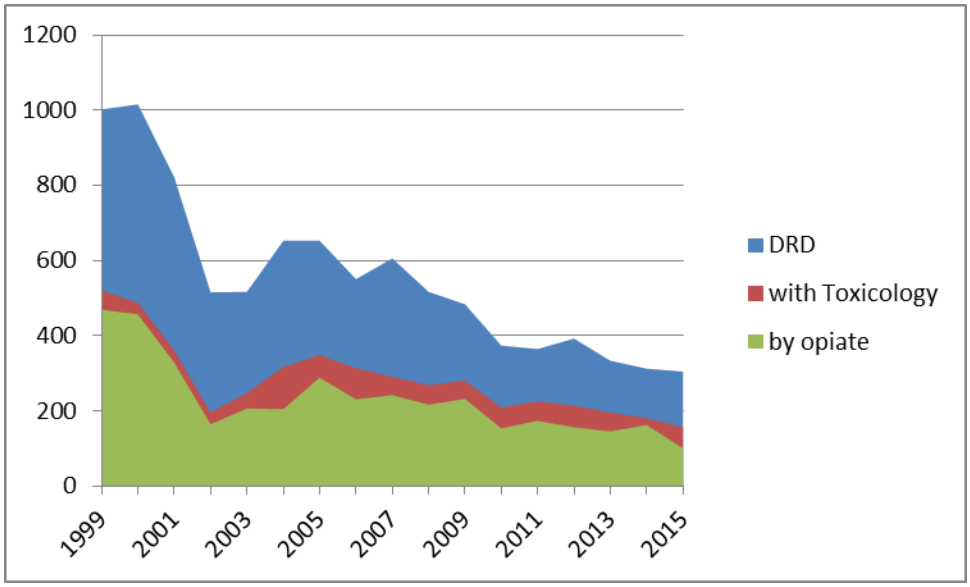

Fig. 2.6 Deaths from OD by psychotropic drugs (Drug Related Death), and by opiates, over time. Elaboration of data DCSA Ministry of Home Affairs

2.2 The background (2). Interventions for the prevention of overdose (OD) and deaths by OD from opiates

Italy has a system of public health services – SerD, Addiction Services[18], for the prevention, treatment, rehabilitation and harm reduction (HR) for drug and alcohol related problems. Within the national health services, there are 525 of these services with 638 facilities present throughout the country[19]. The services are organized regionally and the public system can operate in synergy with private social organizations (the third sector) according to models of accreditation and conventions that are diversified in the 20 Italian regions. This constitutes a model which is not homogeneous under the profile of operative and organizational models.
The access to treatment in the public system or the private accredited system is guaranteed to all citizens. Treatments offered-such as psychological support, pharmacological treatment (OST), clinical tests, antiretroviral therapy (ART)- are guaranteed nationally through the LEA- Essential Levels of Assistance. These health services are established at a national level and coordinated between the central government and the Regions, and the Regions are obliged to guarantee these services to all citizens[20].
Until 2016, the HR services were not included in the LEA and this led to great variability and uncertainty. With no cogent national directive, the HR services depended on the political choices of the local regional

17 Idem
18 TU309/1990 and successive modifications
19 DPA- Department Politiche Antidroga (2016). Report to Parliament on data relative to the state of drug addiction in Italy (2015 and first quarter 2016) in http://www.politicheantidroga.gov.it/
20 Idem; the actual LEAs were defined by a Presidential decree from the Council of Ministries on 29th November 2001, enacted on in February 23 2002; the 2016 revision of LEA introduced new services.

governments. In 2016 the LEA were revised and HR was introduced and during 2017 the relative services should be definitive. In 2000 and again in 2008, working groups of experts compiled the guidelines for HR[21] but in both cases, these did not become operative due to changes in governments that were not favourable to adopting a HR approach for national policies. Both versions explicitly provided for the distribution of naloxone to drug users, accompanied by adequate training and information, with the election of mobile street units and drop-in services to provide this service.
As will be seen, this lack of national direction, political and operative, clearly influences the homogeneous offer of THN throughout Italy and represents one of the critical nodes in the system, which has for years been the centre of an intense advocacy campaign by professionals and civil society. The new LEA in 2017 would include and guarantee THN all over the country.

2.2.1 The role of the SerDs

The SerDs are an important pillar in the interventions for drug addiction, as they are the most capillary network present throughout the country. However their 638 walk-in centres are modest promoters of THN[22] diffusion, which is almost exclusively based on the low-threshold services of HR (drop-ins, mobile needle exchanges, outreach work in natural settings). These services are 98% part of public/private accredited[23] system but, on the contrary to the SerDs facilities, they are present in an unequal and discontinuous way through the country, as is described in the successive paragraph. The modest role of the SerDs centers in the utilization of THN is one of the problematic knots that weakens the potential of the Italian system.
Nevertheless, in terms of an integrated system of interventions, of *cycle of overdose management*[24], the SerDs cover an important role, intervening with treatments of substitute medicine, methadone and buprenorphine (OST) with the aim of lowering OD risk. In Italy, treatment with substitute medicines is a service guaranteed by the public health system, even if recent figures suggest a limited coverage of 57% of problematic consumers of opiates (PDU)[25]

Methadone and prevention of OD in Italy[26]
The use of methadone in Italy goes back to the mid-1970's, with the first experimentation of its use intravenously, mostly in private clinics. The end of the 1970's saw the beginning of the first public drug addiction services (called Medical centers and social assistance, CMAS) in some of the principal cities (Law 685/1975). In the first period of use, the "rehabilitative " effects, described in the '60s by Vincent Dole, were privileged, in particular in the method of MM (methadone maintenance): a reduction in needing street drugs; in pathologies and in the associated micro-criminality; an improvement in scholastic and work-related functioning. Alongside methadone, morphine was also continued to be used as a substitute in some Italian cities for some years (Naples, Florence, Rome).

21 Ministry of Health- Minister of Social Solidarity (2000) Guidelines for HR http:// emcdda.europa.eu/attachments.cfm/att231450 EN IT; Health Ministry (2008) guidelines for HR and risks of pathological dependencies in www.fuoriluogo.it

22 There are no available official data on SerDs walk-in centers that adopt a THN practice. This study has gained data by involving the SerDs of 30 major Italian cities. Of the 21 SerDs who replied, 11 said they distributed naloxone. This data appears to be overestimated: it is probable that in some cases the reply referred to the HR services that are managed by the SerDs itself.

23 Ronconi S. (2016) HR investments: Italy Case Study in HRI- Harm reduction International. Harm Reduction Investments, in publication: Forum Droghe- CNCA (2016) HR and Risk limitation, in DPA- Dipartimento Politiche Antidroga (2016), Report to Parliament on relative data on the state of drug addiction in Italy (year 2015 and first quarter 2016) in http:// www.poilitichеantidroga.gov.it/

24 According to the model *cycle of overdose management* " to impact of deaths by overdose it is necessary to have a combination of methadone therapy, community education, family support, shooting rooms, naloxone distribution for users", in EUROHRN (2014) preventing Avoidable Deaths: Essentials and recommendations on Opioid Overdose in http://www.eurohrn.eu.eu/images7stories/pdf/publications/studyreport euroHRN II .pdf

25 DPA: Dipartimento Politiche Antidroga (2014) Report to Parliament o the state of drug dependency in Italy, in htpp:// www.politicheantidroga.gov.it/

26 Written by Paolo Jarre

In those early years, no-one in Italy hypothesized the use of methadone as a drug for preventing OD, even if in fact high dosages and a widespread practice of self-management created the necessary prerequisites for protection for a large portion of heroin addicts who used the services.

The 1990's, "treatment prohibition"
From the mid-1980's until the mid 1990's (during the full HIV explosion!), in Italy "treatment prohibition" was a diffuse practice, with the prohibitionist offensive by Italian politicians infatuated by the Reagan "war on drugs" ideology and the demonization of methadone as a "state drug" by various and powerful sectors of the therapeutic communities. In the Italian Regions there began to flourish certain measures of limitations of the dosages of methadone "ope legis" (for example in Piedmont, a letter from the Health Councillor in the mid-80's sanctioned the limit as 40mg/day). Official deaths from OD from heroin in Italy -which had been less than 100 a year since 1985- were more than 500 cases in 1990 and reached an historical high of almost 700 in 1996 (in 2015 there were 101). Following the approval of the TU 309/90 (still enforced today, modified), the Decree 445 of the Ministry of Health imposed the use of methadone only on a sliding scale and short-term (this decree expired in 1993 with a referendum which modified the law 309/90 to a less punitive law). Overdose was described and treated as a "fatality" connected to the nature of drug addiction problems and almost no-one voiced a doubt that this could rationally be prevented from happening with the timely use and adequate dose of opiate-antagonists.

The mid-1990's. The HR approach
Things began to change in the second half of the 90's, thanks to a progressive spreading of the first HR interventions (including THN). This was due to the tenacity of a minority of SerDs workers who never stopped studying and practicing "in science and conscience" and to the first studies promoted by the regional epidemiological Observatories, who clearly stated in black and white the inadequacy of many SerDs practices, with respect to what the scientific literature prescribed. The obvious was "discovered": methadone used in doses between 40 and 80 mgs also produces, other than the suppression of withdrawal symptoms, a saturation level of receptors such as to make an OD from heroin taken successively, extremely improbable.

From 2000 until today
Dosages prescribed today in Italy have progressively been in the last 15 years, those prescribed by the scientific literature (the Italian median actually is above 60 mgs), but what is still missing is the concept of a methadone intervention ad interim with the aim of being protective, to initiate in an opportune manner even in non-treatment contexts (needle exchanges programs, drop-ins). In fact this is what happens today in Italy, but without full understanding and therefore a correct and fair plan shared with the patient. Instead an argument often incurs, the very opposite of the "treatment prohibition" era when reduction was imposed, where the person is to be convinced to increase their dosage to protect him/her. Often the user prefers a lower dose to suppress withdrawal symptoms but not the effect of heroin which is used for pleasure.

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Journal of substance abuse treatment, 2014 Mar;46(3):306-14

Degenhardt, L., Larney, S., Kimber, J., Gisev, N., Farrell, M. et al. The impact of opioid substution therapy on mortality post-release from prison: retrospective data 2014, Addiction. doi: 10.1111/add.12536

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substitution treatment
2010, British Medical Journal (Clinical research ed.) 341, p. c3172.doi: 10.1136/bmj.c3172.

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BMJ open , 2014 Apr;4(4):e004666

Kimber J, Copeland L, Hickman M, Macleod J, McKenzie J, De Angelis D, Robertson JR
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Cornish R, Macleod J, Strang J, Vickerman P, Hickman
Risk of death during and after opiate substitution treatment in primary care: prospective observational study in UK General Practice Research Database.
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2.2.2. The Role of HR services

The Italian model of THN, and in general the prevention of OD from opiates and deaths from overdose, is strongly rooted in the operative HR system and the network of low-threshold services (SBS).
As the results of this research have amply demonstrated, there are strong and weak points in this. The first positive points are above all the possibility of reaching PWUDs who are not in treatment; to provide them with information and training regarding naloxone and the methods of prevention and first aid; to educate people in the local context and work to get them to become allies and not obstacles, all of which apply to the fundamental guidelines and criteria for an efficacious policy of THN[27]. The strongest point is above all the quality of the relationships that the SBS have established with their clients: the attitude of listening; of beginning with the objectives of the PWUDs; adopting the client's perspective when considering behaviours and problems; assuming an empowering viewpoint capable of seeing and valuing competencies and knowledge; the familiarity of thinking and acting within a group dimension and the attention to cultural and context variables. All of these aspects are typical of the HR method, as they construct an approach which efficiently (and more efficiently than traditional therapeutic relationships) promotes empowerment, responsibility and social learning[28].
The SBS interventions for the prevention of OD or deaths by OD, other than consigning THN, consist in:
. individual counselling on safer use
. information and consultancy for an OD intervention
. the distribution of informative materials
. support and the dynamics of peer support between clients
. the formation of groups for safer use and for emergency interventions
. collection and diffusion of information and an eventual warning system on drug quality based on client information
. placement of naloxone vials in places where PWUDs frequent
. direct first aid interventions by health and non-health staff.

At the same time, the dominant role of SBS can be measured against the limits of HR in Italy and with the current trend that sees these services reduced and redefined: a recent study has estimated that the coverage

27 WHO (2014) Community management of opioid overdose, in http://www.who.int/substance_abuse/publications/management_opioid_overdose/en/ ;EMCDDA (2016), Preventing opioid overdose with take home naloxone, in http://www.emcdda.europa.eu/publications/insights/take-home-naloxone ; EMCDDA (2015), Preventing fatal overdoses: a systematic review of the effectiveness of take-home naloxone, EMCDDA Papers, in http://www.emcdda.europa.eu/system/files/publications/932/TDAU14009ENN.web .pdf ; EUROHRN (2014), cit

28 Ronconi S. (2003) Peer Support e servizi a bassa soglia (con Molinatto P.), EGA Ed.

of services such as drop-ins and mobile needle exchanges does not exceed 15% of estimated problematic users (PUD)[29]. This figure is strongly correlated to the limits of policies, as cited above. In fact only 2.4% of HR services have a source of funding that is not public. Almost the entire services are sustained by the SerDs, the Regions or the Municipalities[30], which are tied to national and regional choices in terms of policies for addiction services budgets.

SBS services

At the centre of the Italian system for THN are the drop-ins and the mobile needle exchanges for HR, and in a more limited manner, outreach interventions in entertainment venues and night clubs. The most recent monitoring of HR services relative to 2015[31], revealed 115 HR services in total, of which 104 had provided the data requested for the research. Of these, 35 are mobile needle exchanges for HR; 34 are outreach interventions for risk limitation in entertainment places; 23 are drop-ins and 12 are services of another kind. This network of SBS is widespread throughout the country in a very unequal way, with entire areas without any HR services, including THN. As can be seen from the map, there are entire regions in Italy which are without any HR services, with the South and the Islands particularly penalized.

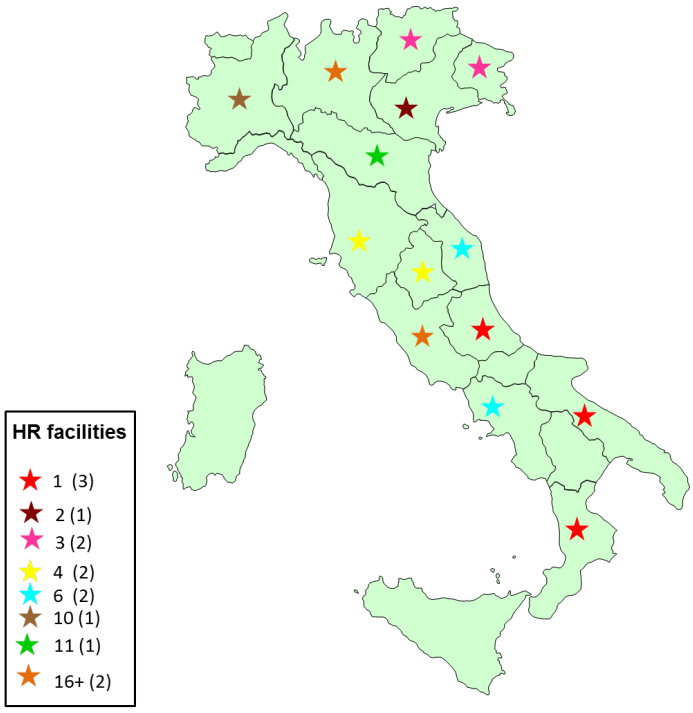


Fig 2.7 - *Regional distribution of HR Drop-ins and Needle Exchanges- data 2015, CNCA*

While it is true that there are more services in regions such as Lombardy and Lazio, where there are higher populations, this does not appear to be a significant variable overall: Sicily, where not one HR service has been documented, is more populous than Piedmont, which has ten such services.
The data, derived from the mapping in different years and from different sources[32], reveals furthermore how

29 Ronconi S. (2016) cit
30 Forum Droghe-CNCA (2016) Harm Reduction and risk limitation, cit
31 Idem. This survey is not institutional. The SIND system of the Ministry of Health that gathers data on drug addiction services does not currently include HR services- for reasons cited in this paragraph. The survey was done by the CNCA researchers- Coordination of Residential Communities- and was carried out using the snowballing method beginning with a mapping of existing HR services and with the contribution of the ITAARD network- the Italian Network for Harm Reduction.

32 DPA- Dipartimento Politiche Antidroga, Reports to Parliament o the state of drug addiction in Italy, years 2011, 2012, 2013, 2015 in http://www.politicheantidroga.gov.it/

there is very scarce development over time, with numbers basically remaining unchanged- both in regions that actuate HR and Risk Limitation (RL) interventions, and those that don't. An immobile, unchanging map is seen, which appears independent to the trend of the data regarding use and related needs of HR and RL interventions. This unequal and static geographic situation brings with it strong and persistent inequalities among PWUDs in terms of health rights. There are also sensitive problems of continuity in the provision of such services. According to the Report to the Parliament 2015, during 2014, due to regional budget choices, less than half of services had the certainty of continuity, while the most part (38%) had a guarantee of between one and two years, 22% for two years and 11% for less than a year[33]. This data was confirmed also by the previously cited 2015 mapping (dated 31/12/15): with the exception of services directly managed by public health (33%), the consignment to private social management will be through conventions for a specified time period, and are not guaranteed renewal.

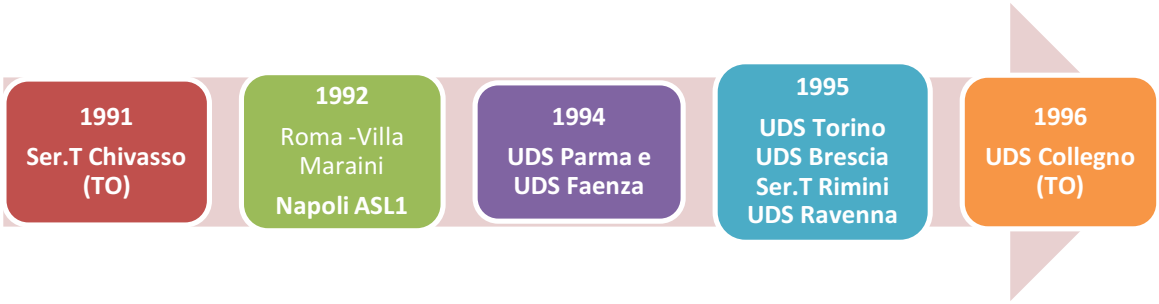
Another limit to the Italian HR system that influences the efficacy of OD prevention, regards the lack of *Drug Consumption Rooms* (DCR) and the scarce and precarious activity of *drug checking*.
DCRs - services that have been active in Europe since 1986 and widespread throughout many countries- are not present today in Italy. The reasons are political and are concerned with the resistance to adopt a HR approach in a coherent manner and the inheritance of the policy line from 2009. The then national Drug Addiction Department (DPA) was not positively oriented towards HR, and specifically excluded DCRs from services provided for, together with drug checking and treatment with medical heroin. Even though this policy line was not shared by the regions, nonetheless no Region decided to experiment autonomously with these services. The DCRs have over time demonstrated their efficacy for the prevention of OD, so much so that those countries who had started them have renewed their investment and new countries have begun implementing them[34].
The practice of drug checking, which can provide users, in real time, information about the chemical composition of the dose acquired, is a valid prevention support. It places PWUDs in the position to know what the illegal drug market keeps hidden and variable, and as a consequence he/she can adjust his/her behaviour. Due to the ostracism of the cited policy lines of the DPA in 2009 coupled with a restrictive interpretation of the current law, drug checking in Italy today is alive only thanks to the informal and self-organized practices of some groups and some experimentation within dedicated projects[35]. Instead, the EarlyWarning system activated institutionally, has had little or no impact[36] due to the slow response time – which is totally inadequate for the needs of those who use and are at risk here and now- and for the logic of inquiry and monitoring, which is basically inter-institutional. It is focused above all NPS and anyway not aimed to inform PWUDs *just in time* or HR workers with the goal of reducing risks.
These two important limits, which reveal a grave lack in the system under what is defined as a *combination intervention*[37]*:* here it is underlined that an offer, when integrated with other services, signifies a major possibility of success for each instrument of the intervention, precisely when they work in synergy between themselves. The EMCDDA states that this is accepting *not only pragmatism or necessity but also a choice based on the evidence and efficacy of the results*[38].

33 Interventions of harm reduction, CNCA-COORDINAMENTO Comunità di Accoglienza, in DPA- Relazione al Parlamento su droghe e dipendenza 2015, http://www.politicheantidroga.gov.it/
34 EMCDDA(2004) Report on drug consumption rooms, in http://www.emcdda.europa.eu/attachements.cfm/att_2944_EN_consumption_rooms_report.pdf.;EMCDDA (2016), Drug Consumption rooms: an overview of provision and evidence, in http://www.emcdda.europa.eu/topics/pods/drug-consumption-rooms
35 Among the active groups, Alchemica, which also works in a network with other European interventions http://lab57.indivia.net/tag/lab57-alchemica/; among the projects, the current European project, BAONPS- Be Aware On Night Pleasure Safety, which includes drug checking interventions in Italia, Slovenia, Portugal and Germany in http://coopalice.net/baonps. In December 2016 the monitoring system BAONPS sent out an alert about the alarming variations in the active principle in street heroin in Piedmont (http://coopalice.net/baonps/alert)
36 Early warning system, in DPA – Dipartimento Politiche Antidroga (2016), cit
37 See also in CNCA - Forum Droghe (2016) Riduzione del danno e limitazione dei rischi, in DPA- Dipartimento Politiche Antidroga (2016), cit
38 EMCDDA (2010) Harm Reduction. Evidence, impact and challenge, http://www.emcdda.europa.eu/publications/monographs/harm-reduction

Finally, but not less importantly, is the critical nature of HR interventions in prisons. This is even more crucial when considering that one of the most recurrent causes for OD is the diminished tolerance a person has following time in prison. From the Pride study[39] - the objective of which was to measure the application of the 15 WHO recommendations[40] for the health of prisoners - it emerged that with respect to France, Austria, Belgium and Denmark, Italy provides less HR interventions in prisons. In general, the most applied measures are antiretroviral treatments for HIV and OST (mostly for detoxifying) for people dependent on opiates. The most neglected measures are needle exchanges, and among the five countries participating in the study, Italy was the only country where condoms were not provided in any prison. In 2016 the Ministry of Health financed a project[41], which concludes in 2017, the object of which is to implement the offer of such interventions. They are at the same time, an objective of advocacy actions by civil society.

2.3 The THN Italian model

The scenario described highlights how the *prevention of OD* from opiates in Italy is based on two main pillars: pharmacological treatment with the prospective of reducing risks and the HR interventions. The *prevention of deaths from OD* is based on two main pillars too: the emergency services system which is present throughout the country and which guarantees ambulance services and subsequent hospital admission[42], and the HR services who distribute naloxone. In this framework, THN managed by HR services in the Italian model, plays a very strong role and -despite limits and discontinuity- has been invested in from the early 1990's, when the first HR initiatives began in the country.
Contrary in fact to what has emerged in the international literature[43]- which lacked the necessary sources- and place the first THN experiences in 1996, the beginning of naloxone distribution from HR services in Italy began in 1991[44].



In Italy naloxone has been formally (by the Minister of Health) classified as an over-the- counter drug in 1996. Nevertheless the first experimental distribution interventions started 5 years before 1996, when some SerD's doctors, on their own responsibility, allowed HR staff to distribute naloxone, aiming to contrast the dramatically increasing number of ODs among opiate users. This pioneering practice, which sometimes was also contested not being formally normed, in fact leaded to the Drug Agency provision in 1996.

There were three preconditions which facilitated this happening: the juridic and legal framework; the pharmacological characteristics of naloxone, and the reasonable cost of the drug.

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39 Michel et al.(2011) Limited access to HIV prevention in French prisons (ANRS PRIDE): implications for public health and drug policy. BMC Public Health 2011 11:400; Michel L et al (2015), Insufficient access to harm reduction measures in prisons in 5 countries (PRIDE Europe): a shared European public health concern BMC Public Health. 2015 Oct 27;15:1093.

40 UNODC: HIV prevention, treatment and care in prisons and other closed settings: a comprehensive package of interventions; Policy brief. Vienna, June 2013.
http://www.unodc.org/documents/hivds/HIV_comprehensive_package_prison_2013_eBook.pdf

41 http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=2299

42 The Emergency services system specifically includes in its response protocol overdoses and other drug related emergencies

43 EMCDDA (2016), Preventing opioid overdose with take home naloxone, cit

44 Revealed from the present study.

2.3.1 The regulatory framework for THN in Italy

In Italy the practice of distributing naloxone to PWUDs has its premise in the national regulatory framework. There are two significant aspects to this: the *classification of the drug* and the penal code regulations that regard the *state of need/emergency and the omission of first aid* .

a) *Classification of the drug*
Naloxone in Italy is an over-the counter drug, which means it is sold in pharmacies without the need for a medical prescription (SOP). This guarantees its accessibility for any citizen. It is a life-saving drug and this factor makes it obligatory for pharmacies to always have it available.

Amongst all the life-saving drugs, naloxone is an exception specifically considered in the Official National Pharmacopoeia. Due to the antidotes and specific actions, these drugs normally require a prescription. Table 4 of the official Pharmacopoeia includes a *List of Products that the pharmacist cannot sell if not presented with a medical prescription (Art.124, letter of the T:U:LL:SS, art 71 of the Presidential Decree of 9 October 1990, n.309 and art. 88 of the Legislative Decree 24 April 2006 n. 219 and successive modifications and integrations).* At point 25 the explicit derogation for naloxone is given: *Antidotes and specific actions, with the exception of injectable naloxone*[45].
The same classification source, Table 2- *Medical substances of which pharmacies are obligated to be furnished (Art.123, from the Consolidating Act of the Health Laws (TULS) approved with R:D: 27 July 1934, n1265; art 34 of the Regulations for Pharmaceutical Services approved with R.D. 30 September 1938, n.1706)*- includes naloxone[46]. It provides specifically that " pharmacies are obligated to be supplied with the medicines indicated in the present table in quantities considered sufficient to undertake their service and in substance- except for different specifications on the list- and in dosages responding to the usual therapeutic necessities, as well as in packaging consistent with their conservation and their practical use".
This legislation is clear about the accessibility of naloxone both under the profile of the possibility of non-specialized personnel administrating it and also regarding its availability.

b) *Regulations regarding emergency situations and omission of first aid*
Notwithstanding the above cited dispositions, it still happens that concerns are expressed by both individual citizens and by non-health and health professionals. These concerns are based on the possibility that non-conforming behaviours or those considered actually illegal in cases of complications or even simply in the case of intravenous administration- a health practice that is limited under Italian regulations to professionals only- will be contested.
The Italian Penal Code (CP) offers a sufficiently clear orientation for these hypothetical cases.
Article 54 CP (*emergency situations*)[47]states that "a person cannot be punished for having done something where they were constricted by the need to save themselves or others from actual danger of grave damage to the person, a danger not caused by the rescuer voluntarily, nor otherwise avoidable, always given the fact that it was proportional to the danger". And in the case of eventual correlated damages to the first aid deemed necessary (for example broken ribs during cardiac massage), Article 54 reduces the behaviour from a crime to non- criminal behaviour.

Article 593CP (*omission of first aid*)[48] sanctions whoever omits to provide their help and states that a crime is committed by: " any person finding(....) a human body that is or seems to be inert, or where a person is injured or otherwise in danger, and omits to give assistance at the time or to advise the authorities". It provides for penal sanctions for up to 1 year in jail or a fine of up to 2500 euros[49]. If the omission of aid results

45 XII Edizione della Pharmacopeia Official della Republica Italiana,in http://www.iss.it/binary/farc/cont/integrazioni e correzione alla XII ed FU.pdf
46 Idem
47 CP title III http://www.altalex.com/documents/news/2014/12/09/del-reato
48 CP title XII http://www.altalex.com/documents/news/2014/10/28 dei-delitti-contro-la-persona
49 The penalties have increased with the law n.72/2003,

in injury to the person, the penalty is increased and it results in death the penalty is doubled.
The law therefore sets out the actual obligation to assist in cases of danger and has- for citizens who volunteer aid and not for medical personnel- derogations only in exceptional cases: natural external events, inevitable and unavoidable, such as a serious illness by the helper; physical obstacles preventing one from arriving to the person to assist; assisting in real and consistent conditions of danger (fire, inhalation of toxic gases, the presence of exposed electrical cables etc.) which could put the life of the person assisting in danger.

2.3.2 Pharmacological characteristics of Naloxone

One factor that undoubtable facilitates the THN practice are the pharmacological characteristics of naloxone. It does not have undesired effects and is therefore a "safe" drug and easy to use. Some of the negative consequences for PWUDs are the relative acute withdrawal that can occur following administration and the consequent risk of another opiate dose. These risks can be avoided through the correct administration of the dosage, the method used and by accompanying the person throughout the event[50]

The pharmacology of Naloxone[51]
Naloxone was developed in the 1960's and was introduced as treatment in 1971. The fundamental characteristic of the drug is its competitive antagonistic effects on three different types of opiate receptors: mu, kappa and delta. The mu receptor is the most important in terms of the expression of the depressive effects of natural opiates and its synthesis for the central nervous system. It is important to note that naloxone has no effect on "clean" subjects. This is valid both for the absence of consequent physiological effects on blocking the endogenous opioid system and for the absence of non-specific physiological effects of the drug. Both of these situations permit the prediction of notable security in using this drug, which in fact its massive clinical use has amply confirmed.

The pharmacokinetic characteristics of naloxone contribute greatly to its antidote efficacy in opiate overdose (Civility, 2015; Kim & Nelson, 2015). In particular, naloxone is a lipophilic drug (logP of the repartition coefficient octantal/water: 2.1) with a discreet distribution volume (2.7l/kg) and a consequent rapid elimination from the circulatory flow and overcoming of the brain-blood barrier. The onset of its effect is therefore particularly rapid, around 1-2 minutes with a peak at around 5-10 minutes. The duration of the drug in the body is relatively brief with a plasma half-life of between 30 and 80 minutes. Metabolism is prevalently hepatic with the formation of a glucuronic derivative which is so efficient as to render the oral bioavailability of the drug almost zero for its elevated extraction following the first hepatic filtration.

The antagonistic action of naloxone on respiratory depression from opiates is limited and not longer than an hour and a half. This has been verified experimentally in a study where different dosages of naloxone and morphine were administered, singularly or in combination, to healthy volunteers (Kaufman et al. 1981). This study has in fact demonstrated that within that interval of time the action of naloxone follows the principle of competitive antagonist on the same agonist receptors, allowing for the calculation of the dose of naloxone necessary to halve the dose of morphine in terms of its efficacy: thus 1.55mcg/kg of naloxone was able to reduce the effect of 12mgs of morphine to the effects of 6mgs of the analgesic. It is important to note that this principle cannot be extended to the actions of naloxone with respect to opiates with more receptor affinity than morphine. This is the case for buprenorphine, which has a slow kinetic dissociation from the receptors, compared to a rapid kinetic elimination of naloxone, making it necessary to deal with an eventual overdose of buprenorphine by adopting a regime of antagonist infusion (Yassen et al, 2007).

The pharmacokinetic characteristics of naloxone influence the methods of administration. Parenteral routes are obviously preferred and in locations outside of hospitals, the intravenous route is not necessarily considered the most rapid with respect to intramuscular considering the time it can take to find a vein. In

http://www.camera.it/parlam/leggi/03072l/htm

50 This aspect is looked at further in the following chapter.

51 Authored by Paolo Nencini, former Professor of Pharmacology.

this particular context the introduction of a nasal spray has been of considerable interest, for the ease of use and the for the rapid onset of action, which is in fact comparable to that attained via intramuscular use. The lipophilic aspect of naloxone and the lack of pre-systemic hepatic extraction of the drug predict a good bioavailability via this method. Studies to date have shown that the bioavailability varies between 10% and 40%, in function of the concentration of the drug nebulized, but nevertheless considered sufficient to invert respiratory depression from overdose. Further studies are undoubtedly necessary for optimizing the use of naloxone through this method of administration (String & McDonald, 2016; Winstanley, 2016).

Adverse reactions to naloxone

As discussed previously, the administration of naloxone to healthy volunteers results in no significant pharmacological effects. In patients chronically exposed to opiate drugs on the contrary, it can result in adverse effects mediated by neurovegetative hypotonia and the release of cytokine when withdrawal symptoms occur. The English National Health System has therefore published a Patient Safety Alert (NHS/PSA/W/2014/016; 20 November 2014) concerning elderly patients in chronic analgesic treatment where a withdrawal crisis could in fact cause hyperalgesia and anxiety. Life-threatening events associated with naloxone administration to opiate dependent subjects are however rare. Cases of acute pulmonary edema are to be included, probably caused by the brusk return of respiratory activity following the first episode of apnea in absence of adequate ventilatory support (Kim & Nelson, 2015). Cases of ventricular tachycardia are also described, again attributed to the sympathetic hyper-stimulation during withdrawal (Lameijer et al, 2014). Also problematic is the administration of naloxone during pregnancy, for the possible consequences of acute fetal withdrawal syndrome. This same treatment in the first days of life is also a risk as it may precipitate a convulsive crisis in the neonate (Silviotti, 2015; Kampman & Jarvis, 2015).

One significant complication of resuscitation with naloxone in drug-using patients is the rude awakening in acute withdrawal. This condition is experienced as extremely adverse (Neale & Strang, 2015) inducing on occasion violent behaviour towards the person providing emergency assistance and can lead to the patient abandoning treatment. Considering also the risks of cardiac and pulmonary complications connected with the precipitation of withdrawal, the posological approach to antidote treatment with naloxone is modified, from the full dose of 0.4 - 2.0mg of naloxone as initially recommended for rapid resuscitation and ventilatory reactivation, to a titration of the naloxone dose that permits the immediate reactivation of good respiratory activity without manifesting serious withdrawal. Such initial dosages are close to what is theoretically considered possible for halving the receptor occupation by an agonist such as heroin, its metabolites, monoacetylmorphine and morphine. As was previously noted, this is theoretically 1.55mcg/kg with the actual suggested dose to begin with being 40mcg followed by successive administrations calibrated according to the reaction from this first dose (Kim & Nelson, 2015).

The available evidence demonstrates that the methods of naloxone use in emergency overdose are founded on a robust pharmacokinetic- pharmacodynamic rationale and testify to a notable level of safety of the drug. It is important to observe that these methods have been seen to be effective and secure even when the drug is used in pre-hospital situations by paramedic personnel (Yealy et al, 1990) and even in cases where the patients have refused further assistance (Levine et al, 2016). The rationale of the “Take Home Naloxone” program is derived from this evidence, and permits parents and friends of drug users to intervene in the case of overdose, unfortunately always a possibility. These programs are showing to be particularly effective, such as that conducted in the city of San Francisco, where in 2013, 253 cases over heroin overdose were treated in this manner and contributed to a decline in mortality from heroin (Rowe et al, 2015). Even more convincing is the very recent meta-analysis of 22 observational studies where 2249 successful treatments out of 2236 administrations of naloxone - 96.3% of cases - were reported (McDonald & Strang). In agreement, the guidelines of the American Society of Medicine for Drug Addiction recommends the home distribution of naloxone for treatment of overdose, as well as the training and authorization for firemen and police officers to use naloxone in emergency situations (Kampman & Jarvis, 2015).

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2.3.3 **The cost of naloxone.**

The central role that public services play regarding drug addiction in the Italian model of HR and for THN, shows that the distribution of naloxone is exposed to the risks of regional and health centers budget oscillations and therefore this represents a risk, as health budget cuts are forever increasing. However with respect to cost, this role has been facilitating. Naloxone distributed to PWUDs is that provided to hospitals who in turn provide the HR services and the SerDs. Naloxone is not a costly drug, and the acquisition by

public health services in bulk quantities, reduces this cost even more so. According to data from 2016[52], one phial costs the public health system on average 2.07 euros (calculated from different productions). There have been insignificant variations over the years (it was 1.7 euros in 2013; 1.8 euros in 2014; 1.93 euros in 2015). In 2016 naloxone was sold to private pharmacies at prices ranging from 2.62 euros (Galenica Senese srl) to 4.54 euros (Hospira Italia srl). The average price for 2016 was 4.2 euros.
The following is the estimated costs in one year (2015) on average by each of the 57 HR services that distribute naloxone[53] :

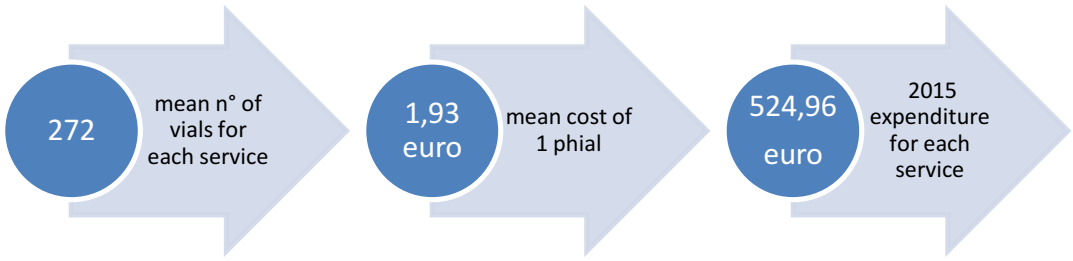


Fig 2.8 – Naloxone estimated annual expenditure for each service

Considering the number of vials distributed overall in 2015, according to the same data, the national total money spent is estimated at:

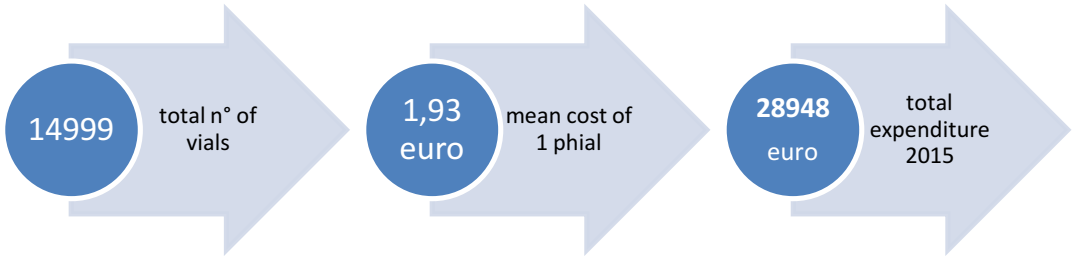


Fig 2.9 – Naloxone estimated annual expenditure for 57 THN services

This data indicates the undoubted sustainability of the THN intervention, considering that the services of counselling, information and training that accompany the consignment of the drug are part of the professional client offer, and provided for within the HR services.

2.3.4 The distribution of naloxone in the HR service system

CNCA data (2014-2015)
Among the HR services revealed by the mapping study(2015)[54], 57 mobile needle exchanges programs and drop-ins distribute naloxone.
In 2015 these services can be seen to be distributed in an unequal manner throughout the country: the major coverage is in Lombardy, Lazio, Emilia Romagna, Piedmont and Campania. The regions which are totally without services are: in the north- Aosta Valley, Liguria; in the center- Abruzzo and Molise; and in the south

52 Data from Local Health Agencies (ASL)
53 Data relating to HR services that distribute naloxone are in: CNCA-Forum Droghe (2016) HR and LdR in DPA-Dipartimento Politiche Antidroga (2016), cit:
54 CNCA- Forum Droghe (2016). Harm Reduction and Limitation of Risks in DPA, 2016 cit

– Basilicata, Sicily and Sardinia.

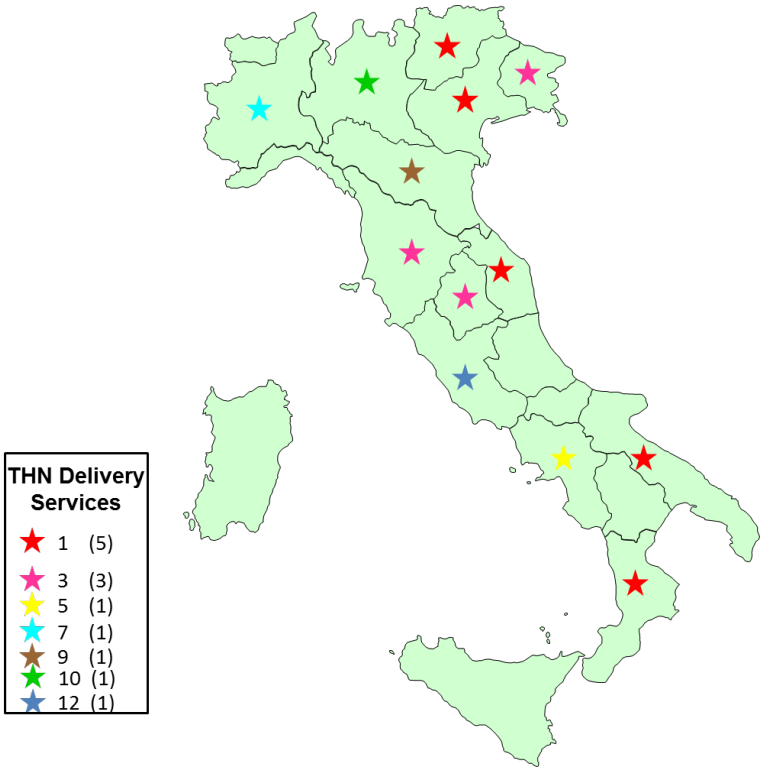


Fig 2.10 - Services that distribute THN in Italian Regions (data 2015), CNCA

Between 2014 and 2015 the same source registered an average increase of 6% in the number of services that distribute naloxone (from 54 to 57), with a positive increase for some regions and a negative downturn for others:

Region	Data 2015	Data 2014	Variation %
Calabria	1	0	+100%
Campania	5	2	+150%
Emilia Romagna	9	6	+50%
Friuli Venezia Giulia	3	0	+300%
Lazio	12	14	-14%
Lombardia	10	7	+43%
Piemonte	7	12	-42%
Puglia	1	0	+100%
Toscana	3	4	-25%
Trentino Alto Adige	1	1	-
Umbria	3	3	-
Veneto	1	4	-75%
Marche	1	1	-
Total	57	54	6%

As has been observed for HR services in general, there is not always a correspondence between the presence and the number of THN services and the resident population. There are regions which are very populated and have none or scarce THN coverage:

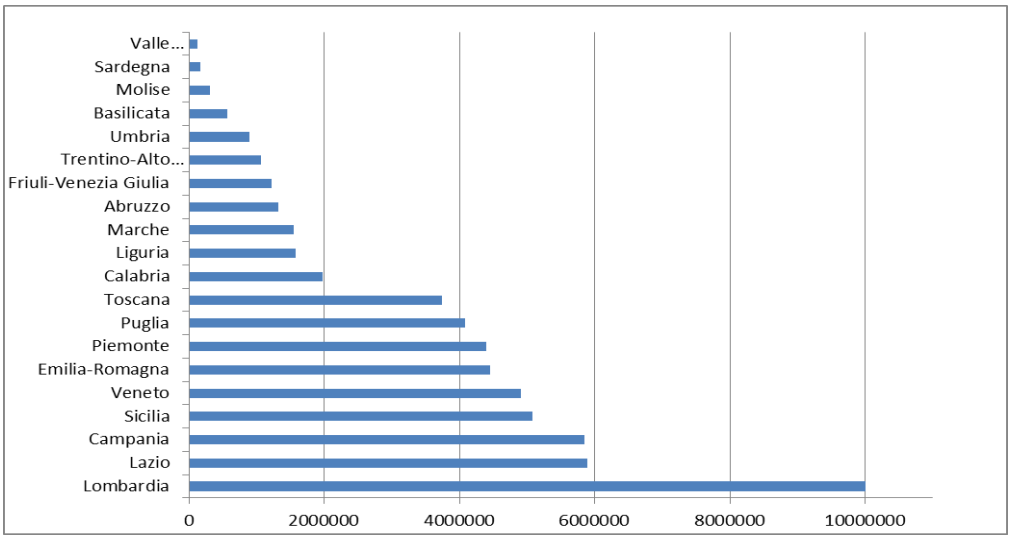


Fig 2.11 Resident population on 1/1/2016 for Regions (source: ISTAT, 2016)

In 2015, of the 57 services that distributed THN to their clients, 2 did not provide data. The 55 services for which activity data is known, showed a total volume of 14.999 vials distributed, an average of 272 vials per year.

According to this source, the median number of contacts per service is 10.735. For contact it is intended every service given to the client every time he/she visits the service. Most HR services register this data and not, or only a few, register data relative to the number of clients (physical people). This is because of the particular nature of these services (anonymous; interventions on the PWUDs population and not the single person) and because of different methods of monitoring the activities.

The number of contacts includes therefore the offer of different services, other than the distribution of naloxone: counselling on different issues, listening to different socio-health problems; referral and accompanying them to other services; giving out sterile materials and collecting used ones; giving out condoms; doing tests. It is estimated that for every 39 services provided, considered altogether, 1 consists in giving out naloxone.

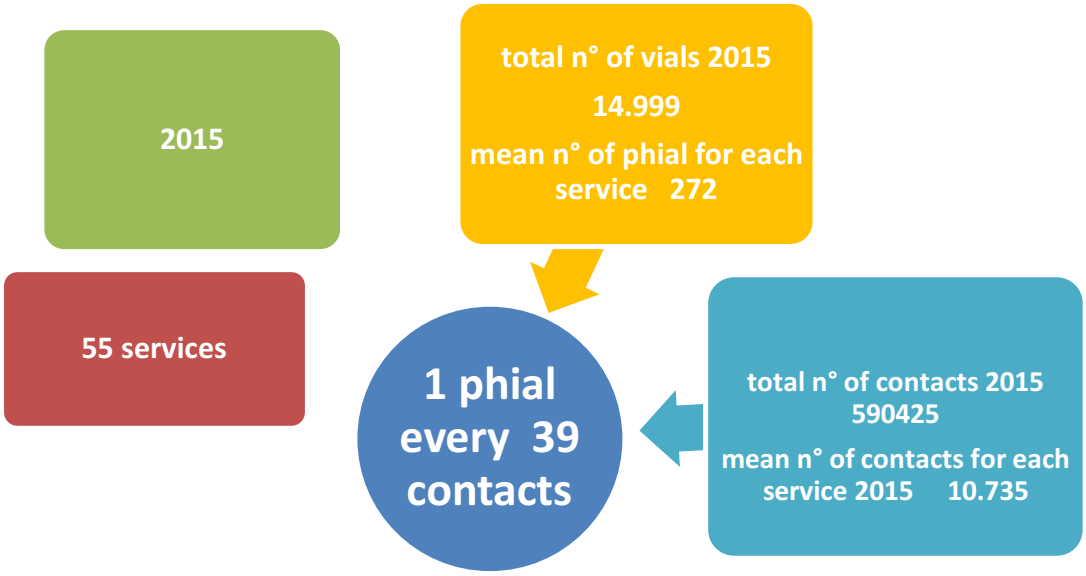


Fig 2.12 – Naloxone vials / number of contacts – CNCA data

Data from the present study

Within the scope of the research an in-depth study was done concerning the data from some services,

selected from those who had participated in the research, based on continuity of THN distribution and willingness and accessibility to the process data. 10 services[55] returned the required data out of 20 services approached.
The graph shows the data available in increasing order for number of services responding (out of 10 services):

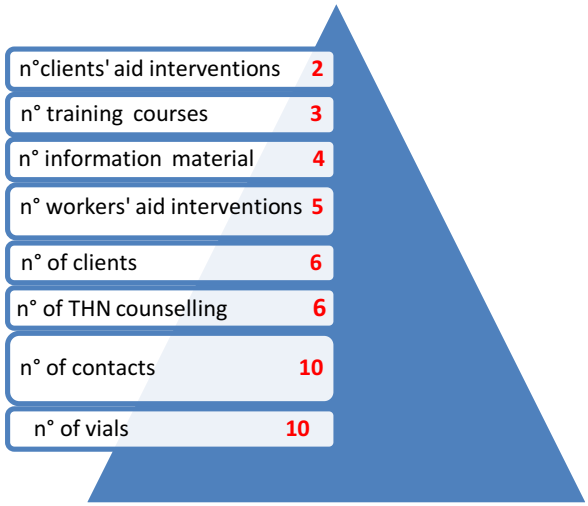


Fig 2.13 – Data available / number of services

Based on the information regarding the accessibility of data regarding activities, it was verified that these were available for most of the respondents from the first years of activity (the mid-90's) but that most were available in electronic format only from the year 2000. The study therefore regards a period of time between 2000 and 2015.
The graph shows the years when data on activities are available in electronic format for number of services responding (out of 10 services):

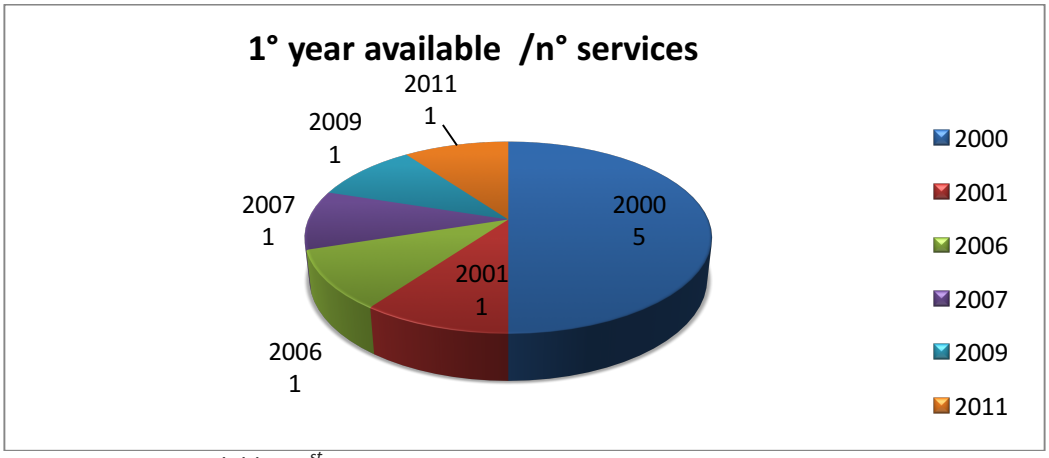


Fig 2.15 – Data available – 1st year

The Year 2015

The final year of recording data on process (2015) includes data relative to *vials distributed* and number of *contacts* provided by all 10 services responding (for contacts it is intended how many, as described above, in terms of the various services included). These totals altogether highlight how, on average, for every 40

55 The10 services from where data was obtained are: **Piedmont:** Drop in Prassi ASL exTO2 – Torino; UDS CanGo ASL exTO2 – Torino; Drop in ASL TO 3 – Collegno (TO); **Veneto:** Drop in e UDS Comune Venezia; **Trentino –Alto Adige**: Drop in Caritas - Bolzano; **Lombardy:** UDS Cooperativa Calabrone – Brescia; **Emilia Romagna**: Drop in AUSL e Cooperativa la Quercia – Reggio Emilia; **Campania:** UDS ASL Napoli1 – Napoli; **Lazio:** Centro Prima Accoglienza Parsec- ROMA; UDS Parsec - Roma

contacts/s, one includes the consignment of naloxone, confirming the data from the previous survey:

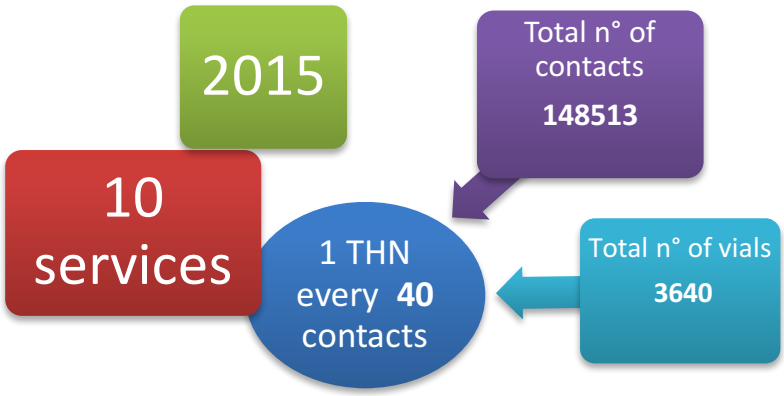


Fig 2.15 – Naloxone vials / number of contacts – Data from the present study

Of the 6 services that produce numbers regarding *clients*(physical people), on average for every 5 clients, 1 receives naloxone:

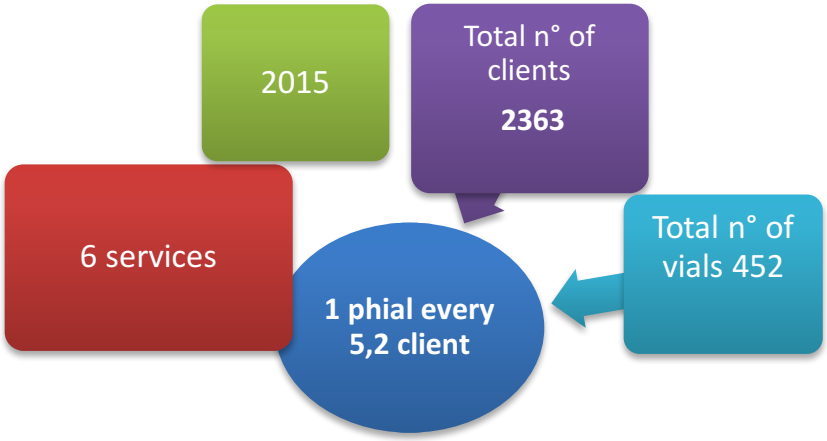


Fig 2.16 -Naloxone vials / number of clients – Data from the present study

As far as information sessions and counseling are concerned, correlated with the consignment of naloxone, among the 6 services that had provided this data it was possible to consider only 3. The remaining 3 had provided data regarding all types of personal sessions, and had not provided disaggregated data regarding the object of the interview session itself. The same 3 services also indicated the number of informative materials about naloxone distributed at the same time as the consignment.

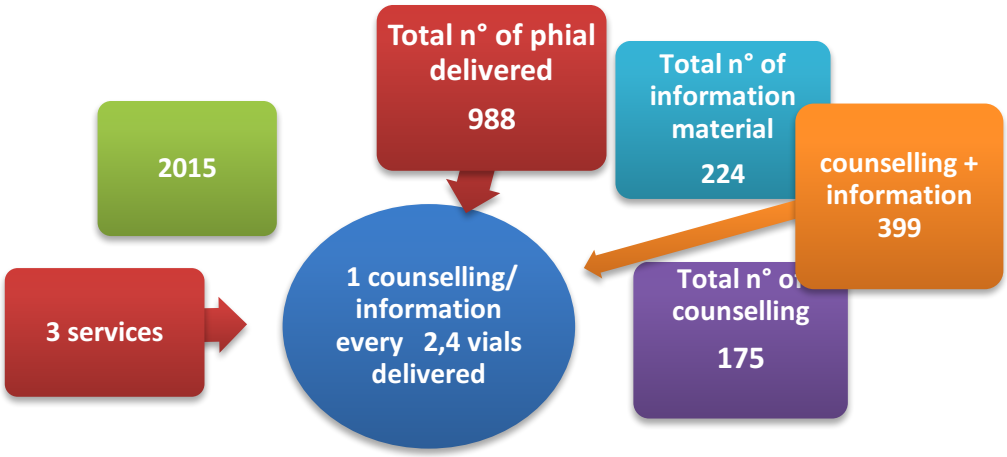


Fig 2.17 Counselling and information / Number of vials delivered

The result- one interview/information every 2.4 consignments- needs to be read considering how many among the clients had already received naloxone during the year or who are receiving it not for the first time.

Only 3 services out of 10 report data on training courses and first aid interventions for groups of PWUDs. Each service had organized, during 2015, between 2 and 3 events.

Regarding first aid provided directly by health workers and educators to clients in OD that were found in the vicinity of the service, 5 services provided this information. Altogether in 2015, they undertook 88 interventions, with a range of 48 being the maximum and 1 being the minimum.
Only one service in 10 gathered data concerning emergency interventions undertaken by PWUDs in 2015. There were 200 interventions monitored by the mobile needle exchange program in Naples (24.000 contacts/year), while a second service, that of Venice, reported 26-28 a year from 2008-2010 (7.300-10.600 contacts/year).

Trends 2000-2015

Considering all 10 of the services and the distribution of naloxone in the years between 2000 and 2015, there is a relative fall both in the number of vials consigned with respect to the total number of contacts/services and with respect to the number of clients.

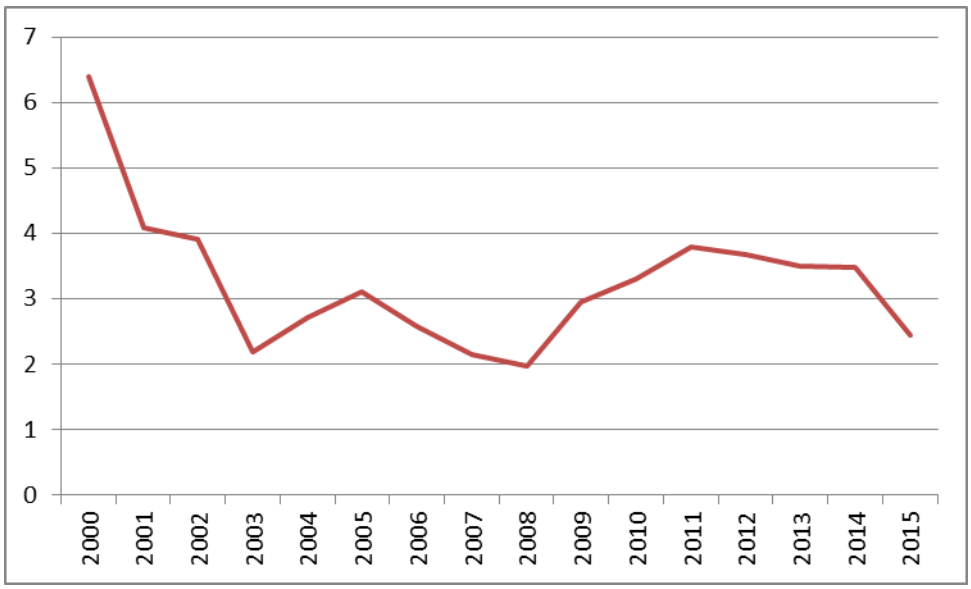


Fig 2.18- Trend of the distribution rate: median number of vials per 100 contacts

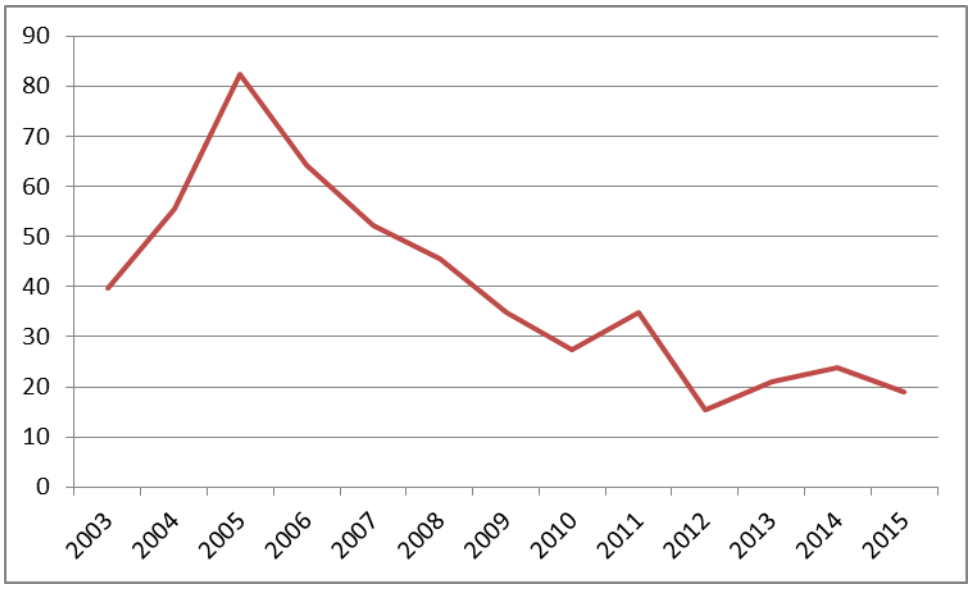


Fig 2.19- Trend of the distribution rate: median number of vials per 100 individuals (data available from 2003)

The reasons for this decrease- verified by this study[56] - are a multiplicity of factors that characterize the Italian context.

➢ **Factors regarding the client base of services**: between 2000 and 2015 some HR services registered a decrease in the number of contacts/offers of services or of clients. Others, while maintaining or even increasing the volume of activity, signaled changes in the client composition- differentiated for style of use, with the emergence of clients who were not using opiates (for example the elevated affluence at the drop-ins of immigrants who use mostly alcohol) or those who used only every now and then and not by intravenous injection (for example young PWUDs). These all have a relative and diverse sensibility towards OD risk. Furthermore, it needs to be considered that the percentage of new clients regarding the total of clients over time, diminishes (and most HR services in Italy are over 20 years old) and therefore the percentage of clients who already frequent the service and are already in possession of naloxone increases. Apart from exceptions for interventions in natural settings for drug use and entertainment venues, HR services, drop-ins, and mobile needle exchanges that are active in THN, rarely intercept new users of opiates.

56 For further analysis see Chapter 3.1

- **Factors regarding the context and drug policy:** the effective decrease of OD over the years has lead to a lowering of attention by national policy makers about OD itself, an attention opposite to what was emphasized by the alarm for the drug-related deaths in the 90's. This lowering of attention is reflected, according to HR workers, also within the services, in a moment where nonetheless OD from opiates continues to represent a significantly correlated factor and slightly on the increase in the past two years. In general it can be seen that scarce investment and political support for HR is reflected by the absence of national guidelines, the lack of investment in research aimed both at understanding styles of drug use and monitoring and evaluating HR interventions and that of THN in particular.
- **Factors regarding resources**: the politics of austerity have also affected the public service system and the Third sector drug services that have an arrangement with the public system. This influences not the acquisition of naloxone itself – that represents a contained cost as was demonstrated- but rather an overall reduction of resources, of personnel, of the total hours and hours of opening/intervention. The factors altogether reduce the operational aspects and this in turn affects the THN program. These cuts also bring with them a difficulty in make teams grow and renovate, with consequent situations- as reported by the workers- of tiredness and burnout, again at the cost of a constant, attentive and motivated offer of naloxone, when it is not the client asking for it and coming because they have been encouraged to do so.

2.3.5 The role of pharmacies in naloxone distribution

Naloxone, as an over-the-counter drug, is for sale in pharmacies and can be freely acquired without a medical prescription, by any citizen. Furthermore, as a life-saving drug, pharmacies are obliged to always have it in stock. Notwithstanding this, pharmacies do not have a relevant role in the THN model in Italy. In the current study both PWUDs and HR workers confirm this anecdotally: PWUDs rarely go to a pharmacy, in part because of ignorance about the accessibility of the drug and also because of factors relating to the not always easy relationships with pharmacy personnel. They see themselves as being " unwelcome clients". This in turn deprives the pharmacists of the potential opportunity of becoming a reference point-network for PWUDs, with a view to prevention and health promotion. This could be true both for sterile materials and for naloxone[57]. This is undoubtedly a lost opportunity, if one considers the capillary presence of pharmacies in the 8000 Italian municipalities: in 2015 there were a total of 18.201 pharmacies in Italy (16.560 private and 1642 public), a median of 1 pharmacy for every 3.340 inhabitants, which is in line with the European average[58].

There are no data available on the total number of naloxone doses sold in pharmacies in Italy. It is possible however to have an idea relating to the naloxone market through data provided to pharmacies of hospitals and health centers, on one hand, and to private or public pharmacies, on the other[59].

In the period of 3 years between May 2013 and May 2016, hospitals and health centers bought 999,942 boxes of naloxone (an average of 333,314 per year), with respect to pharmacies who bought 62,273 vials for private sales (an average of 21,757 a year). Considering the number of pharmacies throughout the country, each year each pharmacy buys 1,1 vials of naloxone. This is an extremely low number and an indicator of a very reduced market.

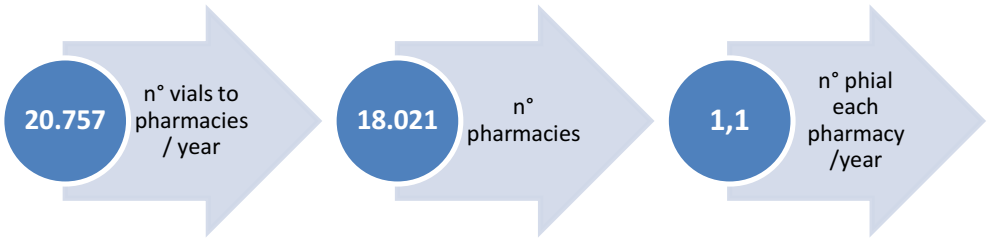


Fig 2.20 – Naloxone supply to pharmacies / year

57 For a more in-depth analysis see Chapter 3.2
58 Data from Federfarma in https://www.federfarma.it
59 Data from Local Health Agencies (ASL)

3. The results of the research.

3.1 The perspective of drug services professionals[60]

This chapter illustrates the results of the research conducted through on line questionnaires and focus groups and the final discussion.

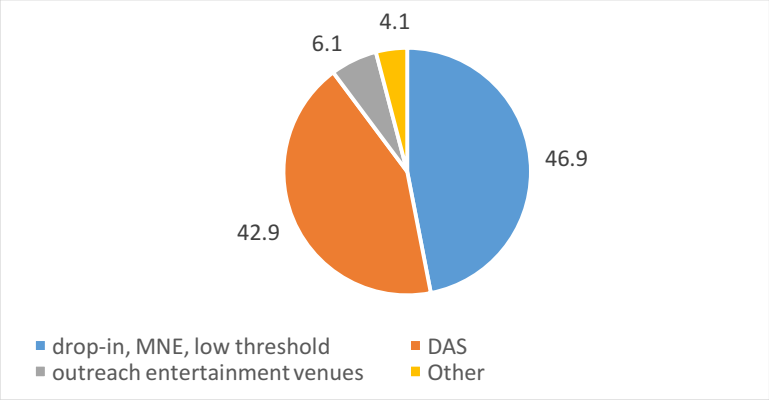
3.1.1. Results of the research on addiction services workers

1. Sample
2. Distribution of Naloxone
3. Prevention strategies and negative outcomes of overdose
4. Practices regarding THN
5. Changes over time
6. Opinions concerning Naloxone and about THN

1. Sample

The sample group is composed prevalently from drop-in services, mobile needle exchanges (MNE) and other low threshold services (dormitories, night services), which together constitute slightly less than half of the sample (46.9%) and from SERD (Drug Addiction Services, DAS) (42.9%). Three other services also responded who are involved in outreach work in entertainment venues, and two rehabilitation centers, one therapeutic and one social rehabilitation, which are counted under the "other services" heading.

Fig 3.1. Sample composition for type of service (%) (N=49, 14 n.r.[61])



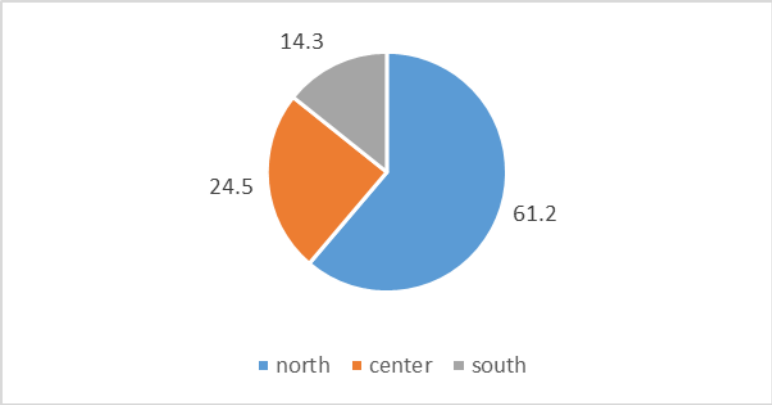
The major part of the services that responded (61.2%) are in the northern regions of Italy, while only one in four (24.5%) are to be found in one of the regions of central Italy. The services in the south of Italy constitute a small minority of the sample, less than 15%. In line with data from previous research[62] this composition reflects the reality of less diffusion of services that distribute naloxone in the southern regions

[60] By Sara Rolando and Franca Beccaria

61 "no reply", the number of missing responses, in this case with respect to the general sample

62 DPA- Parliamentary Report 2015, Harm Reduction in http://www.politicheantidroga.gov.it/attivita/pubblicazioni/relazioni-al-parlamento.aspx

Fig.3.2 Sample composition by geographic area (%) (N=45, 18 n.r.)



As was requested, given the pragmatic nature of the questions, those who compiled the questionnaire were mostly operators in charge of services or running the services, who constitute altogether almost 70% of the sample, while managers were around 25% of the sample.

With respect to the professions of the respondents, most were doctors and educators, who represent respectively 37.5% and 35.4% of the sample. In third position are psychologists (10.4%) and fourth are nurses and peer workers (both around 4.2%). In the category "other" are two nursing assistants (AS), a sociologist and a street outreach worker. The doctors, who are the most numerous (N=18) are mostly specialized, in order: psychiatry, general, emergency and toxicology.

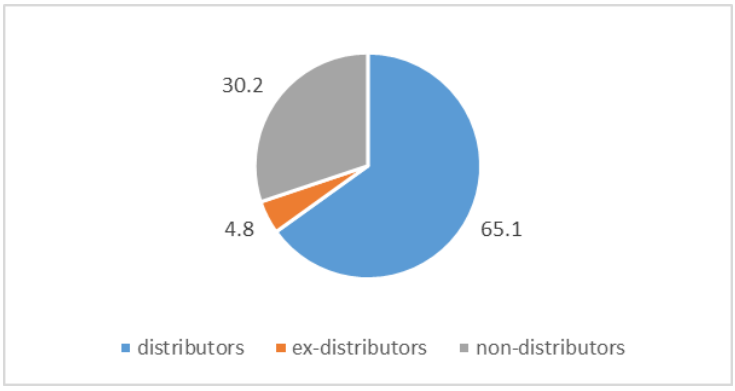
The average age of the respondents is 49.5 years, the over 50's represent a majority relative to the sample, constituting almost 50% of respondents while the under 40's are only 16.7%. This composition reflects the request indicated for the compilation, aimed particularly at those who possess an "historic" perspective regarding the THN practice and policy.

The gender of the respondents is prevalently female (58.3%) even if the gender distribution is overall balanced.

2. Naloxone distribution

Coherent with the aim of the research and with the strategy of diffusion adopted, most of the sample is constituted by services that distribute naloxone or that have distributed it in the past (around 70%). The remaining part of the sample is composed of services that have never distributed the drug, among which are also some SERD, even if prevention of death by OD overdose is part of their mission. For this 30% of the sample group a reduced selection of specific questions was proposed.

Fig.3.3 Distribution of naloxone in the services involved (N=63)



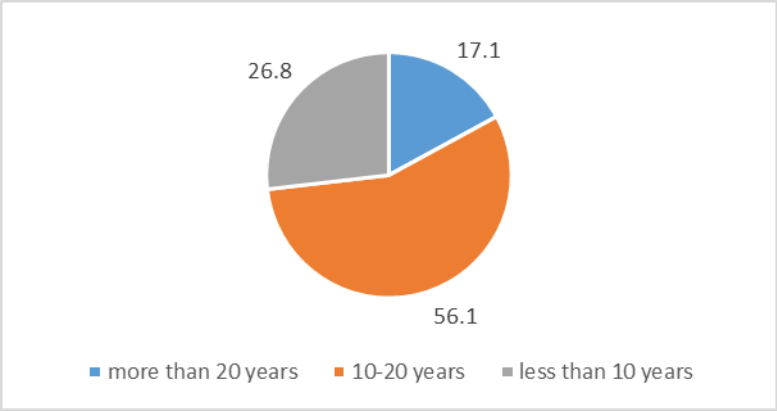
Cross-referencing the data on type of service and distribution of the sample (Table 1) it can be seen that those who do not distribute naloxone are the rehabilitation centers (included in the category "other") and a little less than half of the SERD's (47.6%). All of the outreach services in entertainment venues do distribute it as do the major part (78.3%) of the drop-in services and other low threshold services that responded.
As can be seen in the following table, the major part of services in the north involved in this study (80%) distribute naloxone, as do those in the central Italy, even if to a lesser degree (58.3%) in contrast to the south which, as well as being a numerically inferior sample, is also prevalently composed of services that do not distribute naloxone (6 out of 7). This distribution, while not representative, does mirror what emerged from the previously cited mapping work undertaken in 2015.

Tab. 3.1 Distribution of naloxone by geographic area (N=49, 14 n.r.)

	Geographic area	
	north	**south**
distributors	24	7
	80.0%	58.3%
ex-distributors	0	1
	0.0%	8.3%
non-distributors	6	4
	20.0%	33.3%
total	100.0%	100.0%

Services that currently distribute naloxone (41) on average have done so for many years: more than half of the sample (56.1%) for at least 10 years and 17.1% for more than 20 years. Those that have adopted this practice for less than 10 years, that is after 2006, represent only slightly more than a quarter of the sample (26.8%). The time-span goes from 1990 to 2013, the media represented from 2001 with a standard deviation of 6.64 .

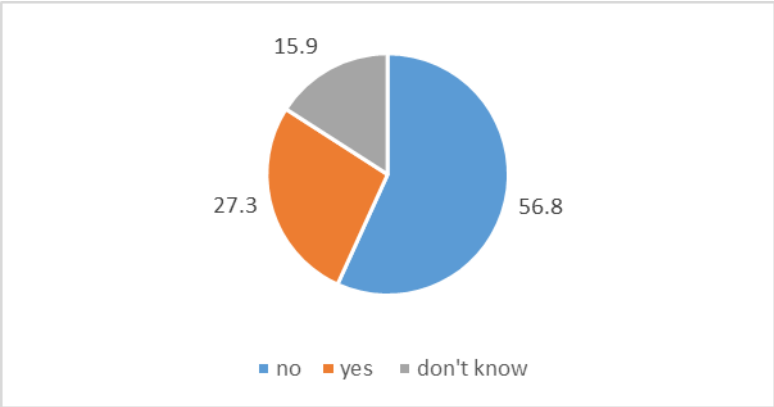
Fig.3.4 Length of time of naloxone distribution (%) (sample distributors, N=41)



Of the three services in the sample group denominated "ex-distributor", one had distributed naloxone for a long period of time (14 years) whereas the other two had had a more brief experience (4 and 7 years). According to what was stated, the distribution was interrupted for diverse reasons: a reduction in the needs of clients (based on changes that occurred in drug use) (3 cases out of 3); lack of funds (2 cases out of 3) and due to changes in the organizational structure(1 case). The answers regarding who decided these interruptions were vague. Only one respondent in three in fact indicated that the decision was taken at a managerial level.

The introduction of the Take Home Naloxone (THN) practice according to more than half of the respondents did not meet with any opposition, while in 27.3% of cases problems were indicated.

Fig.3.5 Obstacles to the introduction of THN (%) (sample distributors + ex-distributors, N=44)



In more than half of the cases, 12 respondents in total make reference to difficulties in accepting this intervention by or the workers in general (4 cases), or by health workers (2) or volunteers (1). Other obstacles identified regard the lack of support by the Regional council (3) or the health authority (2 cases); difficulties with law enforcement officers (2) and those of an organizational nature (2).

Tab.3.2 Obstacles to the introduction of naloxone (N=12)

	N	% of cases (N=12)
difficulty in acceptance by workers	4	33.3%
lack of Regional support	3	25.0%
lack of managerial support	2	16.7%
budget problems	2	16.7%
difficulty in acceptance by health workers	2	16.7%
problems with law enforcement officers	2	16.7%
organizational problems	2	16.7%
difficulty in acceptance by volunteers	1	8.3%

Of the services that distribute or have distributed naloxone in the past, more than one in three (70.6%) declared they have data monitoring the distribution, but only 5 services have conducted research into the ways naloxone is used by clients.
Looking at services where naloxone has never been distributed, according to half of the respondents one of the reasons for not having adopted this intervention is it not being appropriate with respect to the mission of the service. Other motivations, less frequently cited, are the lack of acceptance by health workers (3 cases), the scarce presence of opiate consumers among clients (3 cases), the lack of resources (2 cases) and the iatrogenic effects of the drug (1 case). Among the motivations freely expressed under the category "other", some sustain (denoting a certain confusion) that *" the greater aim is to prevent overdose rather than treat it"*, or that distributing naloxone *"was not identified as the priority"*. Others however make reference to problems of a more bureaucratic nature that have until now been an impediment.

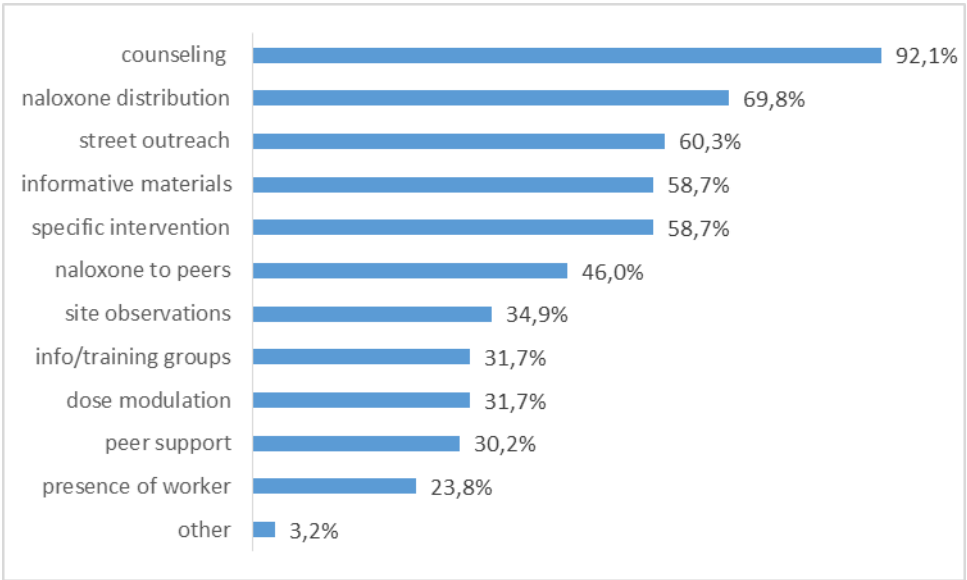
Tab.3.3 Reasons for not distributing naloxone (sample non-distributors, 2 n.r.)

	N	% of cases (N=14)
inappropriateness of the intervention	7	50.0
unacceptable for health workers	3	21.4
scarce presence of consumers	3	21.4
other	3	21.4
lack of resources	2	14.3
iatrogenic effects	1	7.1
lack of proof of efficacy	0	0.0

3. Prevention strategies and negative outcomes of overdose

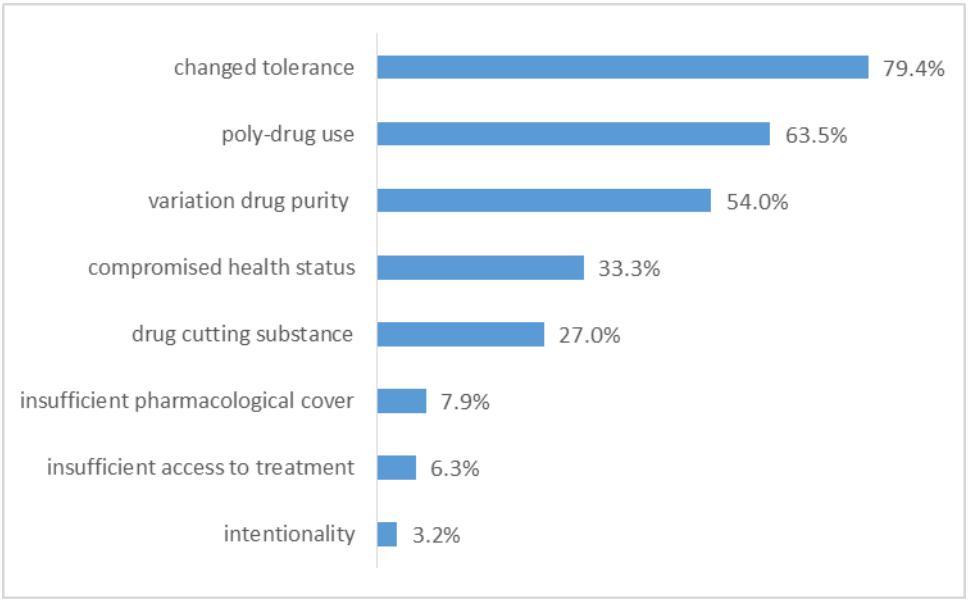
To prevent episodes of OD and mortality from heroin OD, services use diverse strategies.
Among the most mentioned is individual counseling identified by more than 90% of the respondents. The distribution of naloxone to individuals is in second place, indicated by more than two respondents in three (69.8%). Cross-referencing the answers for type of service it can be seen that the percentage of services who distribute naloxone rises to 82.6% in drop-in's and other low threshold services and is 100% in the outreach services in entertainment venues, whereas it drops to 57.1% in the SerD. Following this, with similar values at around 60% are street outreach interventions and in drug consumption places (69.8%); the distribution of informative materials (58.7%) and the activation of specific protective interventions aimed at high risk subjects (58.7%). Less than half of the services (46%) give out naloxone - other than to people who use drugs (PWUD)- to peers, acquaintances or friends. More than one service in three (34.9%) adopts the strategy of observing the mobility of PWUD and the variation of meeting places in the zone in question (34.9%). Less than one service in three (31.7%) uses information or group training or modulation of dosages and the dispensing of opioid antagonist drugs.
Around 30% of services work with peer support, also via the involvement of opinion leaders. Finally, in 23.8% of cases, services guarantee the physical presence of a worker with naloxone and a defibrillator in drug consumer places. Other strategies that were spontaneously identified by respondents are to leave the naloxone available in the SerD and in the drop-in's and to adopt protocols of intervention in cases of intoxication.

Fig. 3.6 Prevention strategies for heroin overdose (% of cases, N=63) (multiple responses possible)



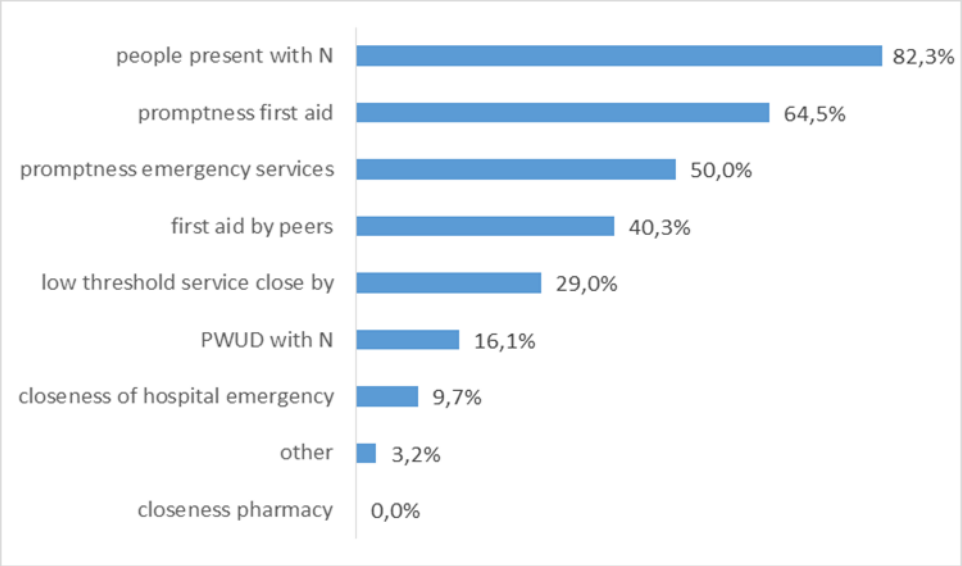
The most cited cause of OD by respondents (79.4%) are changes in tolerance levels by PWUDs, for example following a period of abstinence in prison or in rehabilitation. Following this is multiple or poly drug use- the simultaneous consumption of diverse psychoactive drugs (63.5%). Thirdly is the variation in the purity of the substance, cited by more than half of the respondents (54%). Following these causes are: a compromised health status, indicated by one respondent in three (33.3%) and the different and unknown composition of the substance used to cut the drug (27%). Less than one respondent in ten indicated an insufficient pharmacological cover due to a low dose of an opioid antagonist and scarce access to treatment among the principal causes of OD. Finally, only two respondents included a certain level of intentionality on the part of the user as one of the main causes of OD.

Fig.3.7 Principal causes of opioid overdose (% of cases, N=63) (multiple responses possible)



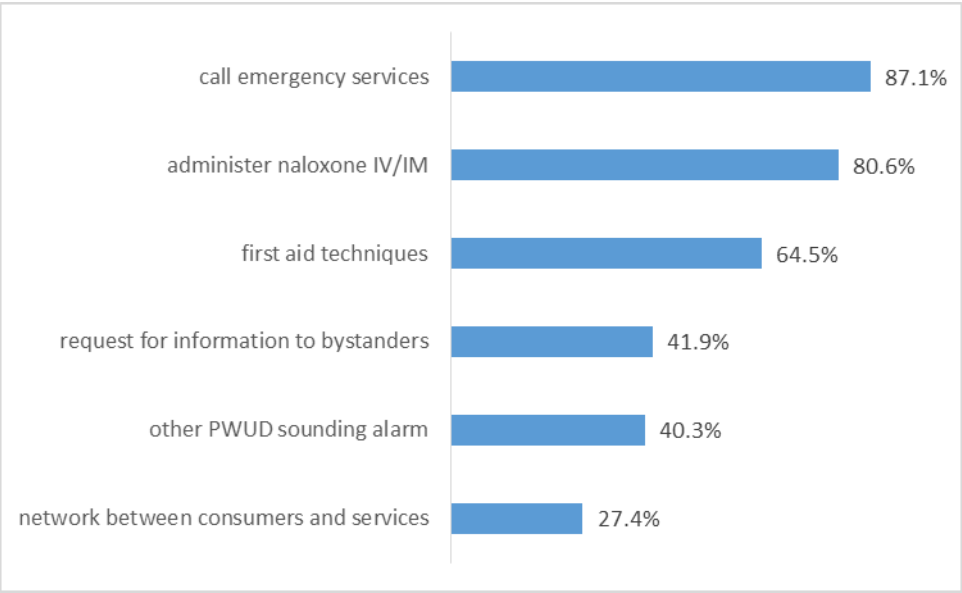
The possession of naloxone by people present if the most frequently mentioned condition by the respondents as the predictive factor for a positive outcome of an OD (82.3%), along with the promptness of first aid intervention (64.5%) and that of emergency services (50%). These convictions are widespread above all in the services that distribute naloxone or have done so in the past, more so than in services that do not distribute it. The statistically significant difference is revealed by the Fisher test (p1=0.025; p2=0.033). The possession of naloxone by the PWUDs involved appears much less effective, given that it was identified in less than one respondent in six (16.1%). More important however is first aid knowledge by peers, indicated by 40.3% of the sample. With reference to the presence of specific services in proximity to the OD episode, only low threshold services appear to be useful in avoiding a negative outcome, according to 29% of respondents. The proximity of a hospital emergency room seems to have little impact (9.7%) and that of a pharmacy/chemist, zero (0%). Other predictive factors cited spontaneously by the respondents are the availability of anexate, a benzodiazepine antagonist and the fact of not consuming in an isolated place.

Fig.3.8 Predictive factors for a positive outcome of overdose (% of cases, N=62, 1 n.r.) (multiple responses possible)



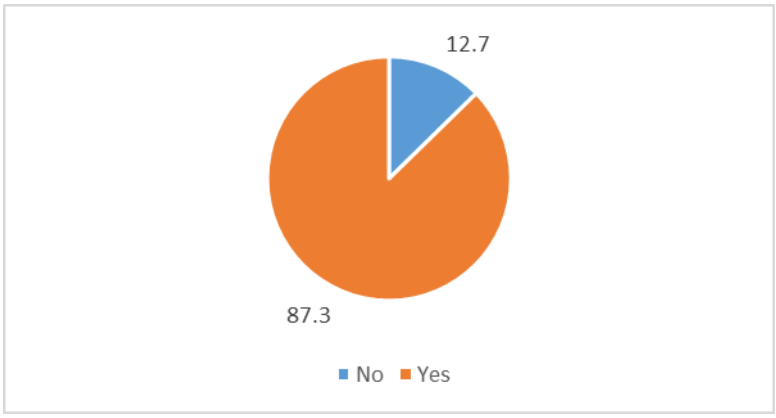
Almost 90% of respondents declared that their service gave workers instructions to call emergency services in the case of an OD. Also the administration of naloxone, intravenous or intramuscular, is diffuse, cited in 80.6% of the sample. First aid procedures, including techniques known as *Basic Life Support* are mentioned in more than half of the respondents (64.5%). The request for information from people present on the scene, sounding the alarm and advising other PWUDs is placed at around 40% of cases. Activating ways of collaborating among consumers and services, to work as both an antenna and a monitoring system, regards only 27.4% of the sample, but with a great difference between types of services. In fact these strategies are adopted in more than half of the HR services (56.6%) in contrast to only one SerD among 21 respondents, around 4.8%. In the SerD other consumers sounding the alarm and the request for information from those present is also less diffuse.

Fig.3.9 Operative indications for managing overdoses (% of cases, multiple answers possible)(N=62, 1 n.r.)



The operative indications adopted in cases of OD by services are shared also by non-health workers (educators, outreach workers, volunteers) and peer support workers in an overwhelming majority of cases (87.3%). This level is even higher in HR service with respect to SerD (91.3% versus 85.7%).

Fig. 3.10 Shared operative indications by non-health workers and peer support workers (%, N=63)



In more than one case in three from the sample (34.9%) all workers present on-site are authorized to administer naloxone. Excluding the responses "all" and "none" (the latter regards the drug rehabilitation and social reintegration centers), the professional figures cited are prevalently health workers, that is, doctors and nurses.

Tab.3.4 Workers authorized to administer naloxone in case of emergency (N=61)

	Responses	
	N	**%**
all	30	34.9%
none	3	3.5%
doctors	24	27.9%
nurses	19	22.1%
health educators	3	3.5%
peer workers	2	2.3%
volunteers	2	2.3%
other	2	2.3%
psychologists	1	1.2%
total	86	100.0%

Grouping the answers by profession, in most services (60.3%) both health professionals (doctors and nurses) and those with a social profile (mainly educators but also peer workers and volunteers) are authorized to administer naloxone. This overall data however hides the marked difference between SerD and low threshold services, with a significance confirmed by the Fisher test (p=0.001; p2=0.001). In the SerD in fact mostly doctors and nurses are authorized (61.9%), compared to HR services where all professionals are authorized including those with a "social" profile (87%). From comments that were added by respondents under the heading "other" it is clear that non-health workers are subject to restrictions in some cases. In one specified case the workers can intervene only after contacting emergency services who may authorize administration. In another case, naloxone can be administered only by intramuscular injection. One respondent complained that workers in her organization who administer naloxone are personally liable as there is no regional law in this matter to cover them. This response indicates that within drug services there is a certain confusion regarding the legality of the intervention, which does not require any specific regional law.

Tab. 3.5 Professions authorized to administer naloxone in services (% value, N=63)

	Type of service				
	drop-in, MNE, low threshold	SERD	outreach entert. venues	other	total
Health	3	13	1	0	17
	13.0%	61.9%	33.3%	0.0%	34.7%
Health and non	20	7	2	0	29
	87.0%	33.3%	66.7%	0.0%	59.2%
No-one	0	1	0	2	3
	0.0%	4.8%	0.0%	100.0%	6.1%
	23	21	3	2	49
	100.0%	100.0%	100.0%	100.0%	100.0%

4. **Practice relating to THN**

In the services that adopt, or adopted in the past, the practice of THN, naloxone is/was given to all the workers in the operating unit (22.7%) or else to diverse professional figures: educators are cited in more than half of the cases (56.8%), doctors in slightly less than half the cases (47.7%). Following these figures are nurses, cited in more than one case in three (36.4%) and psychologists, in less than one case in four (22.7%). Peer support workers and volunteers comprise a small number of cases (both are mentioned by only 5 respondents), even if they could be included in the category "all workers" or "street outreach workers". This last group are spontaneously cited in the category "other", perhaps to indicate that the discriminating factor is the role rather than the professional title, which in general is that of educator[63].

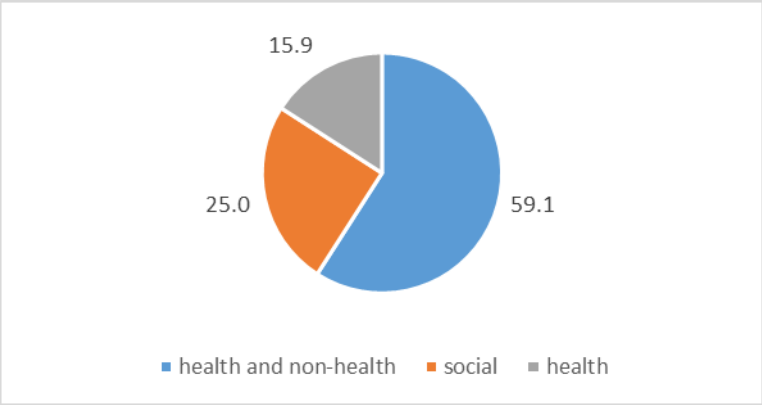
Tab.3.6 Who distributes/distributed naloxone (sample distributors + ex-distributors, N=44)

	Responses	
	N	%
educators	25	26.0%
doctors	21	21.9%
nurses	16	16.7%
psychologists	10	10.4%
everyone	10	10.4%
peer workers	5	5.2%
volunteers	5	5.2%
others (street outreach workers)	4	4.2%
total	96	100.0%

Grouping the professional categories, it can be seen that in the majority of cases (59.1%) naloxone is distributed, within the same service, both by health and non-health professionals. In one case in four (25%) it is distributed only by the figure with a more "social" profile (included here are educators, psychologists, peer workers and volunteers). The distribution exclusively by health professionals (doctors and nurses) only occurs in a minority of cases (15.9%).

63 Or else street outreach worker is used by the minority group that does not have a recognized title.

Fig.3.11 Professional figures who distribute naloxone (sample distributors + ex-distributors, N=44)



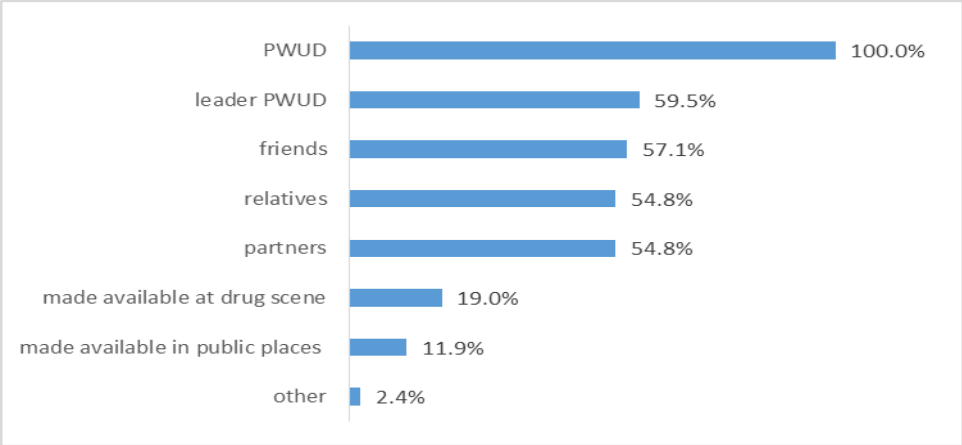
Examining the answers provided by the different services, in none of the HR services nor the outreach services in entertainment venues is the distribution trusted exclusively to health professionals, just as in no SerD is it trusted exclusively to personnel with a social profile.

Tab.3.7 Professional figures who distribute naloxone and type of service (sample distributors + ex-distributors, N=44)

	Type of service			
	drop-in, MNE, low threshold	**SERD**	**outreach entert. venues**	**Total**
Health	0	5	0	5
	0,0%	45,5%	0,0%	15,2%
Health and non-health	10	6	2	18
	52,6%	54,5%	66,7%	54,5%
Social	9	0	1	10
	47,4%	0,0%	33,3%	30,3%
	19	11	3	33
	100,0%	100,0%	100,0%	100,0%

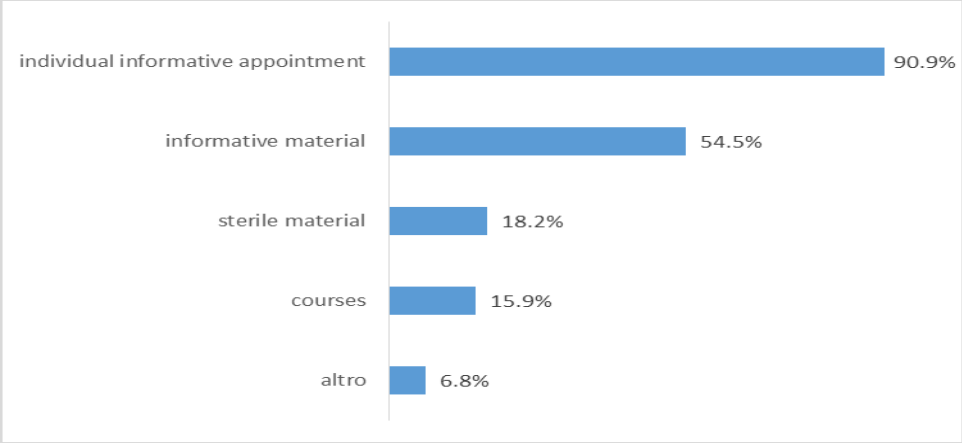
Naloxone is or was distributed, as well as to the individual consumer, to consumer “leaders”- people who are reference points for others- in around 60% of cases. Again, in a majority of cases, naloxone is distributed, in order of frequency, to friends (57.1% of cases), to partners (54.8%) and to relatives of the PWUD. There are a minority of cases however whereby naloxone is made available at places where drug consumption occurs (19%) and in other places or public venues (11.9%). In one instance naloxone is made available in the SerD OST centre (“other” category).
Looking at the differences between services it is clear that the distribution to consumer “leaders” and friends is less practiced by the SerD than by the HR services, while the SerD deal mainly with partners and relatives.

Fig.3.12 To whom THN is distributed and how it is/was made available (sample distributors + ex- distributors, N=44)



The distribution of naloxone in more than 90% of cases occurs during an individual informative appointment. In more than half of the cases (54.5%) the service consigns informative materials at the same time while in only one case in five (18.2%) are sterile materials, such as syringes and water, are given together with naloxone. In even fewer cases (15.9%) are training sessions activated regarding the drug and first aid techniques. This statistic regards only the HR services as these issues were not identified by any of the SerD.

Fig. 3.13 Modality of THN distribution (sample distributors + ex-distributors, N=44, 1 n.r.)



For the open question "with what indications" is/was THN distributed, half of the sample replied in a generic way, saying methods of administration were provided but not specifying details. Among those indications specified, the most common one cited was to call for emergency services (38.6% of cases). This was followed by the advice to never use drugs alone, indicated by a quarter of respondents, coherent with indications to advise other PWUDs (9.1%), Other specific indications regard the method of injecting naloxone (in total 29.6% of cases), which are diverse and also incongruent. In five cases it is advised to use intravenous or intramuscular injection. The same number of cases indicate that it must only be used as an intramuscular injection. In one case, apart from these two methods, also subcutaneous injection was indicated. Other advice regards the risk of withdrawal to the PWUD following administration and therefore the need to not leave the person but remain and monitor the situation or accept temporary hospital admission. Finally, some provided information on how to conserve the THN and legal information regarding it.

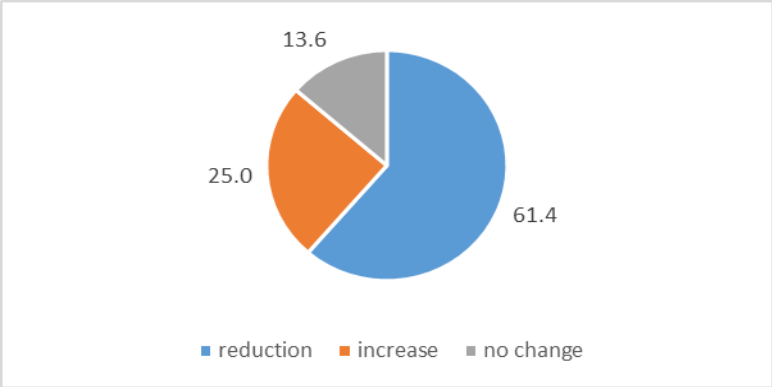
Tab. 8 Advice given when consigning THN (multiple answers possible) (sample distributors + ex-distributors, N=44)

	N	% of cases (N=44)
generic advice (life-saving drug, how to administer)	22	50.0
call emergency services	17	38.6
never use drugs alone	11	25.0
method of IM injection	5	11.4
method of IM or IV injection	5	11.4
advise others	4	9.1
danger of withdrawal	3	6.8
never leave the person	3	6.8
method of IM IV or injection	2	4.5
accept admission	2	4.5
other (legal info, expiry date)	2	4.5
method of subcutaneous injection	1	2.3

5. Changes over time

Most of the services that distribute or have distributed naloxone (86.4%) have over the years modified the number of vials distributed, more or less in a negative direction (61.4%). This is true, even with different percentages, for those services that have had more than 20 years of experience, for those with between 10 and 20 years of experience and for those with less than 10 years experience. The reduction of distribution is furthermore the most common response given by both the SERD who responded to this question and the HR services.

Fig.3.14 Changes over time of the number of vials distributed (sample distributors + ex-distributors, N=44) (%)

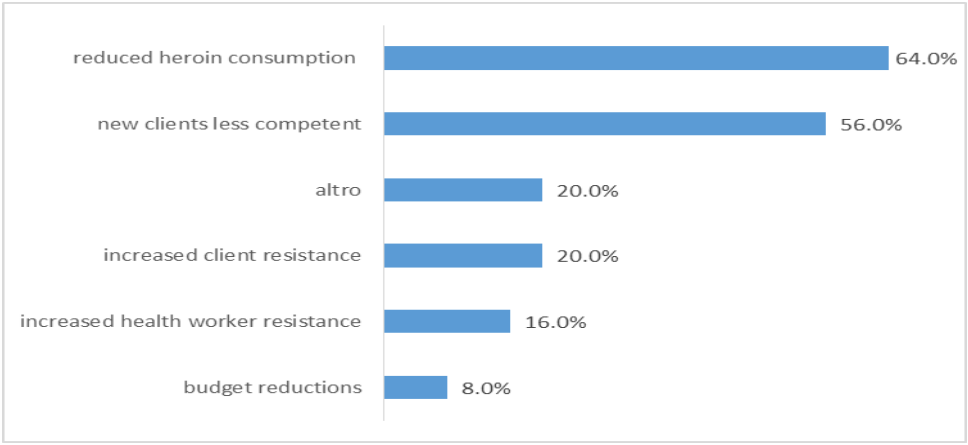


Tab. 3.9 Changes over time and length of service operations

	years of service operations		
	more than 20 years	**10-20 years**	**less than 20 years**
No	1	3	2
	14.3%	13.0%	18.2%
Yes, an increase	2	5	4
	28.6%	21.7%	36.4%
Yes, a reduction4		15	5
	57.1%	65.2%	45.5%
Total	7	23	11
	100.0%	100.0%	100.0%

According to the majority of respondents, the reduction in the number of vials distributed occurred because of the reduction of heroin users (64%) and due to the influx of new clients less "competent", that is, less receptive and aware of the risks (56%). One respondent in five affirmed they are more resistant to the idea of carrying naloxone with them. One is six (16%) stated the resistance arises also from the workers. Among the spontaneous responses provided it is worth noting that a couple of respondents asserted that the episodes of OD had diminished thanks to improvements in substitute drug therapy, while others cite the reduction in the diffusion of new and less dangerous ways of using heroin (smoked and inhaled).

Fig. 3.15 Causes in the reduction of number of vials distributed (N=25, 2 n.r.) (multiple responses possible)



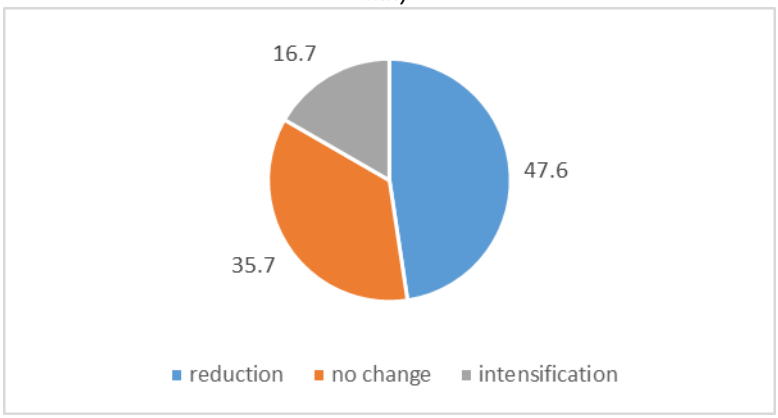
Vice versa, the reasons for an increase in the number of vials distributed, which regards a limited number of cases (11) are to be found, according to the respondents, mainly in an increase in the competency of PWUDs (9); in their reduced resistance (6) and due to a more intensified offer by health and non health workers (6).

Tab. 3.10 Causes for an increase in number of vials distributed (N=11) (multiple responses possible)

	Responses	
	N	**%**
increased heroin consumption	1	3.7
decreased client resistance	6	22.2
increased client competency	9	33.3
increased offer	6	22.2
increased budget	3	11.1
other	2	7.4
total	27	100%

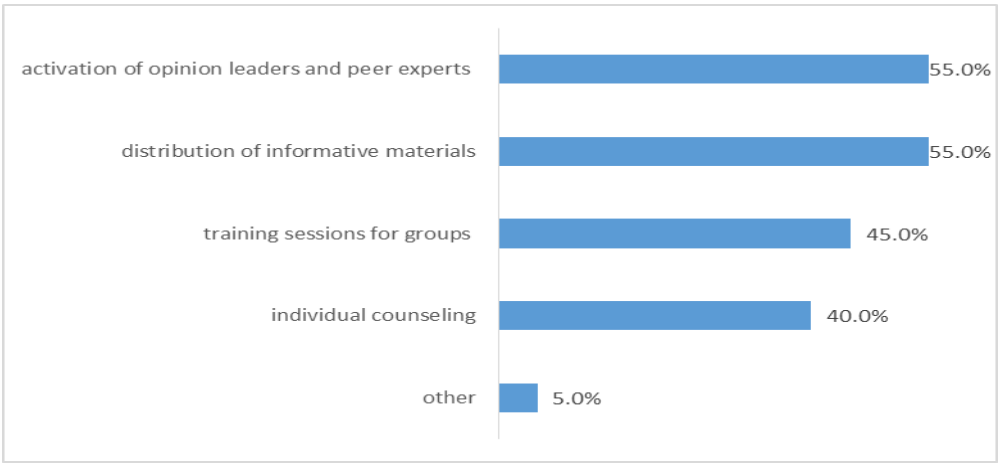
According to a relative majority of respondents (47.6%) there has also been a reduction in the interventions that include the distribution of naloxone over time, supporting what has emerged regarding the number of vials distributed. Only 16.7% (equal to 7 cases) claim that there has been an intensification of these interventions and in particular an increase in individual counseling (7) and the distribution at drug- user locations and/or in other public places. Observing the differences between the years of operational services who distribute, it can be seen that between those with the oldest history (more than 20 years) and those more recently established (less than 10 years) the answers that indicate no change prevail.

Fig. 3.16 Changes over time in interventions connected with distribution (sample distributors + ex-distributors, N=42, 2 n.r.)



A reduction in interventions seems however to prevalently regard the distribution of informative materials and the activation of opinion leaders and peer experts (11 cases out of 20), followed by training sessions for groups (9) and individual counselling (7).

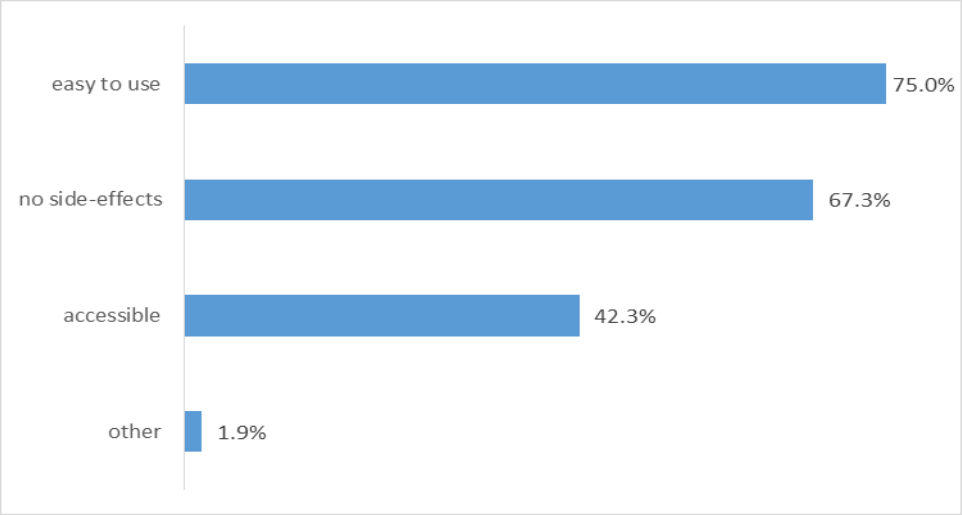
Fig. 3.17 Interventions that have been reduced over a period of time (N=20) (multiple responses possible)



6. Opinions about the drug and about THN

According to two thirds of respondents- including those who distribute or have distributed naloxone and those who have never distributed the drug- the ease of use is one of the principal advantages of the drug. Following this for number of responses (67.3%) is the absence of side-effects, while the accessibility of naloxone as an over- the -counter drug is a useful characteristic in only slightly less than half the respondents (42.3%). Some in fact specified that the availability of naloxone in pharmacies is “not clear”, making reference to the fact that not all pharmacies conform to what is expressly required by law. Another useful characteristic cited is the possibility to use the drug via nasal inhalation (not yet practiced in Italy).

Fig.3.18 The most useful characteristics of naloxone (general sample N=52, 11 n.r.) (multiple responses possible)



The distribution of answers does not alter much comparing SerD and HR services, however in services that have never adopted the practice of THN the opinion that naloxone is easy to use is less diffuse.

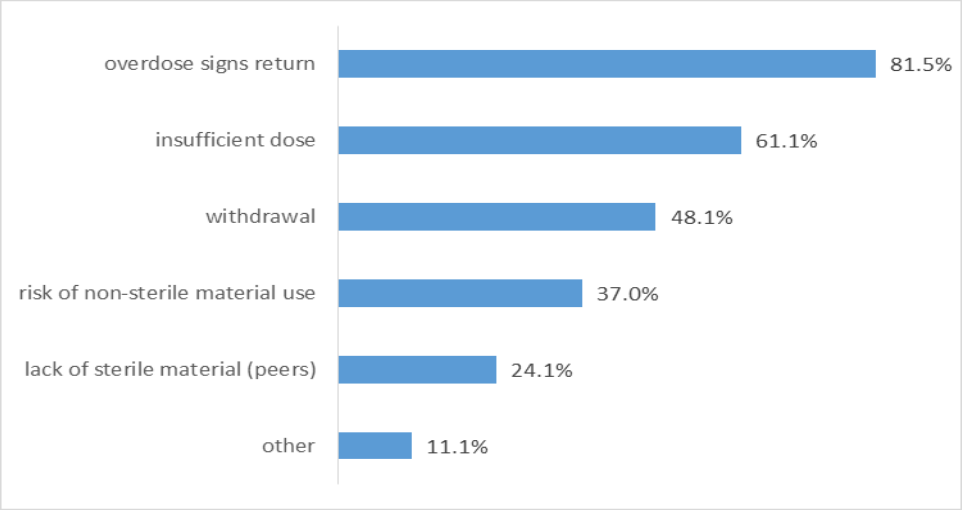
Tab.3.11 Most useful characteristics of the drug and services that practice THN or not

	yes	**in past**	**no**
accessibility	15	1	6
	41.7%	100%	40.0%
easy to use	29	0	10
	80.6%	0.0%	66.7%
no side-effects	24	0	11
	66.7%	0.0%	73.3%

Among the main limits of the drug, the most cited (by 81.5% of respondents) is that following the first administration of the drug there is the possibility that signs of OD return, followed by the possibility that the dose given may not be enough (61.1%). Almost half of the respondents (48.1%) included in the limits the possibility that the drug could cause withdrawal symptoms for the PWUD. Referring to this, one respondent commented: for this reason *"we advise to use at least one naloxone phial via intramuscular injection to enable a slower and prolonged effect".* Finally, the risks associated with using the drug with non-sterile materials and the lack of sterile materials by peers was indicated respectively by 37.0% and 24.1% of respondents. Other limits to the drug that were mentioned freely by respondents regard the very invasive method of use; the impracticality of the kit (the desire is for a product ready to use in the syringe or in a nasal spray form); *the "limited effect specifically in cases of poly-drug use with methadone and other opioids");* and the limited availability in pharmacies.

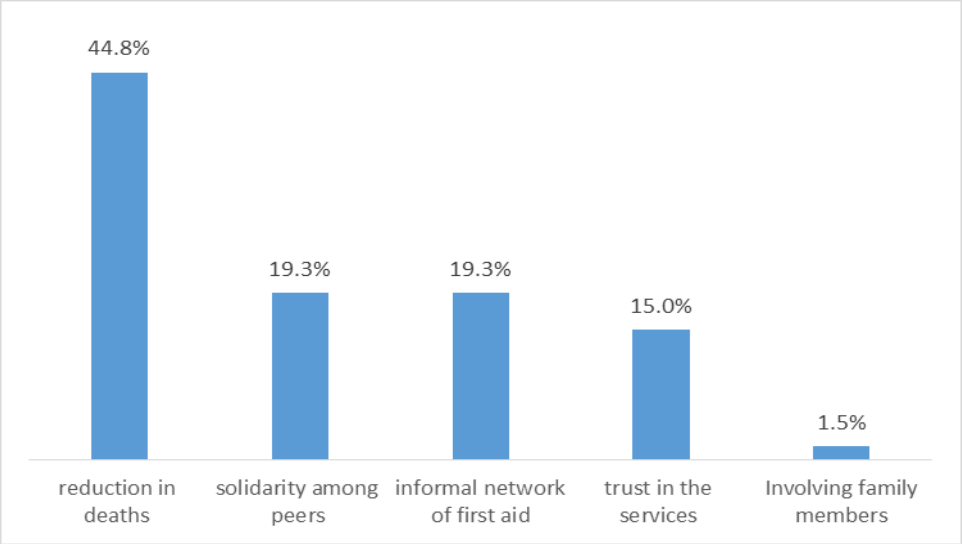
Observing the difference among types of services, the risk that OD symptoms reappear is more felt in the HR services than in SerD (91.3% versus 76.2%). The same applies regarding if the drug causes withdrawal symptoms (57.1% versus 43.5%). Furthermore the possibility that the dose is insufficient and that the signs of OD will reappear are felt more in services that distribute naloxone rather than those who have never distributed it (67.6% versus 43.8% and 89.2% versus 62.5%).

Fig. 3.19 Limits to the drug (general sample N= 54, 9 n.r.) (multiple responses possible)



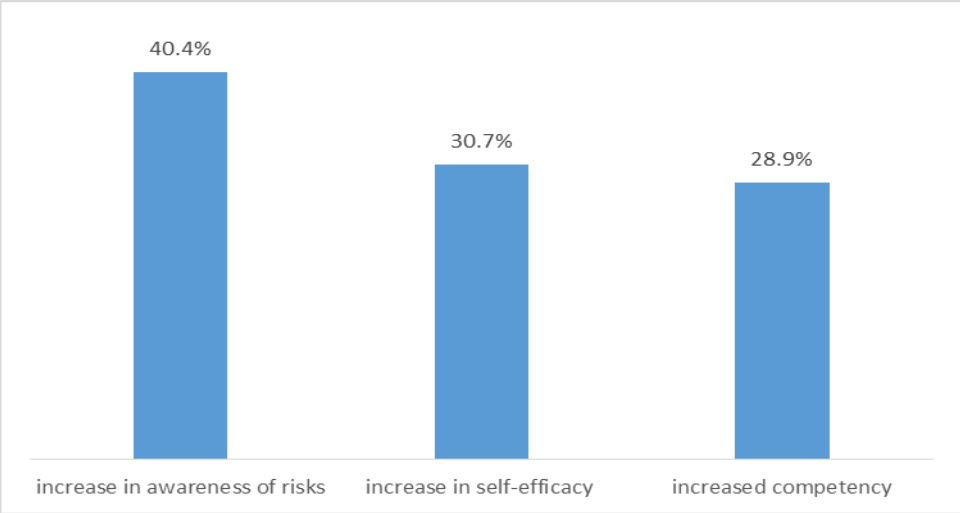
Respondents were asked to choose from a list of five items, the three main advantages of THN for the socio-sanitary system, in order of importance. Figure 20 sums up the total sum of the votes in percentages (with 3 points assigned to the first position, 2 to the second and 1 to the third) A reduction in deaths is the advantage that gathered almost half of the total points (44.8%). The promotion and support for solidarity among peers and the availability of a widespread informal network of first aid help are both in second position, with a total of 19.3% of votes. An increase in trust in the services is in third position, with 15% of votes. Involving family members of the consumer however obtained a residual score.

Fig. 3.20 Principal advantages of THN for the socio-sanitary system (% of total points, N=326)



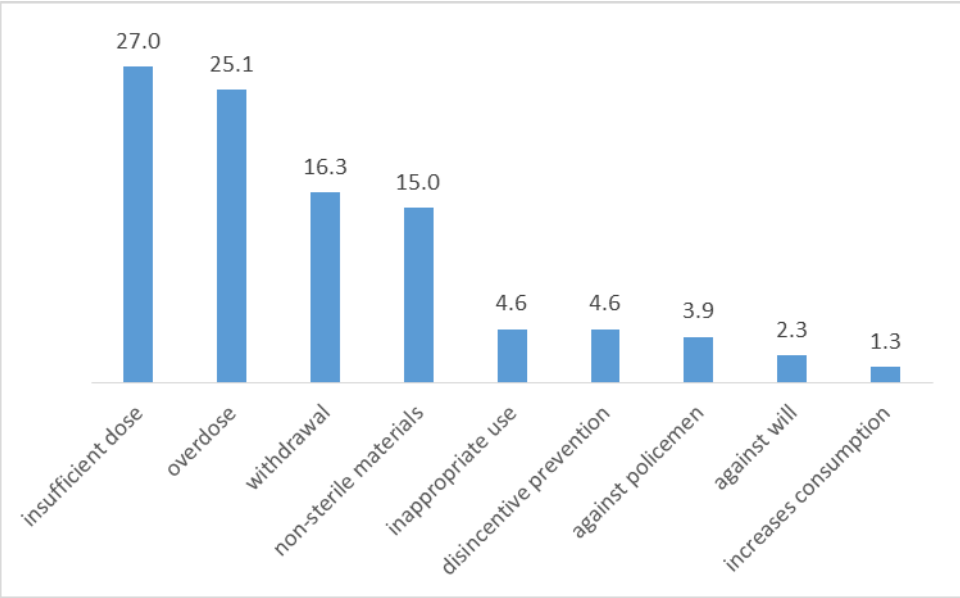
Moving attention to the advantages for the PWUD, 40.4% of total votes by respondents referred to the increase in awareness of risks. Secondly, the increase in self-efficacy in knowing how to deal with a crisis and thirdly, an increased competency in the actual intervention.

Fig. 3.21 Principal advantages of THN for the PWUD (% of total points, N=322)



The principal risk, which totaled 27% of all the respondents votes, is that one phial is not sufficient with respect to the quantity taken. The second risk in order of importance, with 25.1% of votes, is that after the administration of naloxone, the PWUD- also due to the withdrawal symptoms caused by the drug- will take another dose of heroin and induce another OD. A further risk that acquired a significant number of votes is the use of non-sterile materials. Inappropriate use or against the will of the subject were chosen by a restricted minority of respondents. Few people also believe that THN is a disincentive for prevention behaviours or that it induces an increase in consumption. The latter opinion was found only in services that had never distributed naloxone.

Fig. 3.22 Principal risks of THN (% of total points, N=307)



For the question *"how are the risks of the drug and THN managed"*, given to the sample group of distributors and ex-distributors, 36 people responded. This was an open question and it was codified by grouping similar answers. As can be seen from the following table, the modality most frequently adopted to avoid risks (47.2% of cases) is to provide specific information about the correct use of the drug at the time of distribution and at times also providing written materials. In one case the information was provided through a sensitization campaign aimed at clients of that service. Another method by which respondents claim to manage the risks are through individual sessions, with counselling most cited as the practice used. This is followed by the prompt calling of emergency services and giving the client more vials to prevent eventual "rebound overdose" situations. Some specify that they give as many vials as the client requests. Others state there is no limit to

the quantity distributed. Another claimed the opposite: *"we ask the PWUD to only use it if absolutely necessary so as to avoid sending someone into withdrawal".* Actual training is mentioned in only four cases, as is the distribution of sterile materials (syringes, antiseptic swabs). In two cases, courses that envisage the involvement of peers is mentioned, which is another factor considered important to prevent the risks of THN. To prevent the risk that the PWUD could experience withdrawal symptoms following the administration of naloxone and therefore take another dose of heroin, the practice (and advice) is to "*monitor the overdose*", as it has been named. This entails keeping the subject under observation for a few hours following the administration of naloxone. As has been previously seen, some maintain that the administration of the drug via intramuscular injection is the way to prevent withdrawal symptoms.
" I mostly administer the drug via intramuscular injection to monitor the effect without peaks and relapses in overdose, regulating the quantity that is deemed sufficient in order for the person to recover without reaching an excessive withdrawal phase and the desire to do more drugs, staying with the client for the time necessary to monitor the recovery".

Tab. 3.12 Management of risks associated with the drug and THN (sample distributors + ex-distributors, N=44, 8 n.r.)

	N	% of cases
informative materials (including written)	17	47.2
counselling/appointment	11	30.6
call emergency services	5	13.9
give more dosages	5	13.9
training/counseling groups	5	13.9
distributing sterile materials	4	11.1
activating peers	3	8.3
monitoring overdose	3	8.3
campaign	1	2.8
IM injection	1	2.8
other	1	2.8

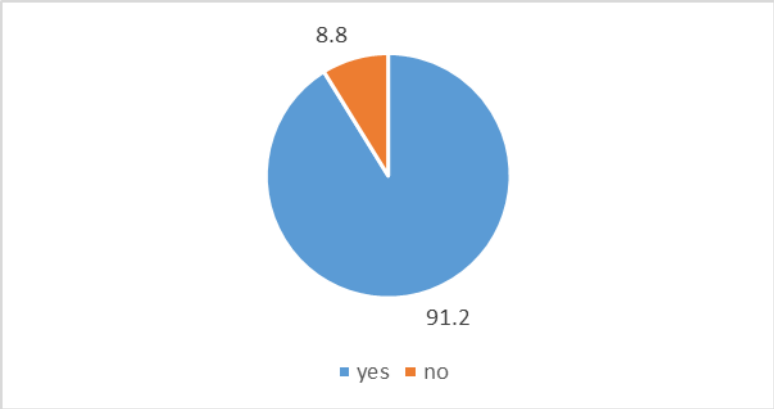
Almost all of the respondents affirm that the intervention THN model previously described- in substance, accompanied by information and counseling sessions- has increased the competency and the ability of the PWUDs to prevent OD. The reasons, freely expressed, are to be found above all in the increased understanding of the risks, not only those connected to OD but, as some specified, also those relating to drug consumption in general. In fact, *"through the distribution of this drug it is possible to sensitize the clients to the dangers of certain behaviours".* Other motivations are the increased level of information by the client and increased responsibility as well as improved trust in the service. As one respondent specified: this intervention model *"creates an occasion for a more intense therapeutic relationship".* THN also increases a sense of self-efficacy for the PWUDs, both as an individual and as a group, as it influences the ability between peers to provide help. The following written citations make evident how this practice can compensate for the scarce recourse to the drug- connected, according to respondents, also to the limited availability notwithstanding the provisions of the law in this matter- and the limited recourse to calling emergency services for fear of legal consequences:

"other than the practice which not everyone is aware of, it has facilitated assistance among peers which was previously difficult. It was necessary to pay for it in the pharmacy (if they even gave it out) and above all there was fear about the consequences of a call to get an ambulance. The emergency number activated the arrival of the police and successive controls. This all made an early first aid intervention possible only for the few who had bought it or who had HR workers in the vicinity"

Respondents who on the contrary did not believe this model increased the competency of the consumers, do not make reference to the limits of the model itself but to the lack of a uniform application of this model throughout the national services system (*"it seems it has to be the prerogative of the HR services only"*).

Criticism is also made to its limited capability for the new generation of PWUDs who, according to some, are not aware of the risks of OD.

Fig.3.23 Has this intervention model increased the competencies and capacities of consumers to prevent overdose? (sample distributors + ex-distributors, N=34, 10 n.r.)(%)



In conclusion, a comment left freely by one respondent who shines a light on an important aspect of THN as it has developed in Italy, even if in a patchwork manner: the recognition and the importance of the competencies of the PWUDs:

" the so-called Italian model teaches that no matter the context and the conditions where psychoactive drugs are used, on the street or not, people have the ability to control their own lives and are open to new learning experiences....notwithstanding the processes of marginalization and stigmatization...work that includes accompanying people, installing a relationship with weak ties and an attitude of acknowledging the other person represent a constituent basis for every social and socio-sanitary professional capable of giving value to these processes".

3.1.2 Results of Focus Groups with addiction services Workers

Method

Two focus groups were conducted, one in Turin and one in Naples. Those who participated were workers – health workers, educators, outreach workers and peer educators - from the public and private drug addiction services that are the most active in naloxone distribution in different regions across Italy. A total of 18 workers participated- from the private social services sector (9)- cooperatives, associations and foundations that manage low threshold services- and from public services: local councils (1) and above all SerDs (Public Addiction Services) (7) which also include Drop-in services and Mobile Needle Exchanges (MNE). The cities represented were Brescia, Collegno (Turin), Florence, Latina, Milan, Naples, Perugia, Prato, Reggio Emilia, Rome, Settimo Torinese (Turin), Turin and Venice[64].

Results

The past situation- between emergency and opportunity: the foundations of Take Home Naloxone (THN)

At the beginning of the 1990's, an emergency social and health situation caused by the heavy use of heroin and even more so by the high number of deaths from the AIDS epidemic, favored a "policy window": questions were asked and drug addiction services had the occasion to assert themselves and to introduce innovative models and intervention practices[65]. The introduction of THN was therefore part of a wider process which, on the wave of this emergency, saw the consolidation of SerDs, the birth of low threshold services such as needle exchanges and drop-ins, and increased collaboration between public and private sectors. It also meant an increased consensus in general with respect to treatments - substitute treatments and in general all of the practices that come under the harm reduction approach (HR) -which had until then been the object of political and ideological resistance

When this work started, all of Italy was paying attention, there was money, there was the emergency, there was AIDS (…) and it was this stuff that gave some impulse to the low threshold services (INT. 15, private social, Turin).

At that time we did actual courses ad hoc on the use of naloxone for clients (…) However overdoses were 1-2 a day! I recall when there was still "the hill" in Brescia, a place where you could buy and use. There were many overdoses and often they would come and call us (INT. 16, private social, Brescia).

From the beginning the policy of THN was developed around principles that today are still the foundations of this policy: the formation of a mixed team where **educators[66]** worked alongside health professionals. There was also the recognition and the enhancement of the capacities of drug users themselves in the **role of peers,** as a main point of reference for users and as efficient intermediaries between services and potential clients.

In fact in that time heroin was used a lot and therefore they asked for Narcan...the young guys would ask for Narcan (….) the people in the needle exchange unit were mixed, there was a health worker, a nurse, a social worker, a psychologist and then there were one or two outreach workers. We dealt with the overdoses on the number ten platform... there was an abandoned train carriage and it was there that we went to treat the overdoses...an ambulance would never arrive... it was those same guys... or they would call out "run! run! there's an overdose!! or else one of them was already trained to treat an overdose (INT.5, Drop-in of SerD), Naples).

[64] See in Chapter 1

[65] Beccaria F. e Rolando S.(2013). Stakeholders' Role in Contemporary "Substitute Drug" Prescribing Policies in Italy. *Substance Use & Misuse*, 48:943–953.

[66] professional socio-educational workers who work in health and social sectors within public services or external agencies

We had peer workers that worked with us in the service, then through the SerD there were work grants to work there, within the department, and therefore the users gave out all the information. It worked, especially as we who worked there and were not users, were never listened to, so this was a good thing (INT.11, Drop-in of SerD, Collegno).

Notwithstanding this push - which could also count on the work of "some public health workers particularly illuminated" who followed the practice of "the three less: less deaths, less infections, less in prison" (INT.8, private social, Florence)- the introduction of the THN practice was not without some difficulties, as those who lived through that period recall well. The first critical issue was to legitimate the educators for the administration of naloxone in an emergency. This was in fact considered an action to be undertaken only by health professionals.

I began in '92 working in outreach... therefore...everywhere...we as educators could not do it, only doctors could... so that was probably the battle.. (INT. 2, private social, Rome).

The critical issues obviously also regarded breaking down ideological resistance that persisted not only with respect to public opinion but also at institutional levels. This was a barrier to relationships between other services in the area, above all law enforcement, emergency services and pharmacies.

What was extremely critical was the relationship with other services. The pharmacies that in fact by law should give Narcan without a medical prescription, often and deliberately did not provide it, according to our regular clients, and asked for a prescription, as there was considerable ignorance regarding this (INT.12, SerD, Turin).

In those years a huge amount of work was done for this reason, not only with users but in the local area, in order to create a network with other people from different occupations who came into contact with the problem. This networking was done largely through formal agreements, and partly via the construction of informal relationships and personal collaborations. In Venice for example, through an agreement with the Order of Pharmacies and with general practitioners, an awareness campaign was organized that led to an increase in pharmacies willing to have drug users as clients. (INT.10, Local Council, Harm reduction (HR), Venice).

In the 90's when we began with our harm reduction project the pharmacies were let's say the stakeholders (…) it was necessary to come to an arrangement, not only regarding Narcan but also regarding syringes (…) Then clearly there was the work in the area, the community, the important testimonies, who could be the coffee shop owner on the corner or the local community group (INT.8, private social, Florence).

When we had to deal with, for example, the traffic police. After a month, two months, three months, they became aware of the issues and also the police force (…) this happened spontaneously thanks to the interpersonal relationships we created (INT.5, Drop-in service, SerD, Naples).

The 1990's therefore were a period where the practice of THN was diffuse, even if uneven, thanks to the construction of networks and the good practices connected to the specificity of each single context, the local areas and the institutions. Amongst these it is important to remember the training of therapeutic/ rehabilitation centres' workers by SerD staff and the publication by some health centres of ad hoc information guides for those who were released from prison (INT.12, Drop-in, SerD, Turin).

The workers who experienced this process first hand, and had therefore participated in the "battle" for the diffusion of the THN practice in Italy, have no doubts about its usefulness and efficacy. The positive aspects are almost taken for granted and the outcomes, even with a lack of official data, appear to be confirmed by professional experience. Other than it can save lives, workers emphasize that the practice of THN has been an **instrument for a relationship with drug users**, capable of increasing their **awareness** of the risks

connected to heroin use and also in spreading solidarity amongst peers.

Therefore preventive harm reduction, as we did, made sense. I would now challenge anyone here in this room to say that a drug user is unaware of how you get HIV; twenty years ago he didn't know (INT.2, private social, Rome).

As far as positive effects go, we continually have feedback from people who tell us how they were saved or have saved other peers using Narcan (…) People who once upon a time used to say they would not take Narcan with them because it bought bad luck, after years and years of discussion back and forth, are often the ones that now ask us- so not only do we have even more reason to promote Narcan but it is they who ask us, above all those leaving rehabilitation/detoxification or prison (INT.12, Drop-in SerD, Torino).

I think the access to naloxone from outreach workers rather than from services was one of the facilitating factors in transferring good practices within drug-taking groups and I feel the need to say that an important step was taken here from the grassroots, from the users themselves, who maybe in the beginning had some resistance- connected more to street rules or beliefs (INT.4, private social, Perugia).

The practice of THN seems to have been useful, other than for the user, also in the end, to make services evolve towards a greater integration of competencies and collaboration. This was not only valid between public and private sectors but also between drug addiction services and other services, such as police or also rehabilitation clinics.

In past years (…) we have had no problems at all, neither with the police force nor with health workers, nor pharmacies (…) above all we have had no problems with users who are the ones requesting it from us. We have distributed 31.866 vials of Narcan during the lifetime of this mobile needle exchange. (INT.18, MNE, SerD, Turin).

Today: A period of reversal

The generalized impression is that THN today is in a "reflux" phase, characterized by less attention to the issue and a reduction in interventions. This is confirmed by a reduction in diverse services of the number of vials distributed and the information and awareness initiatives aimed at users. The causes for this change, which emerged during the analysis of these questionnaires, are diverse. Firstly, as different workers underlined, the original push for the diffusion of the THN practice was the social/health emergency of the 90's, determined by the AIDS epidemic and the elevated number of deaths from OD. Once the emergency ended, thanks to a reduction in the numbers of OD and HIV infection, a disinvestment occurred, also at training levels and with peer based activities which had always constituted the cardinal points of the THN strategy.

We went from an experience where peer support workers were actually the ones at reception in the SerD, the first filter was in fact done by peers, and today we have gone backwards damn it! (….) over time there has been a great ignoring of this issue (INT.8, private social, Florence).

A reduction in the number of OD according to workers, is not only due to a reduction in the number of heroin users and those amongst them that use intravenous injections, but also to a reduction in the quality of the drug. As one worker underlined however, this reduction in OD could transform into a risk factor when it induces the user into a "false sense of security", for example when a person is convinced they cannot overdose if they only smoke or inhale heroin. This is possible according to workers, even if the risk is inferior to that if it is injected intravenously. Furthermore particular at-risk situations remain, such as leaving prison or a rehabilitation/therapeutic centre without finishing therapy.

In Venice we have never had a great number of overdoses. We have rather low quality heroin here so that those who overdose do so for excessive mixing of drugs or the classic just out of jail, which happened a few

days ago, or someone leaving a rehab centre (INT.10, Local Council- HR, Venice)

In Brescia right now, nobody collapses, not even when they leave prison. This gives you some idea about the quality of heroin on the streets (…) I returned to Brescia three and a half years ago, nobody has ever collapsed. The last overdose I can recall was in Cremona...and that was six years ago, a person who had been in jail for quite a long time. Plus there is what the users say. " I wish I had the possibility of overdosing!" This is exactly what they say. (INT.16, private social, Brescia).

Also here in Reggio Emilia the quality of the drug is so low that we have not had an overdose case in a few years. The worrying thing however is it induces a false sense of security in users because they don't believe in Narcan anymore (INT. 14, private social, Reggio Emilia).

The reduction in interventions connected to THN are also attributed in some way to a political disinvestment. The topic of drugs has not been part of the political agenda for years and this has translated into a lack of resources, a fact lamented upon by many sectors: for example even the National Fund for the Fight against Drugs. Within the private social sector, a relatively common situation for example, is that naloxone is not provided by the SerD but services must now find the money for THN from their overall budgets, or from ad hoc projects designed to maintain what is in fact an ordinary activity.

With respect to the Florence area (….) these are not practices that are exactly legitimized, therefore there are a few HR services that promote it... but in economic terms to put it plainly, our budgets, if we buy naloxone, means we give up worker hours.. (INT. 8, private social, Florence).

For the past 15 years we have been submitting the same project. What sense is there? A waste of time, of energy. Is this an adequate service that functions? Enough! I feel like this is a bit of a joke (INT. 2, private social, Rome).

The Milan MNE and the Milan Drop-in are without funding and therefore we use the resources of our cooperative to stay open, while we wait for the official arrival of a new project. (INT.17, private social, Milan).

According to some however this is not a problem of just a reduction in resources but also a reduction in energy among the health educators involved. Other than a feeling of delegitimization, what is missing is a generational change between workers in drug addiction sector that has also contributed to a situation of **"tiredness"**.

Now the low threshold services are in a situation where they themselves are in low threshold....we are no longer have the same enthusiasm nor the economic resources of 20 years ago (INT. 15, private social, Turin).

New users, new challenges

The aging has also concerned the older user population obviously, who are no longer motivated to play the role of peer.

I agree with you. However other than our getting tired- because in our area for example there are no newcomers- there is also a tiredness in the users themselves, in that even they don't want to talk about their experiences anymore to younger people when the chance occurs... (INT. 11, Drop-in, SerD, Collegno)

The **"generation gap"** (INT. 8, private social, Florence) between older users and younger is a subject that was emphasized more than once in the course of the focus groups as a critical factor. According to some, the lack in transmitting competencies to younger people depends on the fact that between the two groups a generation of heroin consumers who could be considered "credible" as peers, is missing (INT. 10, Local council HR, Venice; INT. 17, private social, Milan). The thirty-year -olds are too unawares and too involved in their own drug use.

We have noticed that there is an actual generation gap. In fact the competencies let's say given to the historical users are not passed on to the new generation, to new ways of using. The basic rules like "never alone" or "never too hidden from sight" , or "if you bought from a new dealer" etc- all these elementary rules seem to have absolutely not been passed on (INT. 8, private social, Florence).

We actually have a generation missing. The old oldies- we even had survival courses with the ones at the beginning, some peers who taught other peers how to manage etc...that generation now (…) they have settled down, (…) therefore they come less to the drop-in, they are less around the streets, looking for stuff less, they are more stabilized on therapies...(...) Instead we have a group of 30 year olds who are really out of it on drugs so they are not credible as peer support. They are not able to tell a younger person how to avoid an overdose or how to use correctly, if they don't do it first (…) Therefore at this time there is a lack of Italian users who are able to be shaped let's say. (INT.10, Local council, HR, Venice).

On the other hand the distance between older users and those who are younger seems to make the peer-to-peer work that constituted and still today constitutes one of the most important strategies of the THN practice and more generally that of HR, much more difficult. This distance reflects not only a more general difficulty with intergenerational communications- which regards also non-users- but also that ways of using are different: not only have things changed in how people come to use but in the end, the relationship with the drug has changed, as with the young user doing heroin alone.

The big discussions (…) between the older ones let's say and the younger ones seem to be conversations from a bowling club or something.. " What the hell with this stuff! In our time...!" And this is something that we as workers- we discussed this in a staff meeting- that leaves us mystified. They block what could be a peer method, in that they have this kind of attitude: "Come back to me when you have started using a needle!" (INT. 13, SerD, low threshold, Settimo).

The difficulty in passing competencies from the older to the younger users I think is pretty generalized. I think this is due to different user modes, because it's not that younger users don't inject but that smoking it is much much more common (…) Younger people have a relationship with heroin that is very different from older users, therefore we can't compare them in any way. They came to this in different ways (INT. 14, private social, Reggio Emilia).

The fact that injecting is not the prevalent method of use among young heroin users- who prefer to smoke or inhale it- makes this target group less accustomed and less disposed to use a needle, even with respect to a life-saving drug. This problem regards eventual third parties who could intervene in the case of an overdose. For this reason workers maintain that the commercialization of intranasal naloxone or in a ready-to-use kit could be useful to get the attention of young users.

The most critical issue I think, the biggest, is the method of administration- the fact that it is given intravenously. I know there is a lot of talk about experimentation- nasal route, a small machine that you put on the leg and it does it automatically...I am not well-informed but it seems that if there are new methods that are really produced, realistic, then they could change the problems you talked about earlier (INT. 10, Local Council, HR, Venice).

The naloxone spray is coming out, however it costs more and it is drug that clearly a person can use. We give naloxone to the family; if it was a spray it would be much better (INT. 2 private social, Rome).

Heroin users actually represent only a minor part in the panorama of actual drug use. Cocaine users are more numerous- and require "a rapid relationship now, very different to before when people stopped for hours and hours to talk" (INT. 11, Drop-in SerD, Collegno)- and poly drug users. Another phenomena reported in many places (Naples, Rome, Florence, Turin), and one that presents a challenge for workers, is the consistent presence of young people who use **methadone intravenously.** According to workers, a methadone OD

requires higher doses of naloxone with respect to heroin and at times even repeated doses because as a life-saving drug it "has a much shorter half-life than that of the drug and even less than that of substitute drug therapy (INT.15, private social, Turin).

A large number of overdoses today are from methadone, and are from injected methadone.. at least that is the impression we have from the information we get here in Naples. Also because the quality of heroin in circulation is low here in Naples! And people start using methadone for this reason (INT. 7, SerD, Naples).

The use of methadone intravenously is connected in some cities to specific ethnic groups of users, such as Georgians in Rome. The identifiable presence of foreigners among young users represents another important challenge to be faced for workers: estimates range from one in four to one in two. Above all there is the need to overcome linguistic barriers. Those cited are Indian, Nepalese and immigrants from eastern Europe-Romanians, Ukrainians, Russians. They represent the new emergency, while those from the Maghreb are now considered old users and part of the system now.

One of the aspects we are dealing with now is the linguistic difficulties we encounter, in that before 90% of users who came to us were Italians, but now we have heroin users, cocaine injectors and smokers and they come from all over the world (INT. 17, private social, Milan).

We have lots, but lots and lots of Indians (…) while those from the Maghreb overall have become the older, known users, well-integrated. And then those from the east.. well, they are a huge emergency. There is a big part from the Ukraine and Romania who arrive and they do anything, believe me, even chalk I would say, and it is impossible to talk to them (INT. 16, private social, Brescia).

We have begun to have a large percentage of Rom, Romanians and actual Rom from the Rom camps, and with these the older users who are peers, refuse. They totally refuse and say "I absolutely don't want to have anything to do with these gypsies" and it is pretty true that they use a bit of everything, just about anything that comes along, they use (INT.18, SerD, MNE, Turin).

Some services, such as that of Reggio Emilia, have cultural mediators, but as the intervention reported below highlights, in order to get the attention and the trust of the user, the cultural mediator needs to be as near as possible to the users in terms of both culture and social class. In other words, the challenge that new foreign users bring with them should be dealt with by using peer workers. This has actually happened for example in Venice, where a Tunisian peer user has become an important reference point not only for his fellow countrymen but also for Italian users.

The problem is that some behaviours mutate by training. You learn from your peers, the professional educator but also the cultural mediator, who often is not a user. This is critical, especially when they tell you to do something in one way instead of another and it is clear they have never used. Then they become less credible. Therefore the way, above all with new ethnic groups that arrive, should be, I think, to rediscover the use of peers, in a very profound way. Also because then you adapt to the group and slowly slowly change (INT. 15, private social, Turin).

We have a cultural linguistic mediator who is Tunisian, who has done everything the Tunisians we meet have done and are doing. We got him to start when he was in jail in Padua practically, except now he doesn't use, he has a job (...) Apart from his unique way of getting involved with people from his country he is also paradoxically a reference point for young Italians. A lot of them search him out to talk about drug use. He is someone who did it all really, from heroin to crack. (INT. 10, Local Council, HR, Venice).

Cultural resistance and institutional roles: social versus health, public versus private

It has been stated that the implementation of THN was introduced in an historic moment when, on the wave of a social emergency, it was possible to introduce new approaches and spread new intervention models. The

legitimization of educators and the recognition of competencies by users and therefore the role of peer support workers were an integral part of this evolutive process. It also saw services evolving towards a more integrated approach in terms of socio-sanitary capacities and more collaboration with other services operating in the same area. In this way cultural resistance, that prior to this was an obstacle to this type of approach, was overcome. Nevertheless in the current situation, which is defined as "reversing", these resistances do not seem completely overcome or defeated. Rather, in a political climate of apparent disinterest both from policy makers and public opinion, the distance that separates public services and social services and SerD from the non-government sector, seems to have re-emerged in some areas. The difficulty in recognizing the user as an active subject and a person with competencies is rooted in the medical profession, according to some workers. In other words, naloxone, and more generally the HR approach, represents a "minus" for doctors and for their profession (INT. 7, SerD, Naples). Some of this depends on the history of the SerD, and partly the specific training of the doctors, which is removed from that of workers who work closely with users and those of the MNE. They rather have chosen to do training courses with peers and "we are contaminated, as we should be, by them" (INT. 4, private social, Perugia).

The services that were born with respect to heroin (…) have always tried, more or less knowingly, to respond to an emergency in terms of social control, apart from a few cases. Therefore they are trained to think of a person as an "object" with which they have to work, annoying for sure and in general with no capabilities whatsoever. And they imagined that "object" there as something they needed to work on behalf of others, who needed that "object" silenced in some way (….) Therefore all the talk about a therapeutic alliance or even the recognition of patient competencies, which is already difficult for a normal doctor, was at the nth degree here (…) To overcome this, we once had all this energy, we had peer support courses, reversing the roles (…) now for many reasons, some of which have already been said, and because there is no emergency anymore, we can't do this anymore (INT. 15, private social, Turin).

In some areas therefore a progressive divergence can be observed between educators and health professionals, both in the SerD where they have remained as title holders of low threshold services and between SerD workers and those in the private social sector, where the low threshold services have been given out to the private sector. In this case the risk is that the public role oscillates between the desire to maintain the ownership and that of delegating the intervention.

The SerD workers have a view...an extreme difficulty in imagining Narcan as an instrument for a relationship, therapeutic in some way. I have tried many times since I arrived here to insert Narcan amongst the drugs to be distributed but I find huge resistance between doctors and my service (….). it is as if the SerDs are more fixated on a therapeutic dimension, a niche, and I don't know if this is true in other places but I seem to gather this is so (INT. 7, SerD, Naples).

I think this situation is even more present now, even if at certain times let's say there was more dialogue, even in Rome, between HR and the treatment services like SerD (INT. 2, private social, Rome).

There must be continuity and the public sector should recuperate things. They do reclaim, and strongly reclaim the public role with respect to the private social sector. When it is convenient they delegate, however in some way they want to have ownership, when it comes to assuming responsibility (INT. 4 private social, Perugia).

At the same time, through the delegating to external operators, public services seem to have **partly renounced the role of constructing and governing the networks in their areas**. This is true even with respect to external subjects, like the pharmacies and the police forces, that also represent strategic sources for a complete data base and for understanding the phenomena.

This idea is more or less always in circulation: that a preventive intervention or in an emergency with respect to overdose- and clearly we are talking mainly of a prevention intervention- is passed onto a particular group of workers (INT. 7, SerD, Naples).

I think that the Municipal Police, the police force, the pharmacies, the emergency and ambulance services, the SerD, this is the network that should be working together (INT. 8, private social, Florence).

In other areas, the THN experience was born within a social context and then transited under the SerD mandate. This, according to a low threshold worker, meant "loosing a lot" in terms of social competencies and signaling in some way " a political defeat", a return to a more reductive vision of the problem of drugs (INT. 4, private social, Perugia). In other places on the contrary, the HR services have transited from the SerD to the Local Council, according to a model described as "schizophrenic".

A total transfer from social to health (…) this is a clamorous political defeat I think because the dynamics of drug use is delegated completely to health services without any minimal political responsibility regarding the fact that the dynamics of addiction are also social (INT.4, private social, Perugia).

I see that the regional governments could have a role in this work of reconstructing the levels of interface between local politics and the health agencies that are now relegated to the margins regarding this issue (…) so now the HR workers are paid by Local Councils, the health responsibilities are on the health care agencies and there is a kind of schizophrenia (INT. 1, private social, Prato).

New Essential Levels of Assistance (ELA)[67]

The new Essential Levels of Assistance (ELA) were approved at the Regional Governments Conference on 7th July 2016, and represents, according to the participants of the focus groups, an opportunity to reinforce the THN policy and practice. The ELA should, from 2017, include for the first time HR, a title that now "can be filled with content" (INT. 8, private social, Florence). There are however diverse doubts about this, the first being the fear that in the transfer of the guidelines from a national level to a regional one, the territorial fragmentation that has characterized until today the practices relating to naloxone will re-present themselves. The hope therefore is that standards will be identified at a national level which will not leave too much of a margin for interpretation by the regions.

The risk is that some regions will reinterpret in their own ways. For sure there will be a national HR plan, because the ELA will identify what those HR standards are and therefore finally the work of overdose prevention will have its own legitimate status as a paid intervention by the national health system. This will flow down to the regions and not only in economic terms but also in the structuring of a procedure, of a protocol (…) this could be a great opportunity (INT. 8, private social, Florence).

If it is true that the insertion of HR into the ELA represents on the one hand a form of guarantee, on the other hand workers are afraid that this process could bring with it the **risk** of a more **medicalized** approach to the interventions concerned.
According to those interviewed therefore, this process must also represent an occasion to "re-think the objectives, re-think and recreate what could be the indicators, the parameters through which the phenomena could be read, but above all to identify what could be the new practices that must inevitably involve also public services" (INT.7, SerD, Naples).

The ELA are let's say fundamental but then we need to understand how that will be put into practice because (….) drug addiction is taking a medical turn, at least where we are, meaning an actual medicalized system and this obviously- whether it is ELA or outside of ELA - invalidates the intervention...(...) (INT: 9, private social, Rome).

This is a hiatus that in the first instance touches the objectives of the interventions: "eliminate the symptom" (INT.9, private social, Rome) or reduce the damage. It would be opportune therefore, according to those

67 Health services and assistance that are guaranteed and that all Italian citizens have the right to access.

interviewed, that the objectives of treatment for addiction are redefined in a clear manner. This opportunity resides also in a proposal to revise the pertinent laws, which is in the elaboration phase. Among the participants, there is a certain amount of skepticism about whether this will actually happen, given the current political disinterest in drug issues.

Proposals from workers

With respect to the critical areas identified and based on personal experience, drug workers put forward diverse proposals during the focus groups that, according to them, could revitalize and reinforce the diffusion of THN practice in Italy. They are summarized as follows, grouped by main themes.

Constitute inter-institutional working groups

It is necessary to reconstruct the concerted action groups where diverse public and private sector workers, who come into contact in their area with people at risk of OD, can define strategies and collaboration agreements. This means particularly involving and increasing awareness among pharmacies, police, general practitioners, and also other entities such as owners of local coffee shops and venues. It is widely felt that the governance of this network should be done by a public entity and that this role should be assumed by the Regional councils, Public Health Departments and SerDs at a local level.

Increase accessibility to Naloxone

The inter-institutional working groups should also have the specific objective of making naloxone more accessible- and possibly even free- above all in pharmacies and in the drug services (places where today this drug is not always available)- but also in contexts outside of health institutions that are frequented by users. In particular it is necessary to encourage the distribution of naloxone to users who are leaving jail or rehab/detox centers.

Recognition for the educator

The educator who works within drug services should be considered equal to the professional health worker with respect to the distribution and administration of naloxone in cases of OD. This legitimization should not only be normative but also cultural- a recognition of the importance of social competencies as a priority in the health services sector.

Valuing the role of Peers

Recognizing the competencies of users and valuing the role of peer support workers is a fundamental pillar in THN practice that needs to be re-promoted. This is particularly true with respect to the new challenges presented by the increasing presence of foreigners among service users. In order to properly evaluate the competencies of users it would be opportune to organize training sessions together with workers and peer support workers and solicit and promote the constitution of user interest groups also in Italy, where they are currently few in number and present only in certain regional areas.

Evaluate the introduction of new methods of administering Naloxone

New possibilities of administering naloxone, in particular via the intranasal route, represent an opportunity above all for young users who do not use heroin intravenously. However before this is introduced as a THN practice, it is necessary to conduct a cost-benefit evaluation- also with reference to the pharmaceutical industry's interests- and to look into its pharmacokinetic properties.

Data collection

In order to evaluate the efficacy of the intervention model and to be able to program strategic actions, a priority must be given to closing the existing information gap. A monitoring system capable of gathering all the data across the nation for every region, regarding the number of OD and the number of naloxone vials distributed should be set up. It would also be important to involve not only the SerD and the HR services but also the pharmacies and the hospital emergency rooms in this data collection.

Regularizing and guaranteeing access to THN nationally

Faced with the incomplete diffusion of THN practice nationally, it would be opportune that this become the object of a regulatory revision and that the Ministry of Health provides the Regions with the standards for intervention. The introduction of HR in the ELA constitutes a concrete opportunity to reach this aim, but it is necessary that the standards correspond to specific budgets at a local level. Furthermore it is fundamental that the insertion of THN into the ELA is monitored to ensure it does not lead to a medicalization of the practice itself.

Create a Culture

It is opportune in this "reversal" phase to actively promote a culture founded on the practices of THN. This means promoting a HR approach and spreading a conception of the problem and the treatment of addiction that goes beyond the limits of an individual approach in order to reinforce strategies based on a community approach. This entails involving services and stakeholders that are not part of the health and social system. This approach should be done also by exploiting to the full the opportunities offered by internet and social networks.

3.1.3 A discussion of the results from the questionnaire and from the focus group with addiction services workers

a) The strong points of the Italian model of THN

➢ **Empowerment and peer support: a practice that works for the growth of understanding the risks and for reinforcing preventative behaviours in people who use drugs**

The solidarity practices amongst peers and the creation of informal networks of quick intervention are at the centre of the Italian model for THN. Investing in the competencies of people who use drugs (PWUDs) for managing the interventions means that addiction services workers invest in the diffuse social capacities from an empowerment perspective and one of promoting the health of the community. The vision adopted is that of an "expert consumer" who learns and improves his/her competencies thanks to experience and the socialization of that experience and learning, according to a social learning approach.

The results of the questionnaire highlight the fact that only in those services who have never adopted the THN practice, are there individuals who believe it is inappropriate because it could be an incentive to more risky behaviours. The criticisms that obstruct the diffusion of THN at an international level[68], above all the reassurance effect- that it would lower attention regarding prevention behaviours and harm reduction because of the availability of the life-saving drug- are not evident in the opinion of those who come from services that do distribute naloxone. For the latter, the principle risks of the drug are of another kind, connected to an eventual insufficient dosage and the possible risk of a new OD tied to the assumption of another opiate dose following the abstinence induced by the naloxone. These risks can be efficiently prevented thanks to counselling and information interventions that habitually accompany the distribution of naloxone.

The advantages that were identified however go further than the reduction of deaths by OD. They include a real increase in the understanding of the risks, including those relative to drug consumption in general, an increased perception of self-efficacy in methods of use and intervention and in the general competency of the consumer.

➢ **The role of HR services in the distribution of THN: diffusion of competencies and support for the development of a capillary network of information, intervention and first aid among PWUDs**

One factor for success is to integrate the knowledge and experiences which PWUDs possess with the information and training offered by HR workers. The distribution of naloxone to PWUDs happens in 90% of cases through an individual session whereby the health personnel provides information regarding correct behaviours and how to avoid the risks cited above. The most mentioned among these are to call the emergency number at the same time and the advice to never use alone. Other specific indications regard the method of administering the drug. In more than half the cases the services also give out informative material with the naloxone, while in a minority of services sterile materials are also distributed.

The process of investing in PWUDs has been seen over the years to be successful. The possession of naloxone by people present at the time of an episode is the most frequently cited condition by respondents as a predictive factor for a positive outcome of an overdose, even more so than the promptness of first aid treatment and the arrival of an ambulance. Knowledge of first aid practices by peers is also very important whereas the vicinity of a hospital emergency room seems to have little effect and that of a nearby pharmacy has no effect at all on outcome.

68 Preventing Opiate Overdose Deaths, Examining Objections to Take-Home Naloxone http://muse.jhu.edu/article/400754

For these reasons most services distribute naloxone not only to single consumers but also to PWUD leaders, to friends, to partners and to family members. One service in three furthermore, provides information or group training (the later applies only to HR services) and works on peer support, also through the involvement of opinion leaders.

In this empowerment process of PWUDs, the advantages that directly regard the intervention system in cases of overdose and the services themselves are evident: the promotion and the support of peer solidarity provides for the availability of an informal capillary network for immediate intervention and together, an increase in trust in services by PWUDs. From the experience of Italian professionals active in THN distribution what emerges therefore is that doubts expressed by critics of THN with respect to the distancing of PWUDs from health services is unsustainable[69] : on the contrary, THN multiplies the occasions for meetings, exchanges and information sessions with potential clients.

At the same time the THN model promotes individual and group competencies that make the community more expert, thanks to a virtuous "sliding" of these competencies from the health structures to citizens, which is inherent in the health promotion approach as promoted by the WHO and denominated "whole-of-society"[70].

- **The Health Promotion perspective. The integration of health and socio-educational competencies**

The integration of social and health competencies are another fundamental characteristic of the THN model and are part of the health promotion approach.

In the majority of cases naloxone is distributed within the same service both by health and non-health professionals. There are however marked differences according to the type of service: in the day hospitals of the public drug addiction services (SerD), most authorize only health professionals to distribute whereas in the HR services both health professionals and educators (and also peer educators) are in general authorized. In these services the educators in particular assume a central role.

The same applies for the administration of the drug itself: educators in services that authorize them to intervene in a situation of necessity, do not encounter difficulties in this sense, even if certain contradictory opinions emerge as to the best method of administration (intramuscular or intravenous). According to what has emerged in the focus groups, the fear expressed by a minority of respondents to the questionnaire that a non health professional could incur legal problems if not expressly authorized, has no foundation: the status of the drug as an over-the-counter drug and the Italian normative law regarding the obligation to provide first aid assistance in the case of life-threatening danger, provides a clear juridic framework, within which almost all aspects of the service operate. None of the interviewed have ever reported an experience of legal problems over the course of twenty years of practice. The tension between the areas of health and socio-educational competencies is perhaps the aspect that most influences the observable distance between the THN model which mostly diffused in the HR services (drop-ins, low threshold services) and those that regard the day hospitals of the SerDs. Only a few of the later distribute naloxone or find themselves intervening in a case of OD, as they do not work at drug use sites. They also under-utilize the strategy of involving groups or peers and/or opinion makers in information and training activities. Also evident is the underuse of the strategy of activating the collaboration between services and PWUDs which could be used as an antenna and a monitoring system. Likewise, in the SerDs the distribution of naloxone to consumer leaders is less practiced than in HR services as is the involvement of educators and/or peers in operative identifications and indications.

This hiatus between SerDs day hospitals and HR services was one of the most discussed topics during the

69 Preventing Opiate Overdose Deaths, cit

70 Health 2020. A European policy framework and strategy for the 21st century. Http://www.euro.who.int/_data/assets/pdf_file/0011/199532/health2020-Long.pdf?ua=1

focus group. Some interpret it as a paradigmatic consequence: the prevalence of a "disease" approach within services for treatment by doctors who, unlike educators or outreach workers, have difficulty recognizing the PWUD as an active subject, a person with competencies, "an expert of the self". This distance in viewpoints between health and socio-educational professionals can be observed, according to those interviewed, also in the same public health services where a resistance to HR persists and that ultimately regards the same objectives for the treatment of dependencies. The risk is that a reductionist vision of drug use will prevail, one that is not attentive enough of the social and cultural aspects of the phenomena which requires a multidisciplinary approach and one of community. This means being attentive to intervene not only on the single individual but also on the context of drug use, the setting[71], and more generally on social inequalities and on the processes of marginalization and stigmatization[72] .

b) Weak points of the model and the challenges of innovation

➢ Discontinuity, limits and the scarce political support for HR

According to the participants of the focus group, over the last few years the role of THN aid/protection and of coordinating the local networks by public addiction services, has become less incisive. This is also due to diminished political and social attention regarding the subject of drug use and OD along with cuts in available funding. The practice of THN was in fact born in a period during the 1990's when the use of heroin was at a peak and the AIDS epidemic had created a "policy window"[73] that allowed for the experimentation and the diffusion of HR practices. Today however a phase which has been defined by those interviewed as one of "reflux" can be witnessed. This is coherent with the results of the questionnaire which indicate for most of the services involved, a reduction over time both in the number of vials distributed and in the number of interventions (distribution of informative materials, activation of opinion leaders and expert peers).

The historical map of unequal HR practice in Italy, whereby entire regions do not offer interventions like this or they are offered in only some cities, leads to the question of how increased accessibility to naloxone can be introduced throughout the entire national territory, firstly by public services. The introduction of HR in the new LEA (Essential Levels of Health Assistance), approved by the government in 2016, represents a good opportunity for this to happen, given that it is the normative law that obliges all the regions to guarantee HR interventions and services. Addiction services workers see in this a great opportunity to extend the practice of THN throughout the national territory, as long as this does not lead to excessive medicalization. It would be opportune to this end that the Health ministry provides the regions with the standards of interventions based on a community approach, in harmony with what today is positively validated in the regions that have the most experience and in common with all the national territories.

➢ Widening the network of competent actors

In the THN model, the community approach, according to those interviewed, should include not only those public and private services that are in contact with PWUDs but also other subjects external to drug addiction, above all the police services and the pharmacies. While the relationships with police services were critical above all in the implementation phase, but today seem to be superseded, pharmacies still result as being hardly involved or active. In both the questionnaire and the focus groups it emerged that notwithstanding the fact that naloxone is a an over-the-counter drug and a life-saving drug, and therefore by law should be always available, this is not always the case. Either way, even where THN interventions are non-existent, PWUDs rarely go to pharmacies.
Other important actors who are not involved today are general practice doctors and other services and non-

71 Zinberg N. E. (1984), Drug, Set, and Setting. The Basis for Controlled Intoxicant Use. Yale University Press.
72 Room R. (2005), Stigma, Social inequality and alcohol use and drug use. Drug and Alcohol Review, 24(2): 143-155.
73 Beccaria F. and Rolando S. (2013). Stakeholders' Role in Contemporary "Substitute Drug" Prescribing Policies in Italy. *Substance Use & Misuse*, 48: 943-953.

health contexts frequented by PWUDs. It is a widely held opinion that the governance of the local network should come from SerDs and that role should be assumed by the Region and/or by the Local Health Agency (ASL) at a local level, creating round tables for discussion and inter- institutional agreements.

- **Adapt the THN offer, information and training of peers to different styles of use**

Other than political disinvestment, the diminished activity connected to THN is attributed, by both respondents to the questionnaire and by participants of the focus groups, to a number of factors: the reduction of heroin users who inject; the reduced purity of the drug itself- which gives the PWUDs less fear of having an OD- and the changing patterns of drug use. On the one hand heroin is used in different ways (smoked or inhaled) by young users. On the other hand, there are other opiates that are used intravenously, in particular methadone, which in the case of an OD requires higher and repeated dosages of naloxone than heroin.

The differences in ways of using, one's using career and lastly the relationship one has with the drug, has also created an intergenerational gap between old and new users which makes it more difficult to work with peer support- something that has always characterized the THN intervention model- meaning the transmission of competencies and strategies between expert peers and new users. All of this is further complicated by the overwhelming presence of foreigners, with whom it is often very difficult to even communicate.
Nonetheless, as those interviewed have widely underlined, the prevalent new patterns of drug use, including inhalation, do not eliminate the risk of OD, and a dangerous underestimation of risks can occur. Furthermore the continual changes in the illegal market represent, more than ever, a risk factor that is often underestimated by workers themselves as possible causes of OD. There also remain increased risk situations correlated to tolerance: the interruption of rehabilitation and discharge from prison.
THN therefore remains a necessary strategy to respond to a risk that persists, even in Italy, notwithstanding the significant fall in OD numbers from the 1990's. It does however require innovative methods. It is therefore urgent to ask how to make it really work, by innovating the current model, including peer work in a season where drug use as a factor connected to a specific sub-culture is declining due to processes of normalization and diversification of styles. This is one of the crucial nodes for reinforcing and diffusing THN practices. It could also be significantly advantaged by the introduction of intranasal THN on the market.

3.2 The perspective of people who use drugs [74]

This chapter illustrates the results of the research conducted through on line questionnaires and focus groups and the final discussion.

3.2.1 Results of an investigation into people who use drugs (PWUD)

1.The sample
2.Availability and the use of naloxone
3.Knowledge about the correct use of naloxone

The sample

Demographic characteristics and substance use

The total number of respondents is 204. Those considered eligible- people who declared they had used an opiate at least ten times in the past twelve months- numbered 179, of whom 83.2% (149) were males. The median age is 43 years (IQR=13). People who use drugs (PWUD) responded prevalently from these cities: Turin (N=55, 31%), Naples (N=44, 25%) and Bergamo (N=18, 10%). Nonetheless there were respondents from all over Italy (Pordenone, Salerno, Florence, Rome, Chieti etc.) even if these were from only one individual at times. The following graph illustrates the distribution for geographic area:

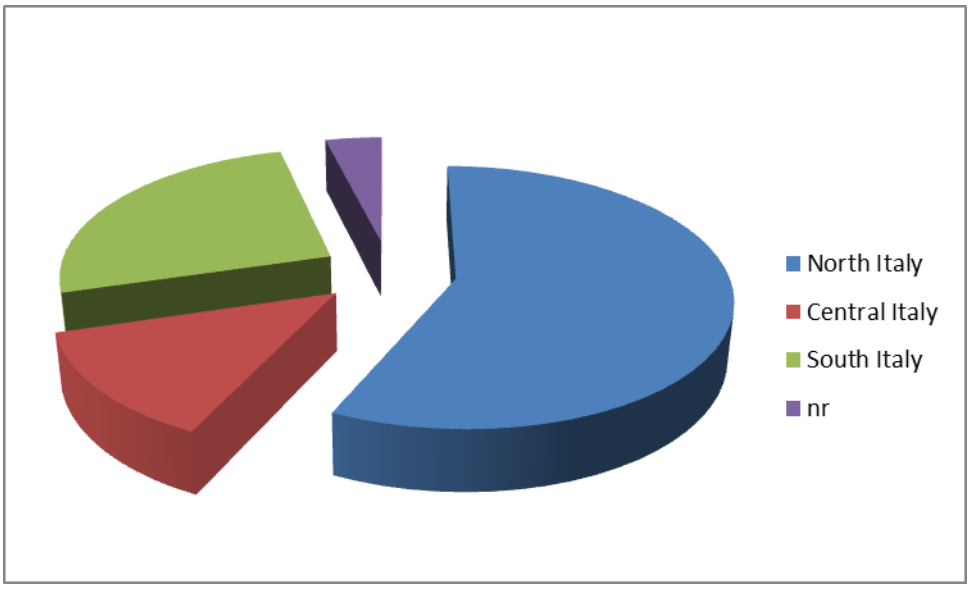


Fig.3.24 Distribution of respondents by geographic area (N=179)

The most frequent method of opiate drug-taking is by injection and heroin is the opiate most used, being the main substance for two thirds of the sample.

Route	N	%
injected	124	69,3
smoked	38	21,2
other	10	5,6
NR	7	3,9
totale	179	100,0

Tab. 3.13 Distribution for route (N=179)

[74] By Antonella Camposeragna and Susanna Ronconi

The primary drug is reported in the following table:

Drug of first choice	N	%
Heroin	129	72,1
cocaine	34	19,0
cannabis	4	2,2
opium	2	1,1
other	4	2,2
NR	6	3,4
Total	179	100,0

Tab.3.14 Distribution for primary drug (N=179)

The prevalent method of use for opiates is by injection (104, 79.4%), when this is the first choice of drug, which is heroin or opium as seen in table 2, while the frequency of use (referring to the past 30 days) indicates a variability.

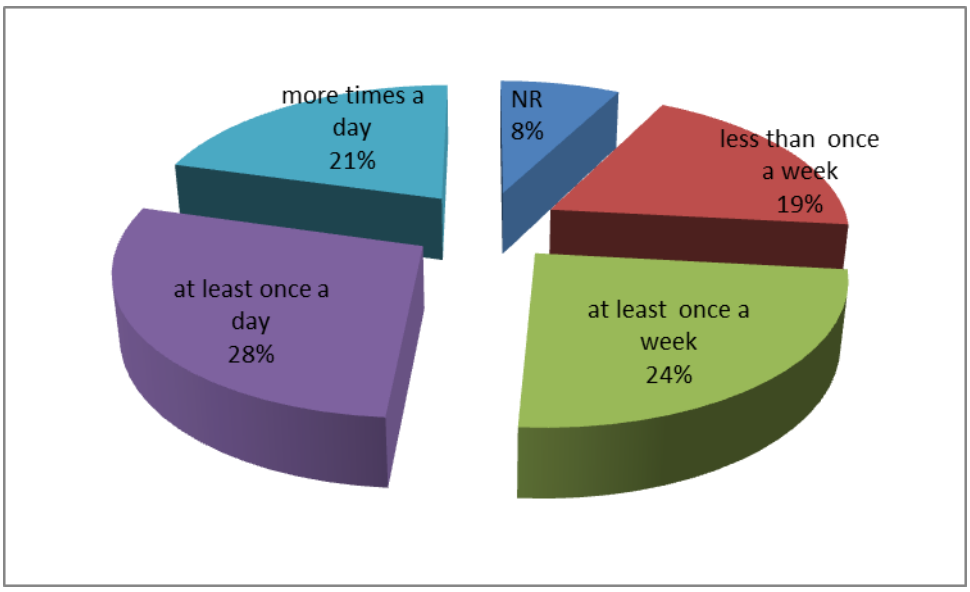


Fig.3.25 Distribution frequency of use of PWUD who indicate an opiate as their primary drug (N=131)

The reported age of first use of an opiate is 18 years of age (mdn, IRQ=5).Considering the actual age of the sample group, the years of drug use are estimated to be 23 (IRQ=18, min=1, max=47). The sample therefore has an important history of use.

Use of drugs in the last month is presented in the distribution reported in figure 3, where the most frequently used drugs are seen to be heroin and cocaine.

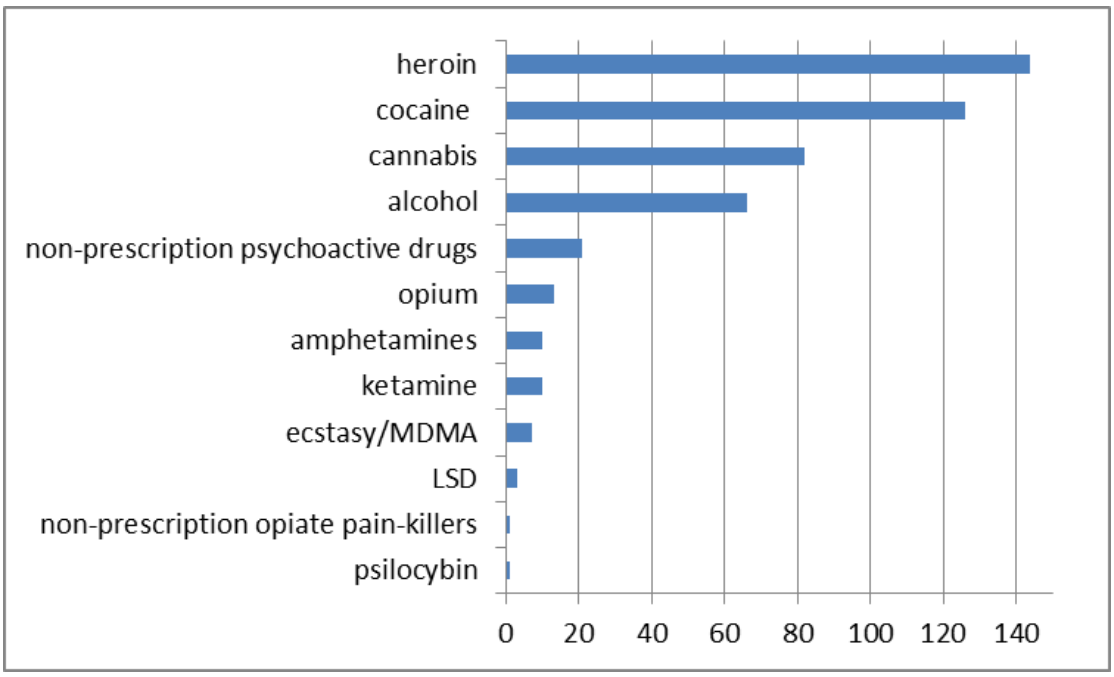


Fig. 3.26 Distribution of drugs reported as consumed in the last 30 days (N=179)

Poly drug use appears to be a diffuse practice in that more than 60% (63.7, n=114) of the sample stated they had used more than one drug in the same day.

Personal experience of overdose

Around half (48.6%, n=87) reported to have experienced at least one non-fatal overdose lifetime.

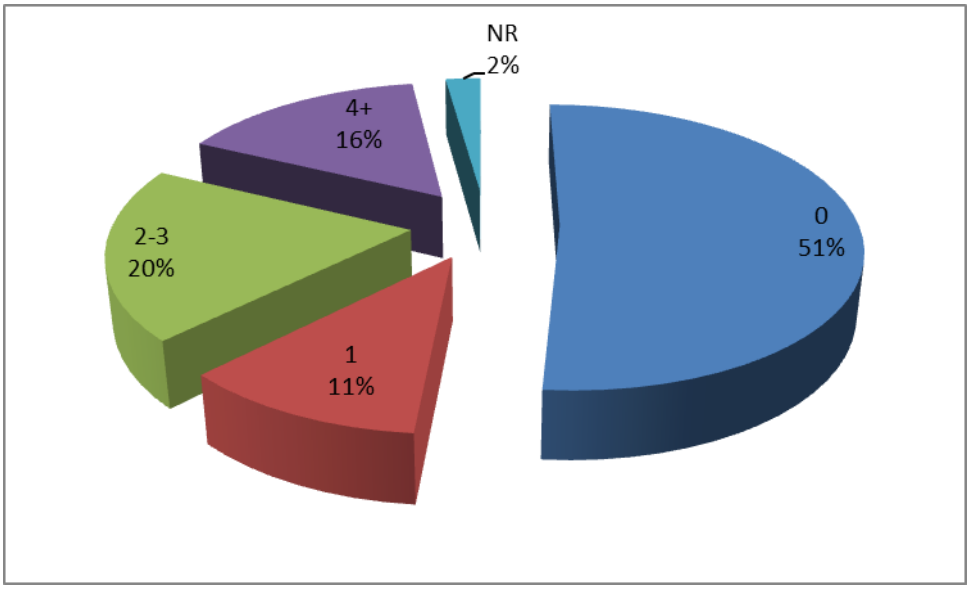


Fig. 3.27 Distribution of non-fatal OD reported (N=179)

The last experience was generally more than one year ago, as is reported in Table 3. Of those who had an OD, 42 people (49% of the sample) were not in treatment with a substitute drug. The importance of substitute drug treatment as a protective factor could be confirmed in the sample, even if only at a descriptive level, as more detailed data was not requested about types of treatment (dosages, length of time etc.)

Period of last OD	N	%
less than 6 months ago	7	8,0
between 6 and 12 months ago	11	12,6
more than a year ago	69	79,3
Total	87	100,0

Tab 3.15 Distribution period of last overdose reported (N=87)

The main cause referred to by the sample regarding their last non-fatal OD appears to be due to low tolerance levels and the use of more than one drug in the same day. Nevertheless a not insignificant part indicated the purity of the drug, meaning the substance used to cut the drug.

Reported causes	N	%
Low tolerance (post prison, rehab)	26	29.9
poly drug use	18	20.7
purity of drug	12	13.8
intentional overdose	11	12.6
unknown	10	11.5
change of dealer	8	9.2
other	2	2.3
total	87	100.0

Tab 3.16 Distribution of reported principal causes of overdose (N=87)

The main place where episodes of overdose occurred were outdoor public squares, parks. Of those who overdosed in a public space (70%, N=58) more than half (35, around 40% of the total) reported it happened in a secluded place. In 35% of all episodes, the person was alone. The person who most frequently assisted in the last episode reported was a partner or a friend. Consequently the person received first aid assistance from a partner or a friend (median answer), a passerby and less often from a professional health worker (emergency services or HR services).

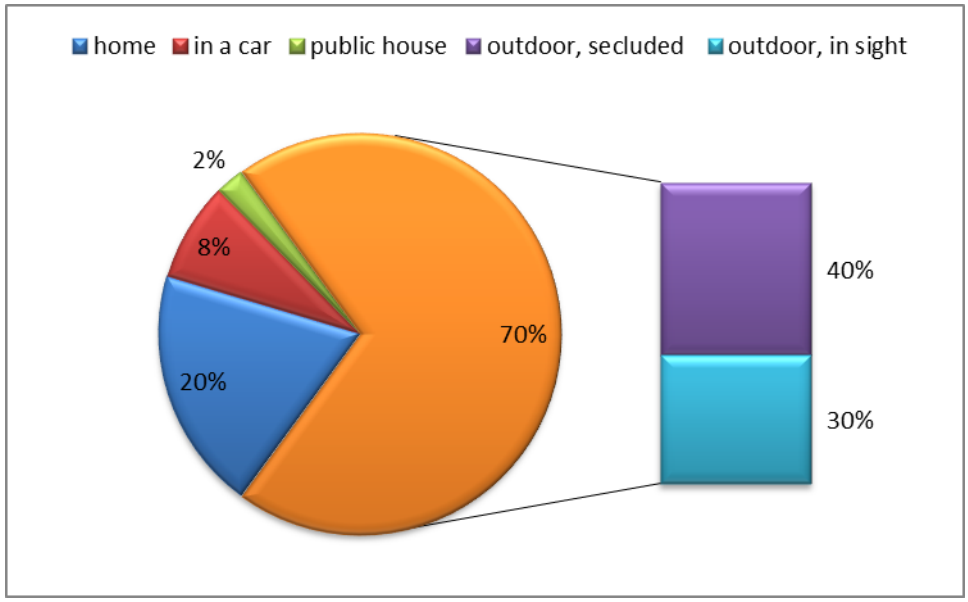


Fig. 3.28 Distribution of places where the last overdose occurred (N=87)

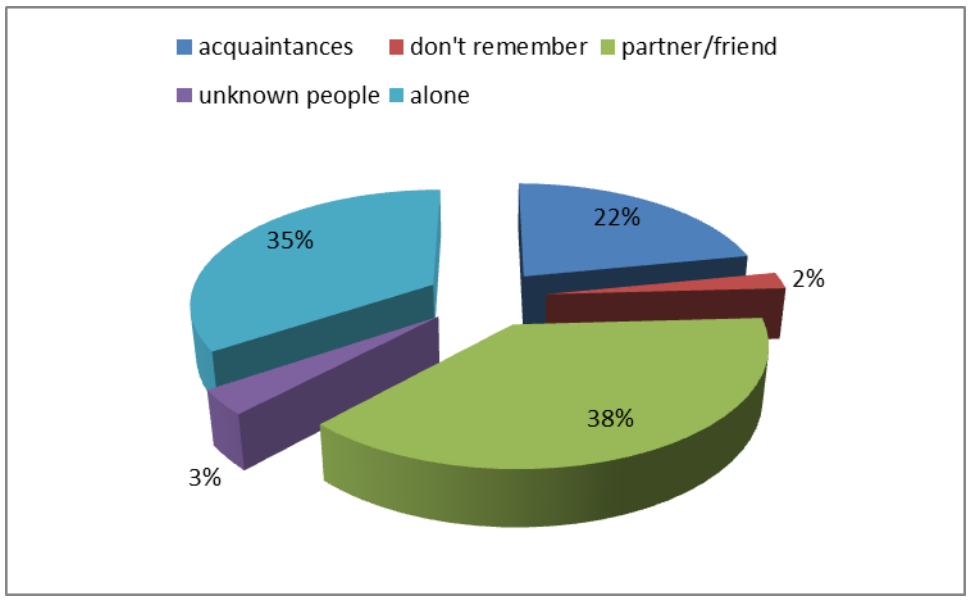


Fig. 3.29 Distribution of people present at last overdose (N=87)

Among the actions taken by those who helped, most called emergency services (N=46, 56.3%), followed by injecting a phial of naloxone (N=26, 30%).

76% (N=66) stated that following an OD episode they altered certain behaviors to prevent another episode Those behavioral changes are reported in table 5.

Precautions adopted to reduce risk (multiple responses possible)	**N**		**%**
I never use alone		25	37.9
I use less if I haven't used for a while	23	34.8	
I always have naloxone with me	18	27.3	
I use a small dose to check effect and then the rest		18	27.3
I started or restarted methadone/buprenorphine treatment	17	25.8	
I don't mix drugs		12	18.2
If I change pusher I always ask others	11	16.7	

Tab. 3.17 Distribution of behavioural changes to reduce risks following an overdose (N=66)

Experience of an overdose as a witness

More than two thirds (N=138) of the sample group have assisted at an OD by someone else. 70% (N=96) assisted at an OD of a person known to them, whereas a quarter (N=31) did not know the person. The remaining 11 (8%) assisted their partner. More than half (N=77) stated to have witnessed more than three episodes in their lives.

With respect to the places where OD was witnessed, the distribution is very similar with respect to what was described previously by personal OD experience.

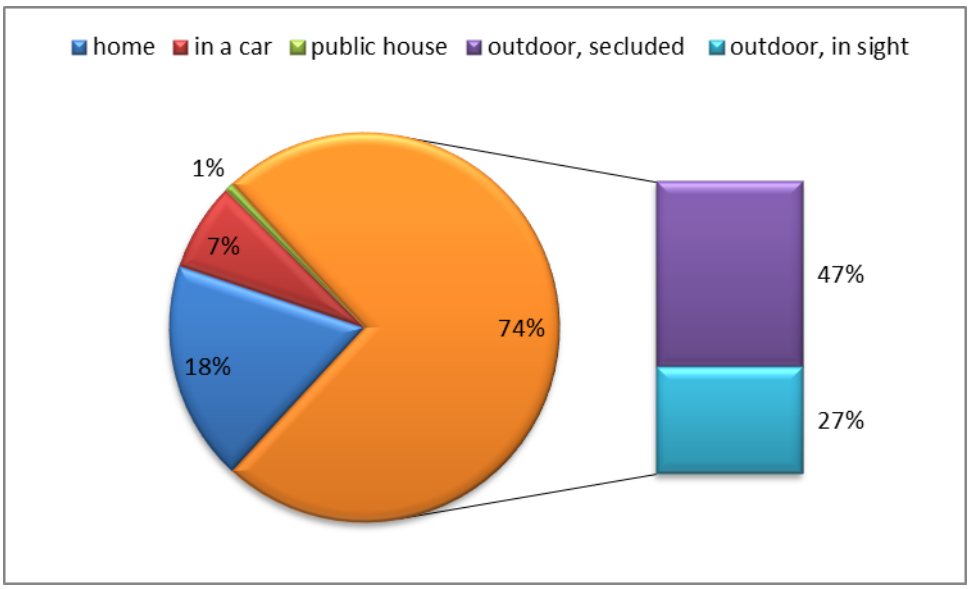


Fig.3.30 Distribution for place where last overdose was witnessed (N=138)

For respondents, the first thing to do (based on personal experience) is to call emergency services, followed by administering naloxone. To define the order of importance (based on what actually occurred) respondents were asked to place the first three actions undertaken in order of importance. In the following graph the median of each action is reported, which replicates the actions undertaken by the majority as first actions.

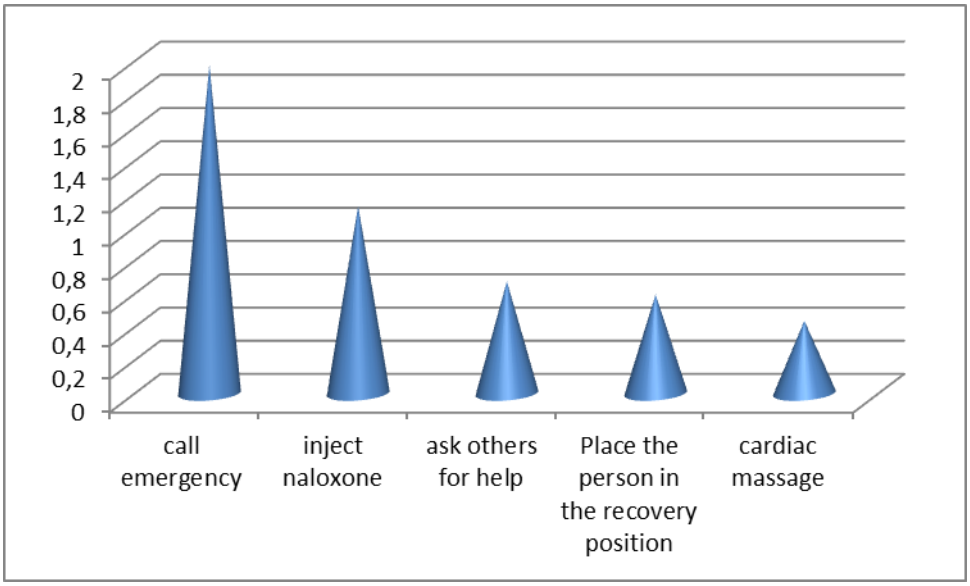


Fig. 3.31 . Distribution of urgency attributed to life-saving actions in cases of overdose (N=138)

Availability and use of naloxone

Offer and availability of naloxone

Fifty-nine percent (N=95) of the sample had received a phial of naloxone as a prevention method for OD. For 8 people (4.5%) there is no information regarding this. In order to understand if there are factors that can increase or decrease the possibility for a person to have the phial on them, the following variables were tested and cross-referenced with the variable of possessing the naloxone.

	Never had naloxone(N=66)		Ever had naloxone (N=105)		total		p
Gender	**N**	%	**N**	%	N	%	
M	**57**	86,4	**86**	81,9	143	83,6	0,406
F	**9**	13,6	**19**	18,1	28	16,4	0,406
Years of use							
Less than 15 yrs	**27**	40,9	**22**	21,0	49	28,7	**0,002**
15+yrs	**39**	59,1	**83**	79,0	121	70,8	**0,002**
Route							
IV	**42**	63,6	**81**	77,1	123	71,9	**0,038**
Smoked/other	**24**	36,4	**24**	22,9	48	28,1	**0,038**
OD Experienced							
no	**45**	68,2	**40**	38,1	85	49,7	**0,000**
yes	**21**	31,8	**65**	61,9	86	50,3	**0,000**
OD Witnessed							
no	**26**	39,4	**7**	6,7	33	19,3	**0,000**
yes	**40**	60,6	**98**	93,3	138	80,7	**0,000**
Ever had information							
no	**29**	43,9	**8**	7,6	37	21,6	**0,000**
yes	**36**	54,5	**97**	92,4	133	77,8	**0,000**
Training courses							
no	**33**	50,0	**62**	59,0	95	55,6	0,209
uess	**2**	3,0	**27**	25,7	29	17,0	**0,000**
nr	**31**	47,0	**16**	15,2	47	27,5	**0,000**

Tab.3.18 Availability of naloxone and individual characteristics. Proportional test.

Having at least one phial of naloxone is not associated with gender, while there is an association with years of drug use: PWUD with a history of more than 15 years are more likely to have a phial with them. Those who use opiates intravenously are also more likely to have a phial with them, as are those who have reported a previous experience of OD and/or have assisted at another's OD.
The data confirm the informative aspect associated with the offer of naloxone in increasing the probability that the user carries naloxone with him/her. The association with ad hoc courses is less clear due to the lack of data provided.

The opinion that PWUD have about the distribution in their cities varies from very bad to excellent. Cities that enable a numerous sample in order to be statistically relevant are Turin, Naples, Bergamo and Perugia (12 respondents). The remaining cities had numbers ranging from 1 to 4, therefore the value of their opinions are considered to be individual.
The median of the distribution for Turin, Bergamo and Perugia was under the heading “good”, while for Naples the median opinion was “scarce”. This difference was significant according to the Median test.
Considering however opinion expressed on the availability of naloxone it can be seen that those who gave a negative answer are associated with not ever having it on them. It is an obvious result if the distribution is seen as scarce then it is more likely there is less inclination to procure a phial of naloxone.

Opinion about distribution	Never had naloxone(N=66		Ever had naloxone (N=105)		Total		p
	N	%	N	%	N	%	
Very bad	**20**	30,3	**4**	3,8	24	14,0	**0,000**
Quite bad	**18**	27,3	**25**	23,8	43	25,1	0,582
Quite good	**20**	30,3	**58**	55,2	78	45,6	**0,001**
Very good	**4**	6,1	**13**	12,4	17	9,9	0,145
NR	**4**	6,1	**5**	4,8	9	5,3	0,688

Tab. 3.19 Availability of naloxone- opinion regarding distribution. Proportional test

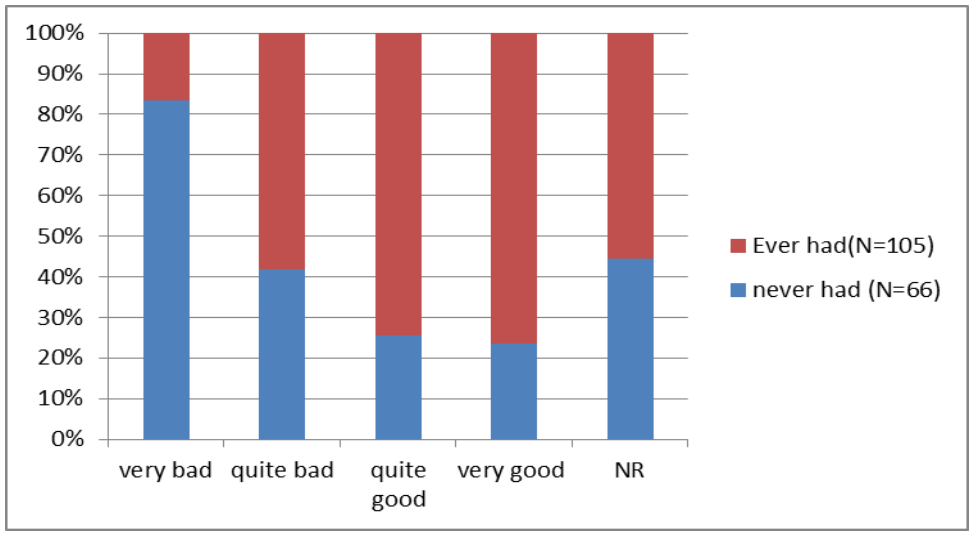


Fig. 3.32 Distribution percentage for opinion

The prevalent ways for acquiring vials are from Harm Reduction (HR) programs (84%), followed by SerD (Public Treatment Centres, PTCs) (11%) while the remaining generically indicated peers. Only one person stated they bought naloxone in a pharmacy as their normal practice. Only 4 people stated they had bought naloxone in a pharmacy.

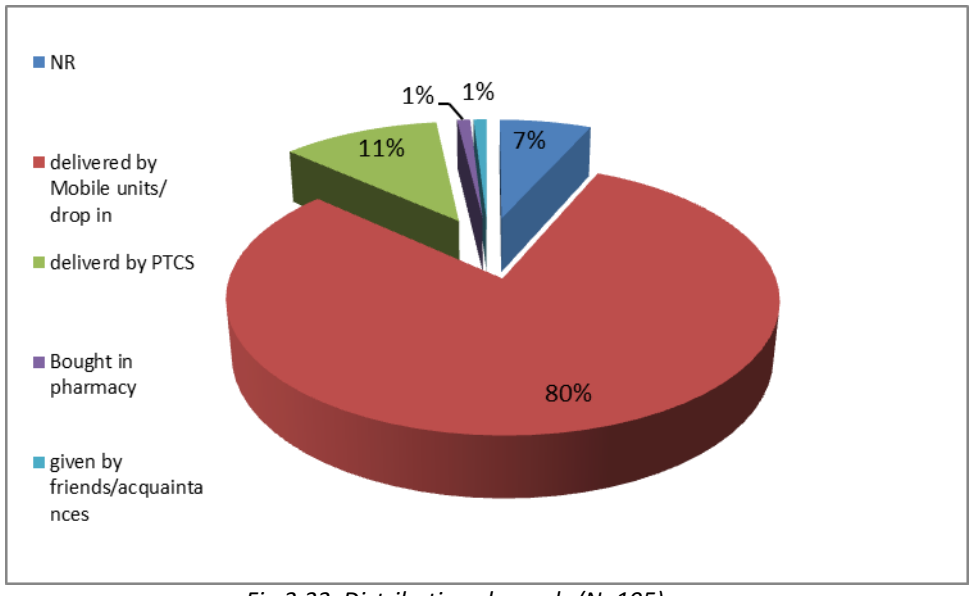


Fig 3.33 Distribution channels (N=105)

The answers provided to questions regarding where the vials of naloxone are kept and who is aware of the fact that the person has a life-saving drug on them in case of OD, provides information that the naloxone is kept in places that if needed is easily accessible and that this information is shared with people close by. It

also provides a picture of a PWUD aware of the importance of the availability of the drug. Unfortunately a significant number of respondents did not answer this question.

Where naloxone is kept	N	%
in my pocket	46	43,8
where drugs are taken	37	35,2
NR	16	15,2
In the car	6	5,7
Totale	105	100,0

Tab. 3.20 Places where naloxone is kept (N=105)

Nevertheless there seems to be a certain reserve as about one third do not tell anyone they are in possession of naloxone, while half told their peers and 8% their family members.

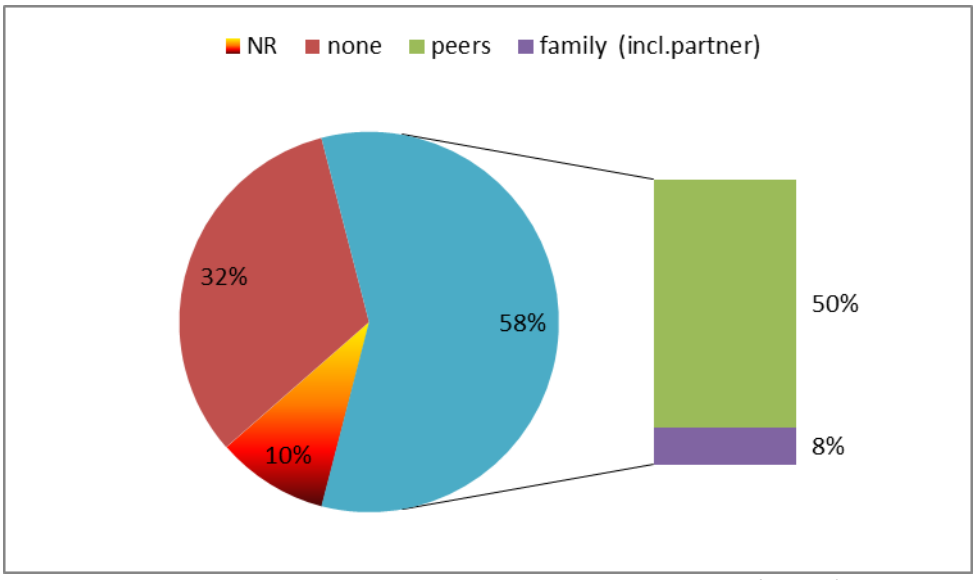


Fig. 3.34 People informed of the availability of naloxone (N=105)

Those however who have never kept naloxone on them (N=66, 37% of the sample) have said on average that they did not know where it was distributed and the lack of offer of the same. A fifth of the sample reported to have never had naloxone due to lack of information about its use (how and when). A certain number of PWUD reported the risk of increasing their legal problems if they have naloxone on them and are stopped by the police. In Table 8 the answers are reported and their relevant percentage, which is more than 100% as multiple responses were possible.

Why have you never had naloxone on you	N	%
don't know how to get it	17	25,8
better look for professional help	13	19,7
nobody ever offered it to me	12	18,2
I don't know what it is	9	13,6
more problems if stopped by police	8	12,1
don’t know when to use it	7	10,6
don't know how to use it	6	9,1
it is bad luck	3	4,5
nobody would want me to use it on them	2	3,0
costs too much	1	1,5
Pharmacies don't have it	1	1,5

Tab. 3.21 Motivations for never having naloxone with them (N=66)

How naloxone is used

With respect to using naloxone, 67% (N=71) of those who had a phial of naloxone on them stated they has used it at least once. In general this sub-group is very expert, considering the cumulative frequency is 80% this indicates they used it more than once.

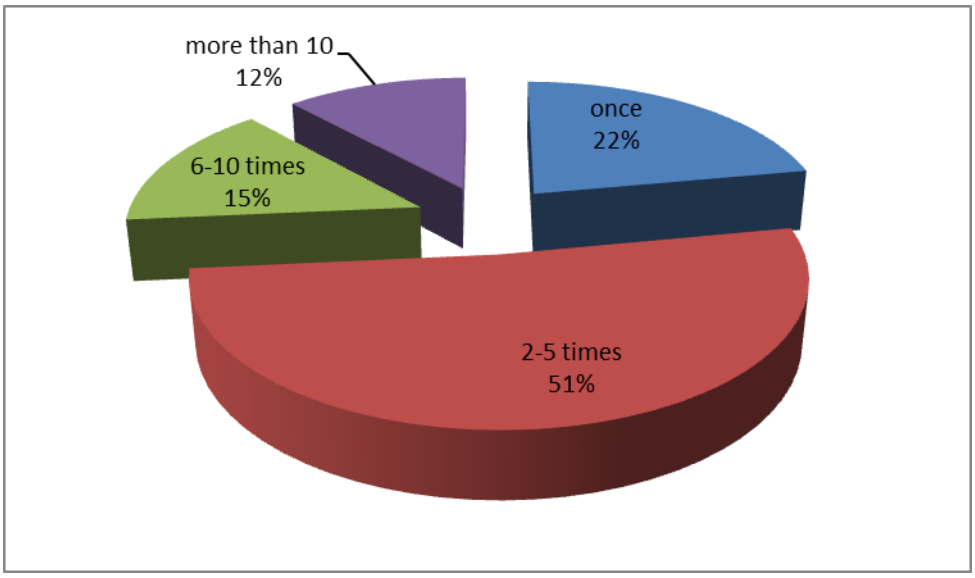


Fig. 3.35 Distribution of number of times naloxone was used to help an OD of another (N=71)

In order to inquire about the method of use of naloxone, the last time was used as a proxy in order to understand how and where the drug was administered, the timeliness of the intervention as well as the consequences of administrating the drug both for the person who was helped and for health personnel. The sample referred to is the same 71 respondents who stated they had used naloxone at least once in their lifetimes.

The number of vials used is generally 1 or 2 (reported respectively by 35.2% of the sample, N=25 for both types of answers), while 22% (N=17) stated to have used 3 or more. The remaining 4 did not indicate an number.

The method of naloxone administration was by intramuscular injection according to the guidelines, for over half the sample group. Nevertheless 41% referred to intravenous injection for administering the drug. Almost all (95.8%, N=68) stated they had use a sterile needle and syringe.

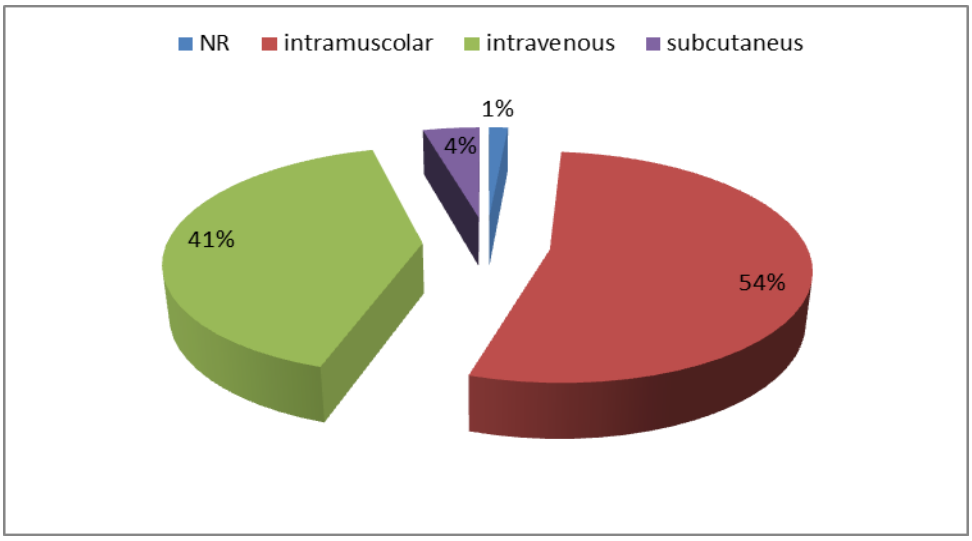


Fig. 3.36 Route of naloxone administration, last use (N=71)

Certainly the very possible undesirable effect of naloxone administration is the brusk reawakening in a state of acute withdrawal. This adverse effect is considered anecdotally by peers to be a valid reason for not using it, in order to avoid a negative reaction from the person assisted. This negative reaction was reported only by some of the sample group: 27 (38%) of cases out of a total of 71 interventions stated the person assisted had a negative reaction.

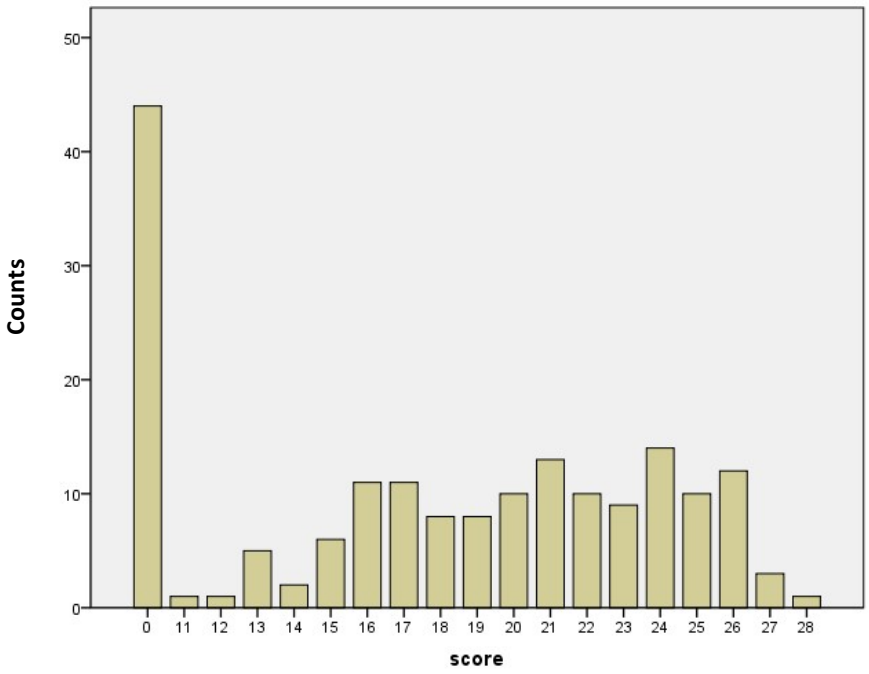
In 49 cases(69%) the emergency services were also called. This is correct procedure and the reaction of health workers was also evaluated with respect to the administration of naloxone by a peer. In this case the presumed anecdotal negative reaction of health professionals to naloxone administration by a PWUD was not confirmed.

Comments by emergency services personnel	**N**	**%**
They said I was not authorized	8	16,3
They thanked me	24	49,0
No comment made	9	18,4
They asked for info about the patient	7	14,3
NR	1	2,0
Totale	49	100,0

Tab. 3.22 Comments expressed by emergency services/ambulance staff following naloxone administration by peers (N=49)

As reported in the chapter on research methodology, a standard tool for evaluating the knowledge of the sample group with respect to the correct use of naloxone was used (Opioid Overdose Knowledge Scale).

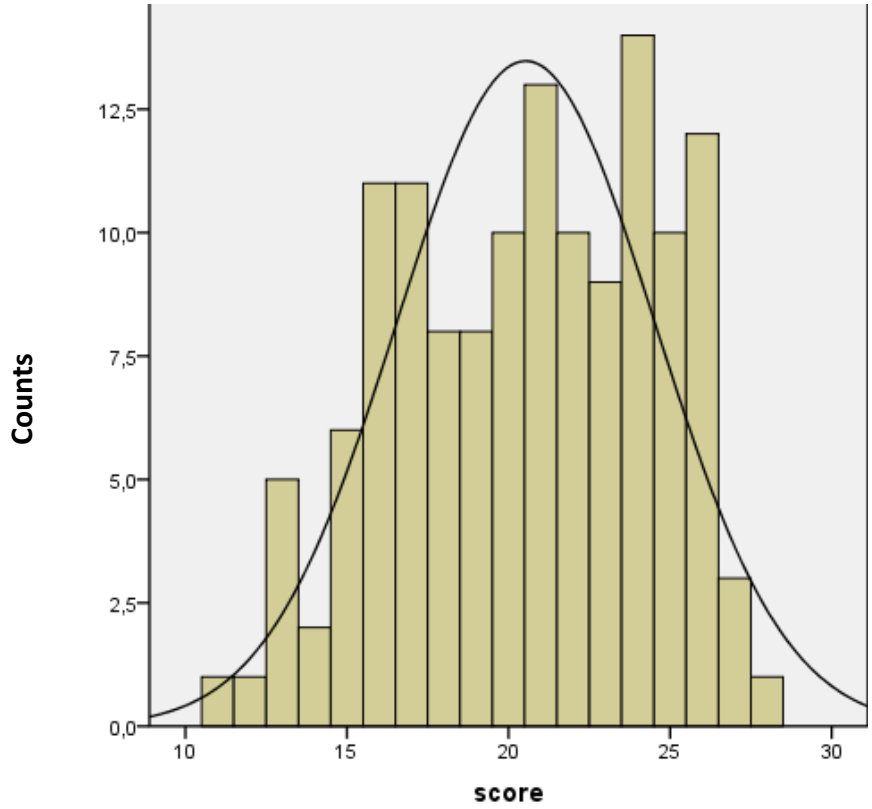
This tool was developed to evaluate the efficacy of courses about OD prevention generally therefore only seven of the fourteen questions were used- those that were deemed more adequate for an OD intervention where naloxone was used. The original questionnaire allows for a maximum score of 45 (in the case of all answers being correct) whereas in the reduced version employed here the maximum possible score is 30.



As can be seen, a high number of those interviewed (N=44, 24.6%) did not provide any answer or where possible, answered " don't know", resulting in a total score of zero. It is not possible to know if these missing

responses were due to not having knowledge about the subject matter or simply the person did not wish to reply. This negative outcome could be due to limits of the tool itself, perhaps the excessive number of questions, and to the self-administration on-line, where it is not possible for the interviewer to control if the compilation is completed. The analysis therefore was conducted only on valid data: a subgroup of 135 respondents for this part of the interview.

The distribution is normal according to the Kolmogorov-Smirnov test, as reported in the following chart, therefore the data is considered as if placed on a distribution of continual probability. The Student T- test could therefore be used as a statistic to highlight eventual differences due to individual characteristics.



Firstly is can be noted that the median point score is 20, equal to 66% of correct answers.
In the following table the median values of the test score for some independent variables as well as significance are reported.

Variable	N	Mean	SD	p
Gender				
M	116	20,5	4,01	0,874
F	9	20,6	4,01	
Years of use				
Less than 5 yrs	33	18,98	4,669	**0,008**
15+yrs	98	20,61	3,735	
Route				
IV	102	20,72	3,913	0,831
Smoked/other	30	19,43	4,066	
Training on naloxone use				
yes	97	20,58	4,12	**0,069**
no	32	18,94	3,592	
Cities*				
Others	27	20,37	4,395	0,113
Turin	48	21,71	3,242	
Bergamo	6	19,83	4,119	
Perugia	7	18,14	4,375	
Naples	43	20,07	4,239	
Polydrug use				
no	44	19,95	4,063	0,664
yes	84	20,69	4,003	
OD experienced				
no	65	20,48	3,941	0,425
yes	67	20,37	4,026	
OD witnessed				
no	28	20,07	4,127	0,871
yes	104	20,52	3,941	
Ever had naloxone				
no	54	20,09	4,186	0,307
yes	77	20,65	3,848	

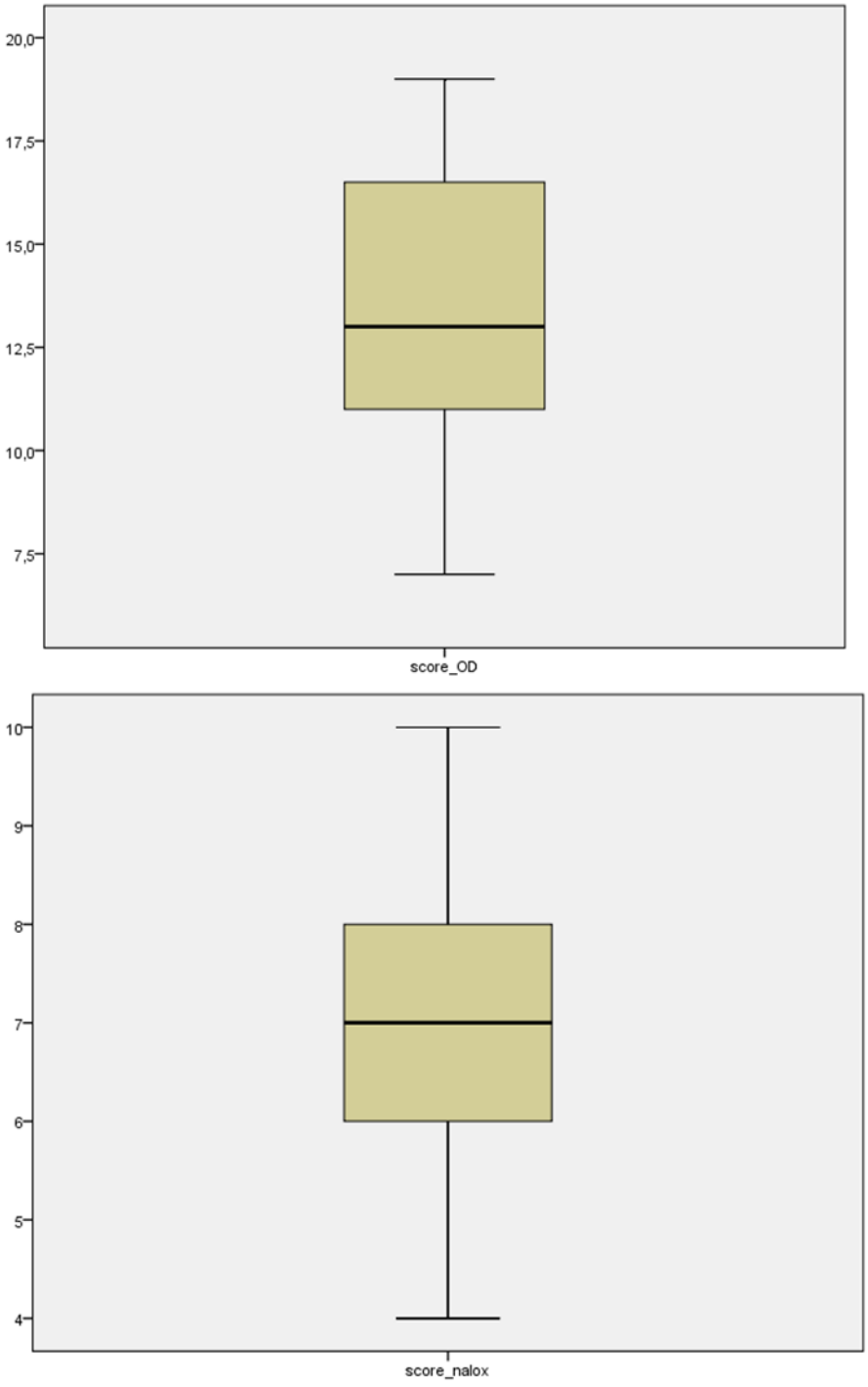
* the ANOVA uni-variated was used.

Tab.3.23 Results for the T-test for some variables regarding mean scores attained

The difference between the scores are associated with experience of use and having received one-off courses on the use of naloxone, confirming the efficacy of learning over time and courses aimed at active users.

The questionnaire predisposes two areas of knowledge- that of recognizing OD and intervening and that regarding the correct administration of naloxone. The scores for each area were analyzed.

In general the area that reports an elevated score regards the correct use of naloxone, while the lesser score relates to knowledge pertaining to recognizing an OD. As is reported in the following graphs, the distribution of scores in the area "overdose", which attributed up to 20 points out of 30 in the questionnaire, has a central tendency around 12.5 (6 correct answers out of 10), while the one regarding naloxone has a central value of 7 (7 correct out of 10).



As with the total scores, eventual differences were verified for some factors.

Area "Knowledge about recognizing interventions for Overdose"

Variables	N	Mean	SD	p
Gender				
M	116	12,1	3,95	0,53
F	9	11,1	4,18	
Years of use				
Less than15yrs	33	10,9	4,18	**0,029**
15+yrs	98	12,4	3,81	
Route				
EV	102	12,5	3,91	**0,002**
Smoked/other	30	10,6	3,71	
Training on OD intervention and naloxone				
yes	32	13	3,7	**0,72**
no	97	11,4	4,03	
Cities*				
Others	27	11,2	4,41	**0,000**
Turin	48	13,5	3,65	
Bergamo	6	8,7	3,15	
Perugia	7	9,3	3,63	
Naples	43	13.0	3,5	
Polydrug use				
no	44	12,1	4,07	0,681
yes	84	11,9	3,83	
OD experienced				
no	65	11,9	4,01	0,895
yes	67	11,9	3,98	
OD witnessed				
no	28	11,9	3,96	0,963
yes	104	12.0	0,399	
Ever had naloxone				
no	54	11,8	3,94	0,739
yes	77	12,1	3,97	

Tab.3.23 a - Results for the T-test

Area "Knowledge regarding correct use of naloxone"				
Variables	**N**	**Media**	**DS**	**p**
Gender				
M	116	6,3	1,78	0,752
F	9	6,1	1,82	
Years of use				
Less than 15yrs	33	6,1	1,96	0,379
15+yrs	98	6,4	1,67	
Route				
IV	102	6,5	1,66	**0,41**
Smoked/other	30	5,8	1,92	
Training on OD intervention and naloxone				
yes	32	6,7	1,72	0,296
no	97	6,1	1,85	
Cities*				
Others	27	5,8	1,94	**0,000**
Turin	48	6,8	1,52	
Bergamo	6	5,2	1,86	
Perugia	7	5,6	1,66	
Naples	43	6,9	1,56	
Polidrug use				
no	44	6,3	1,78	0,915
yes	84	6,2	1,7	
OD experienced				
no	65	6,3	1,78	0,845
yes	67	6,2	1,81	
OD witnessed				
no	28	6,2	1,74	0,426
yes	104	6,5	1,76	
Ever had naloxone				
no	54	6,2	1,79	0,188
yes	77	6,4	1,68	

Tab.3.23 b - Results for the T-test

Years of drug use become a factor for increase in knowledge when it comes to recognizing OD and primary intervention, but not for an increase in the correct use of naloxone. Intravenous drug use however seems to bring with it greater knowledge for PWUD regarding their risks and therefore increased knowledge both for recognizing OD and administrating naloxone.
Courses aimed at PWUD to prevent OD appear to be efficacious regarding early intervention in cases of OD but less so regarding the correct use of naloxone.

Finally, the ANOVA highlighted the different information levels between PWUD in the cities included in the research. In particular, PWUD in Turin and Naples have more information in both areas with respect to other

cities indicated. This data is however dubious due to the different numbers and to the fact that many cities were incorporated under the title “other”.

3.2.2 Results of focus groups with people who use drugs (PWUDs)

Method

Two focus groups were conducted with people who use drugs (PWUDs) The thematic areas that were the object of the focus to investigate from the perspective of the user were: risk factors for overdose (OD); competencies and learning; evaluation of the distribution system of THN; perspectives and developments; obstacles to the distribution of THN; advocacy. The objectives were to inquire further into the experience of the participants and to reflect on the practice of THN. Therefore the focus group was oriented towards PWUDs who came from contexts where THN was offered, namely the cities of Turin and Naples. The Turin focus group had 8 participants, including one woman. Naples had 5 participants, also including one woman. The age of the group ranged from 27 to 56 years, with a median age of 45 years. Of the 13 participants, 5 had had at least one OD from opiates during their life-time (3 in Turin, 2 in Naples). 8 had given aid to someone (5 in Turin, 3 in Naples) and only 2 participants had not had either a personal experience of OD nor had the occasion to assist in an OD or help someone (both from Turin, amongst the youngest and of those who do not use drugs intravenously)[75]

Results

The causes of OD from opiates in the PWUDs experiences

The factors which currently are the most common cause of OD from opiates as described by the participants, are concentrated on two factors considered to be the most significant: the dynamics of the **market** place on the one hand and the **pattern of use** on the other.

This is without forgetting to cite the change in tolerance after a period of abstinence, in prison or in rehab or for other reasons (*I think the quality is so scarce that whoever overdoses has relapsed, got out of prison or rehab and has a low tolerance F53To)*

The market-place. The uncontrollable quality of the drug

There are consignments of drugs...it works in relation to the market above all, more than according to behaviours (M45aTo)

In both contexts - Turin and Naples- the quality of street heroin is generally low and substandard. Those who have used for some time perceive a net decline with respect to the 80's and 90's, and local contexts also present significant oscillations.

It depends on where we are. In Milan there is a higher quality overall, in Turin more or less the same with peaks of highs and lows but generally low (M46To)

If it is true that low quality also means **low purity** and therefore blander effects, this nevertheless does not seem to be a protective factor but on the contrary it emphasizes the risk of OD. Those who use drugs testify from experience of doses with low or a very low active substance while the market nevertheless is exposed to oscillations that the user has no way of knowing about:

It's true that the stuff is so poor that if you happen to get a good load you are so used to doing the poor stuff that you take a gram of this other more powerful stuff and you are gone (M45aTo)

The quality is variable, maybe you only feel it a bit so you continue and exaggerate (M27To)

The low quality of the drug is also correlated to the **substance used to cut the drug**, a variable even more exposed than the purity of the drug to market oscillations and to the management of local pushers. Drug cutting substances are indicated not only as a cause of low quality but actually as directly co-responsible for risks of OD, above all because **psychotropic** drugs are used in an ever more constant and massive way. The

[75] See Chapter 1

scene in Turin is similar to that in Naples:

The stuff they use to cut is really disgusting with respect to a few years ago..then there's the fact that they mix lots of things especially psychotropics. I remember when I used a lot they called it heroin,now you hear them say let's go and get some "stuff" precisely because it is full of chemical stuff inside...who knows what they put in there...lots of psychotropics I think (F40Na)

Anyways the things that make you OD more often are the psychotropics like rivotril, minias, (ndr clonazepam, loremtazepam) combined let's say with heroin, it is all synthetic stuff to sell you more...heroin is hardly there and then it costs 10/15 euros- what kind of heroin do you think that is.. it would be a miracle if there was even 1% of heroin (M47Na)

Here there is stuff that is called white but in reality it is a mix of drugs non well identified; what was once heroin I don't think exists anymore (M45bTo)

This combination also has a significant influence regarding the greater difficulty and the unpredictability of first aid interventions:

I recall this guy at my place and I got the narcan but he was full of psychotropics and he was like a dead person (M37NA)

When there are particular drug cutting stuff it could be an opiate OD but maybe one from the drugs used to cut, for example the high amount of paracetamol (M46To)

For those who govern the heroin market the **economic ratio of the drugs cut** with psychotropics is double-sided. On the one hand "saving" on the dose of heroin and increasing profits, but on the other hand it could provoke, thanks to the psychotropics themselves, a significant effect for the user, who is always a necessary buyer. The Neapolitan users:

The criminal world has always been there, for example in the 80's they sold but it was good stuff, only that they began to be arrested, there were sequesters and to regain their money they did it on the backs of the drug addicts (F40Na)Of course! For them it is just a business to bring kilos and kilos of opium into Italy, refine it.. then they do chemistry in a laboratory (M47Na)

Behaviours and ways of using. The mix

The use of psychotropics is not only a choice of the illegal market but also a ratio of who uses. Psychotropics are "inside the dose" of opiates but are also part of an intentional strategy of those who use, who look to compensate for the scarce effects of low quality heroin, among other objectives. The heroin-psychotropic mix is not a novelty. Enhancing the effect has always been part of it for many users. (*Even back then we filled up with roipnol, (ndr Flunitrazepam) first it was roipnol now it is minias...F40Na)*. Nevertheless, according to the participants, this associated use has become the norm and much of it connected to balancing the low quality and the desired effects. This associated mix is a major risk factor for OD for the participants:

From what I can see the quality of the stuff is the problem; the quality is really low and it is clear that it is a mixture of substances, people take rivotril or other benzodiazepines to get through the withdrawal and then they hit up again. I saw that almost all the people I gave narcan to had done this mix (M47To)

The young guys take it together with psychotropics to feel it more and it is this that pushes them to OD mainly (F40Na)

Even though it is clear it is the ratio that makes most users look intentionally for a combined effect of psychotropics, one user from Naples signaled how the diffusion of this behaviour was connected to a deep-

rooted culture that sees psychotropics in a certain sense "normalized" in everyday life and in medical practice, as well as accessible:

Today it could be this mania for doctors to fill you with medicine, I mean just to tell you one small thing: I went to talk to the psychologist and that day I was a bit sad and probably by talking I shed a tear or two and he said see, you are depressed, or maybe just a bit nervous, or hey you are schizophrenic or better still, borderline, which is fashionable today. I mean who are you talking to? I am a border-liner? Is that for real? Whatever little thing and they give you some medicine because you suffer from some psychic problem. Can't sleep? Take this; can't wake up? Take something else (F40Na)

As well as the risk of the mixes identified, there are also the opiate mixes, the misuse of methadone and subutex, often used intravenously. These have been identified as increasing and extricated from reasons of self-cure or the desire to not be connected to a health service.

A young guy I know does subutex (ndr. Buprenorphine) he crumbles it and then he injects it (M36TO)

Even methadone now is the new frontier. People take it who have never even taken heroin. I am an old heroin user from the 80's but these are people who do methadone and haven't even tried the real thing, I mean really, have you ever even tried it? (M45aTo)

Taking this stuff into your veins is risky, other than a cardio-circulatory collapse, even an embolism is possible (M47Na)

Even though the way younger people use is seen by these expert users as relatively less exposed to opiate OD risk, , the widespread use of heroin among those at rave parties and festivals is a problem according to them. It is connected to some mixes, for example **mdma or speed** and to a relative incompetency:

We went to a rave with the guys from Infoshock and we noticed that there was a return to using heroin, above all at the end of the party to manage the effects of all the other drugs. The problem is that heroin is not made to be used together with all the other stuff that is around at a rave. Unlike ketamine, heroin increases the risk of collapse if taken on top of speed or mdma or something similar. I see them collapse (M47To)

Another aspect of OD risk is the method of use. The intravenous route remains the most risky with respect to intranasal or smoked. The personal experience of the participants, especially the younger members, support what is an actual fact: non-injecting methods represent a minor risk. However their understanding of risks associated with opiate use appears to be weak.

I have smoked drugs for 6 years and have never OD'd, more because if you smoke, about 30 or 40% of the drug enters into circulation whereas if you inject 100% enters (F53To)

I have never OD'd and I don't inject. Those who use with me use like me, smoking it, the so-called new users. I have always thought that in order to arrive at a state of OD smoking it, you would need to do a lot...I think it is the methodology of use that makes the difference (M36To)

A correlation has been made between methods of use- intravenous- and the capacity to control one's use, for example regulating the dose, frequency and period of abstention, and thus preventing the risk of OD. Intravenous use, according to this user, is a factor that makes that control more difficult:

It can also be said that those who inject use more constantly while those who use in other ways-sniff or smoke- tend to do so in periods, even periods of non-use, abstinence, and generally use less and return to have a gratifying experience when they use again. This seems to me to be more difficult for those who inject. (M46To)

Save and save yourself. Learning, competency and ability to intervene

Among the participants of the focus group, 5 had had at least one OD in their lives (3 in Turin, 2 in Naples) 8 had assisted someone (5 in Turin, 3 in Naples) and only 2 participants (from Turin, the ones who do not inject) had not had any personal experience of OD nor had they had the occasion to assist in an OD or provide aid to someone (*I saw someone who wasn't well but it wasn't from opiates. I go to festivals and different parties and so see people who take other stuff, pills M27To)*. Only these last two declared some uncertainty about their competency and ability to intervene in an OD. All of the other participants said they knew what to do if they had to give help.

Yes, if I have narcan on me (M3To)
Yes, give narcan and if it doesn't work I give it again. Anyways, I react (M27To)
Yes, even if I don't have narcan, but it's better to have it, I can recognize if someone is over or not and then respiration and then the emergency ambulance number (F53To)

In the experiences narrated, the role that relationships among peers plays is predominant, with respect to both the first aid interventions and that of learning. Health services appear to be crucial for access to naloxone and training capable of improving upon competencies learnt on the street. The emergency ambulance personnel appear in the accounts more as a subject called upon to follow the correct procedure rather than a decisive factor, and family members do not result as being crucial actors.

The life-saving network of peers

Peer support, indigenous, spontaneous, played out daily, hold up the life-saving network, with or without naloxone.

It happened to me there, on the stairs, this tall guy and I went and called the girls from the squat, this guy was dying and ..see how big he is? We picked him up and we made him walk and we took him home and in the end he is alive thanks to us.. However I myself have lived that life and frankly if that had happened to me then I would have wanted someone to help me (F40Na)

I have saved lots of people not with narcan but with normal resuscitation ...I have never used narcan (M47Na)

This network still has a connection in the **places shared by PWUDs**, notwithstanding the profound changes in the drug scene in the city. This is due to the dynamics of drug dealing- which is now mobile and not permanent in one place- and to the control of the territory by police who aim to break up and disperse any open drug scene.

Yes, the foreigners (dealers) work like that, with a cell phone...however there are always places where people go to use...here there is "the land" for example (M47Na)

The network of users nonetheless modifies and finds new places to share.

I can see at Porta Palazzo if someone feels bad then everyone arrives and they are all there with narcan in their hands, ready..you have to be careful, you risk getting 3 or 4 shots of narcan at once! (M45aTo)

We were in Piazza Garibaldi in the evening, and there were those giving out narcan, I have always taken it and I kept it in my bag and it happened more than once that I helped someone who was bad... (F40Na)

Where I live (in an occupied house) it happened many times that I saw someone who was in a bad way just there on the stairs. Sometimes we gave narcan but we always tried first to see if they could be roused (M38Na)

In general, even when drugs are used in different places other than in the open, the person who is next to a

PWUD in OD is **another PWUD.** It is this that makes their network the most present and capillary potential life-saving system:

I am 37 years old and in 37 years I have OD'd and I have seen others OD. I have helped a lot of people to recover (M37Na)

I was with my friend and she realized- I am someone who jokes and laughs and there I was quiet, saying nothing..and anyway.. she gave me narcan first and it didn't do anything and after a bit she gave me another one and then I woke up (M56To)

Even 20 years ago I always had narcan with me, we were a group and a friend had OD'd more than once. Plus there were problems with the police so for that reason and also to be sure you could act quickly we bought naloxone, 20 years ago. I used to buy it from the pharmacy (M46To)

With naloxone in the pocket. The accessibility of the drug as an enabling factor
I think that even the most stupid person at some point begins to understand some things and anyway you have to give narcan even when they don't ask you for it, explain how to use it, what it is for.. this is what I think (F40Na)Even the most stupid kid at some point gets it, it enters into their brain, even those hard-headed ones (M37Na)

These Neapolitan users say that having naloxone is the best way to **promote learning** and to favour **adequate behaviours**, even among those who are the most resistant.
Not all life-saving experiences had as a decisive instrument the life-saving drug. Above all those from the past implied using diverse abilities when intervening. Nonetheless the accounts of the participants are testimony to the fact that in twenty years of being accessible, naloxone has entered into play as an "ordinary" intervention tool and as such has become an important enabling factor in emergency first aid and above all it supports and **reinforces the perception of one's own self-efficacy.**

I believe that there is more knowledge about narcan today and much more information. And the fact of having it ready on hand is what has helped us the most (M47To)

Correlated with an increase in self-efficacy there is also responsibility-what we could call **social responsibility,** as a citizen one that the PWUD feels about himself at the moment in which he perceives that his intervention could be decisive.

I believe that above all people who use drugs should take on this responsibility and have it always, because even if you only use a bit and are the most precise person in the world it could always happen that you find someone who isn't doing well, who maybe you don't know but you've met on the streets. I think it is stupid to not have narcan in your pocket, given that we are one of the few states that makes it available and it is so easy for us to have it. Even those from the Europod European network ask us to supply them because it's not possible where they are to get it (M47To)

The transmission of competencies, social learning among peers and services role
In the Italian context the PWUD has at his/her disposition multiple opportunities to know, to be competent and to learn skills about OD from opiates. The participants describe the acquisition of their skills as a **progressive process of social learning**, that is part of their daily lives as citizens and as users and that renders them experts thanks to the combinations of diverse opportunities and resources:

I did a first aid course in another way, personally, then with experience, on the street, from other PWUDs and even the instructions from the workers at the drop-in, I learnt about narcan and I got it from them. Plus the information I got and looked for myself you can now get easily from the web.
(M45aTo)
In this plurality nonetheless, the **role of peers** is predominant, both for the characteristic efficacy of

horizontal communications that denotes the relationship among peers and because this is about non-formal learning, connected to lived experience, to which a particular value is given:

There are places where everyone goes to use and from those older than you watch what they do, and here the piazza counts [...]and when it happens that someone feels bad and someone else helps them, then that is the best school, to observe. Watch and learn. They explain it to you and you observe the things so that when it happens to you and you see someone in that state, you do it. You do what you saw them do to your friend. It's not that there is a little lesson, but it works like that (F40Na)

What is interesting is that even those who feel removed from the risk of OD because they don't use opiates habitually or they don't use intravenously, nevertheless assume **adequate active behaviours** towards saving someone from OD, and overcome the obstacle of injecting, with which they are not expert, demonstrating how a culture and a qualification to intervene have become part of daily life.

As I don't use intravenously, I have watched others do it. If I was obliged to intervene I would do an arm or in the bottom, I would do it, maybe intramuscularly, it is a bit slower but still it is good. Then I would call the ambulance (M27To)

I am needle-phobic but I would do it anyway, in an extreme case, I would do it. I learnt on the street, from friends (M45bTo)

Amongst peers, **learning is progressive** and not all practices are adequate, but "one becomes an expert" . This applies not only to the evolution of the experiences among peers but also the information, the training and the offers made by health services can make a difference:

I did a first aid course with the Red Cross for work, but at the time...I began to use drugs at 13..you know how many people I have happened to save? Anyway, at the time we didn't have all the things, the correct manoeuvre but a few slaps and cold water (M47Na)

The question of the withdrawal that can occur following the administration of naloxone appears to be emblematic. It is a factor that leads some to react negatively and in no way appreciative of a life-saving intervention:

I have seen many addicts that are not pleased to have naloxone and even less to receive it because if they are given it they will go into withdrawal (M45bTo)
They will go into withdrawal but at least they are alive (M56To)
Yes but then they tell you to get fucked (M45bTo)

The problem is real and therefore **a greater competency in the administration of naloxone** is, according to the Turin participants, the key to the outcome, as this conversation testifies:

It depends on who gives it to you and how they give it...then you need to wait a while...stay a little while with the person there (M27To)
You need to give naloxone but also teach the protocol, how much and how to use it, if you do it intramuscularly the withdrawal effect is less strong (M46To)
Unfortunately often you don't know how long the person has been in OD and you prefer the fastest route, for security, but if I know that someone is in OD for 2 minutes I can also allow myself to give it intramuscularly (M46To)

The knowledge that not everyone learns on the street- we need to have " a protocol" says one participant- calls into play **the role of services and of the HR workers**, and their collaboration with peers in the processes of learning. A HR service that occupies itself with **the training of PWUDs** in a process of empowerment and qualification for self-care and that of one's peers, seems to be a crucial factor:

It is important to be well informed about use and dosage (of naloxone) because at times if you use too much and then the person wakes up with an exaggerated withdrawal...the risk is that if peers intervene and they are, for example, a bit all over the place due to doing a speedball and all agitated and they give two or three vials.. maybe for fear it won't be enough. So it is good if there is protocol to follow, you give one or two and wait before going ahead with other vials (M45aTo)

If peer training is seen as the most important aspect, then the follow-up of training provided by professional workers is part of the process of qualification for expert users and it is strongly appreciated.

In the beginning we passed information around amongst us. I had a boyfriend who knew things, like "yesterday Luca had an OD" and then continued with the story of what happened. Today I am a veteran of courses.. I have done a hundred..(F53To)

Me and a group of us attended a course at the SerD where there were workers from the Red Cross who did a simulation with us, beginning with how to snap the top off a phial safely, how to draw up the narcan into the syringe, then we did cardiac massage and respiration and then how to manage all this when you are on the street in different contexts (M47To)

There is a request from PWUDs for training from HR or SerD services which is not sufficiently met.

To do a first aid course and to really learn well is a very important thing. To know what to do, not only in the case of an OD but in general, a proper first aid course (F40Na)

I would really like to do a course, but a serious one (M37Na)

The unfulfilled request for training for professionals does not however take anything away from the fact that the participants express great trust in peer relationships even when the learning context and the dissemination of information is from the services. This is particularly so in Turin where peer support has a long history and is very significant. There is dialogue with HR and SerD services where an investment in horizontal communications and sharing of peer experiences is clearly a winning prospective for all involved.

What needs to happen is for groups of peers to go through the SerD. It could make a difference and not create an ulterior service. It is a project that works internally and is oriented towards HR (M46To)

Other than peers. Other (scarce) support relationships

Extending the competencies for OD prevention as a diffuse social practice and to other networks involved, is one of the desirable objectives for reinforcing the THN model. The results of the questionnaire from PWUDs has revealed a scarce investment in family relationships. Few users have made their family members aware of the availability of naloxone in the case of an emergency. Even participants in the focus groups confirm this tendency, and gave reasons for doing this. Above all the families often are not aware of the habits of the PWUDs or else they are but they have an expectation of remission and do not know or do not accept that there is active drug use continuing.

In most cases the family do not know. They don't even know about methadone and it is just crazy to think they would keep a life-saving drug in the house (M36To)

It is difficult, as far as family dynamics are concerned it means dealing with this head- on and this means admitting that you have not quit, that you are still using, and there lies the difficulty (M46To)

The situation is different with a couple, where there is more communication and often things are shared.
I would say partner yes, if you share your life with a person yes...it is also difficult to hide the fact that you use if you are using regularly. And if something should happen then at least there is a remedy (M27To)

Some have observed how the behaviour of the family members is a cultural by-product which is still very much centered on taking care of someone with **an idea of abstinence and not health promotion**. The same culture that the services promote.

In Italy we have a large number of doctors and services but very few for HR. Most of them just want you to quit. And in the family it is even more so: it is very difficult to talk to them about HR, to get them to accept that you continue to use drugs and that there are other drugs that could be used to save your life (M46To)

The role of services could be a decisive factor for families. They could decide to inform them and this information could change their attitudes.

I think that peers are more indicated. Families are less ideal...imagine a mother who sees their child OD! They would totally panic! (F53To)
But with the right information perhaps yes, they would not panic as much (M45To)

In both focus groups there were exceptions where families were actually informed:

I have my grandmother and I tell her everything, no problem (M45bTo)

Yes my mum knew...we had narcan in a wardrobe, behind where we kept our stuff (drugs) (M37Na)

The following experience of a PWUDs from Naples is interesting. The person talks about a mother who invites her two children to use drugs in the house, in order to be sure that in the case of an emergency she could intervene and to be sure they did not use on the streets: an unusual reaction and one that other participants in the group appreciated:

My brother and I used drugs in the house. My mother preferred that we did it there. She said do it here not outside then I am more relaxed because you can help each other. I know it is wrong but my mother wanted it this way so that if anything happened it happened here in the house (M37Na)
Well she was right actually. You should be happy that she helped you. She is a very open person and a very civil person (F40Na)

The addition from the protagonist: *"I know it is wrong but my mother wanted it this way"* was a form of excusing her which was not appreciated by the group. It appeared almost as a rhetoric phrase conforming with common thinking that prefers to reject or to not want to see the situation rather than accept responsibility and care about risk situations one's children are in. According to participants this contributes to the dominate cultural ideas around drug use and is an obstacle to the development of the HR approach itself.

Obstacles for greater distribution of THN and first-aid interventions
As far as social contexts are concerned, there were two obstacles indicated by the groups as negative influences. The attitudes of the police force in the area and public opinion and the media.
The Police Force do not seem to have understood the function and utility of naloxone in possession by a PWUDs and is still seen as "proof" of drug use and an excuse for further controls (but not all the participants agree about that):

You know what? If I take a phial of narcan and the police stop me they give me a really hard time. It creates such a problem you have no idea (M47Na)
The police need to know that it something that saves lives (M37Na)
It is necessary to directly question the HR and SerD services to promote a relationship with the police forces and to inform them. On the other hand a pragmatic tactic has been suggested of providing a pre-packaged single dose to minimize police related problems.

The problem is the phial and the syringe. It should be like heparin, which is ready to use. That way they can't say anything (M47Na)

As far as **social perceptions and public opinion** goes, and that of **the media** which enables and orientates this, the main obstacles are those of a negative image of PWUDs. They are represented by their defects and problems and never by their competencies and resources, and drug use is always represented as ungovernable and unmanageable. These representations make it difficult to think of a media campaign that incentives THN:

If you want to send a strong message to young people, I would do spot advertising, maybe using young PWUDs, who say when you use you must have naloxone (M37Na)
But did you see what the government did for Fertility day? There are the drug addicts all dirty, ugly and non-white-they were the advertisement- while the good friends were all good-looking, blond nice...and you want to do this stuff on television! (F40Na)

Some in the group exposed the social and media ignorance which still turns a virtuous behaviour- having naloxone in the house- into a negative variable, an indicator of problems. It is a paradoxical reversal for one PWUD whose personal story is disseminated with episodes of solidarity and first aid interventions:

There is still a lot of ignorance, even the Iene (a very popular television show) did a show on fentanyl. They go into someone's house and they find a phial of narcan – just as well I say!- and they say look here's this life-saving drug, and at 21 they are already doing it.. they talk about it as if it were an aggravating factor, instead of saying that this was something intelligent...(F53To)

A third factor that is an obstacle is however cited as a past event, in order to emphasize the fact that this obstacle has in fact been overcome. This is **the risk of repression for those who come to someone's aid** - (controls, police stops)- once they called for the ambulance. This practice today has ceased:

In my time there was lots of trouble if you called the ambulance. If someone was bad at your place you had to drag them out onto the street to not risk getting caught up (F53To)
I don't think it is like that anymore (M47To)
No, it's not like that anymore.. they have understood..(M45aTo)

Amongst generations. Obstacles and opportunities for communicating with young consumers
In the course of the focus groups it was decided to inquire into the possibilities that abilities and competencies of expert PWUDs could become learning tools for younger PWUDs. They could be combined to reduce the risks correlated to new styles of drug use. Opiates in fact, and above all heroin, are part of a new wave among younger users, although the pattern of use and even the cultural aspects are completely different from those adopted by more adult PWUDs. For the latter, opiates were the drug of choice for a long time. The idea of a "transfer among generations" of skills and knowledge about OD was discussed by the group under different headings, which illustrates the complexity and indicate the challenges for communications between peers and between them and the systems for intervention.

Another heroin. Patterns of use among the younger generation
I see a much blander use of heroin (M36To)

According to the perceptions and knowledge of the participants, the ways of using drugs among younger people include opiates but in a different way and from a different culture that they experimented during their own drug-taking history. Contexts and culture of use make the difference therefore. There were differences however regarding this aspect between the two focus groups: the group from Naples indicates drug use among younger people that had many characteristics in common with adult use. They describe traditional street contexts, enough so that is precisely those places where the two generations can meet:
I live in a place where loads of young people use drugs. They go by the steps to use, because it's a place

where not many people go by (F40Na)

The Turin group however describe entertainment scenes and night places, far from the street scene, when they talk about the younger generation of users. The ways of using (relative to heroin, opium and methadone) are changing continually and are differentiated according to places and among different cultural youth groups. For example, one participant noted an increase in the use of opium, a niche substance, that brings with it its own specific culture.

I think that between the young PWUDs the link between mdma and opiates is actually opium. I think it's cool, the alternative types use opium. It's more natural, it makes you feel good like heroin does but the sensation is different. After a rave of three days you relax, you feel good, more than chill out... (F53To)
Let's say it's a niche buzz (M47To)

A common thread of perception and knowledge is the **sporadic use of opiates and always associated with other drugs**, included in mixes which have stimulants as the main drug choice. The mode of using, more sporadic and less intensive, also explains the minor attention towards risks from OD, according to some sources.

Young people take more mdma, amphetamines, it's not like it was before. Therefore they don't have narcan. Every now and then they use heroin, but more often methadone (M37Na)

What appears to be significant however is the common perception that opiates remain- even though they have lost their place as the drug of choice- as a **functional drug** in the eyes of young PWUDs. Ideas for this functionality were offered and were generally correlated with the search for desired effects (the combination with cocaine in a speedball) as well as cultural, where heroin assumes the nature of a time of growth and learning, a rite of passage drug, as one person said, towards an adult use.

Now with the kind of heroin available you need to do a speedball to have some effect, heroin and cocaine together (F53To)
But we used to do that too! (M45bTo)
But it's the same now, it's cool at the end of the evening, everyone has the ball (F53To)
Once you have overcome the fear of heroin you move on to the speedball. On the one hand it is even scarier but once you break that taboo it becomes your first choice (M47To)

It's the drug that scares you the most but also the one that makes you feel the best (F53To)
Yeah it's like that test in an Indian tribe to become an adult (M47To)

These observations may be subjective and local perceptions but what they indicate is that in the search for desired effects and young people's experimentation, **opiates are destined to be established as a drug that is used**, even though the objectives and the ways of use have modified. It is therefore opportune to continue to be concerned about them.

Generational information and disinformation
Young people really don't care (M47Na)
No, not true, it depends (F40Na)
There are also the kids that...(M37Na)
I think that young people do it to imitate. They use but they know nothing about the drug nor the dangers. They do it and are not informed, not enough (M56To)

It emerged in the focus groups a traditional adult attitude-even from the younger participants- that tends to see young PWUDs as unknowing, misinformed, and disinterested about prevention and reducing risks. During the course of the debate however elements and above all analyses of factors that are at the base of this (relative) disinformation emerged. These were useful to identify lines of action and practical strategies,

to move beyond the blind alley of rhetoric about "unaware youth".
Younger PWUDs according to the participants, above all do not take care of themselves when it come to risks about transmittable diseases, which are connected to injecting practices. This a problem to be attended to as it is a method of using that in some contexts is once again returning among young PWUDs, and also because other ways of using (intranasal for example) also have risks of infection:

There is a guy I know who is 14 and he has been injecting for two years and has used the phial of another person who has HIV. He realized after he had used the phial that it is the same as if you use the same syringe but he didn't know about vials, he realized later (M27To)

We are talking about young people but really young, like they are 25 years old maximum.. I saw them take syringes off the street to use. I really don't understand these people at all...(F40Na)

This misinformation or lack of attention is correlated in Italy with a decline in attention regarding public health and transmittable diseases. The health system has totally disinvested in prevention aimed at PWUDs and therefore has a very clear responsibility:

I think that yes, they are less informed and above all less informed about diseases connected to drug use. They have not been the objects of a campaign as we were in the 80's and 90's (M46To)

Certain doubts however also were voiced regarding misinformation among youth. It was recognized that they have **a culture of research and experimentation** which is based on information they have acquired, mostly off the internet. These PWUDs suggest that if they know how to look for and find information about drug characteristics in order to make more rational consumer choices, then this could be a good starting point for widening their knowledge base regarding harm reduction.

Above all from the web, but look I think young PWUDs are very well-informed and do their research to find the drug they prefer and are informed. Right now fentanyl is the one, which, just between you and me, I would try just to see what effect it has...., but they search for something new and strong and during this research they get information (F53To)

Regarding the specific risk of OD- other than the already cited pattern of use which is more or less a sporadic and not intravenous use- one factor which is often overlooked is **the lack of direct shared experience**, passive or active. For the adult generation the experience of OD which was shared amongst peers was a source of learning and here is the opposite situation which seems to be the reason for poor expertise and attention.

With OD, if you change the way of using you change the risks. If almost all of us have experienced the risk personally, this does not happen if you use in another way and perhaps have never ever experienced an OD in your life (M46To)

Furthermore, regarding the rift in the social learning prospective (one learns to become an expert user), the following extract from a PWUD from Naples contrasts her own forward-looking behaviour- by being careful after a period of abstinence- to that of youth inexperience, conjugated with an attitude of superficiality in feeling strong and not at risk:

They (the younger ones) are less attentive also because their body is "cleaner", let's say not so run- down.. I think that they are therefore more unaware: " I feel strong. I feel good. I can handle it" that's the problem. (F40Na)

Beyond the generation gap (1) Communications between peers
I am not going to pretend to be a doctor or some kind of a teacher that gives advice, however every now and then it happens that I see someone who is doing something stupid and I say something and they listen

up. Yes, yes as it happens on these stairs. I saw someone take a syringe from the ground and I said I will break your head! Even though I didn't really say it like that....(F40Na)

If drug places are shared and communications seem possible, peer support has many factors that enable communications and that of actually **sharing a place** (for dealing, using, socialization) is a facilitating variable. The fact is that when different ways of using are discussed even everyday talk happens less and a meeting becomes difficult. The stairs described by the PWUDs from Naples don't suit the youth drug-taking style, nor do the entertainment places or night locations represented by the group from Turin. So in the first instance, it happens that the two worlds don't meet.
Looking further, one of the reasons given for difficulties in learning between generations is the **cultural rupture**: the same issue is being discussed but this means very little if this issue determines a different culture of use- as well as objectives and modalities:

There is no communication between the two groups because even though the stuff is the same it is viewed in a different way. If you get to heroin by different roads, not like what happened with us older users who began in the 80's and 90's, there is a cultural generation gap that impedes even the transmission of useful information (M46To)
Anchored to these cultural differences, the question of **social stigma** which was put upon intravenous heroin users (the addict) and belongs to an adult generation or even older people, plays a decisive role according to some: this is an emblematic figure that the young PWUDs contrast themselves to, as they feel distant from this figure. It is clear that this stigmatization works against the credibility of the "mentor".

It is also a question of stigma. If you use intravenously you are an addict. If you don't you don't see yourself as one and you don't make contact with these people, in fact, the opposite. (M46To)

I was in prison and I shared a cell with a person. He was 27 and I was 27. He shot up and I am needle-phobic so for him I was not an addict because I didn't inject, even though we both used the same stuff, just in a different way (M45bTo)

With respect to this aspect the focus groups highlight the fact that in Italy, the long history of peer support and of valuing the experience of PWUDs, carried out in some Italian cities and in general from the practice of HR, has not at a national level been able to invert **the common idea of the incapable addict.** This rhetorical figure has been constructed within the public debate on drugs and young PWUDs overall believe in this social perception.
It is interesting nonetheless to note how there are sensitive differences between the two contexts when it comes to analyzing how the participants perceive themselves in the role of "mentor" for younger users. The Naples focus group- recruited from the MNE's own client base- oscillate with respect to young people. Even though they are expert users and reflect on their use, they are ambivalent about knowing and sharing their own "useful" information for those who are inexpert and the risk of being a negative example or encouraging use. They see they may be emblematic figures- showing how it is possible to use drugs over a long period of time and at the same time maintain (relative) control over this.

They ask me how I manage drugs because I know how to keep stuff in my pocket and maybe take it two or three days later. I manage it. This morning they asked me if I had wanted to use, right? But I manage it, really, because I wanted to come here. And when they ask but how do you do that? I really don't know. Maybe because I am older. No, they see me as a negative example, they say that when you get to my age then I can do even more (M47Na)

The problem is when they talk about me they always say "you are a real addict". Bastards! They see it differently. They don't see "hey she can manage his stuff"; they never say "if she can stay like that then I can use drugs and be careful". I like to use drugs, I like it, but I am careful about what I do...but they don't see you like that.. they see you in a negative way; they want to do what you do and then more(F40Na)

In both focus groups, some remember that the adult PWUDs oscillates in an ambivalent way between being the figure of an initiator (negative) and the figure of an initiator-mentor (positive):

It depends, often you get into a group with someone who is older and me as a younger guy would insist, like an idiot, hey you're not thinking of doing heroin today are you? Often you see someone much older than you and if they aren't a total shit then they will tell you something (M36To)

The concerns around the risk of playing a negative role rather than that of a mentor for using safely, did not emerge in any way in the Turin focus group. This group participates in different ways to a collective dimension of peer support in the area and interest groups. They have numerous occasions to meet each other informally and some of them interact with health services. Self-reflection and experience between the participants from Turin and Naples are similar. However for the former, the risk that an expert PWUD (who regulates him/herself) could be an incentive to use, was never a subject for discussion. The focus in the debates was totally centered on the "how" to socially promote learning and experience with young PWUDs and never on "if" to do so. This difference seems to suggest how a process of peer support that offers other PWUDs a place where their own experience can be used from an empowerment and HR prospective. It supports the positive expertise acquired and legitimizes them, which could be a powerful incentive for the recognition and socialization of self-regulation and the limiting of risks.

Beyond the generational gap (2) Proper services for better communications

Young PWUDs can also be found in **HR services and services that limit risks**, where peer groups work. The challenge lies here, in Italy, as to what services because*: in the drop-ins, young PWUDs don't go! or rather, they go but later when they have experienced the negative effects of drugs and problems, but for sure they don't go in the early phase when it would be useful (M46To)*

As far as drug use connected to raves and festivals goes, where there are interventions for limiting risks and first aid, many doubts have emerged as to the efficacy of naloxone distribution. The type of use is not centered around opiates, even if they do get used, and above all a drug that is administered (here in Italy for now) only by injection is inadequate to users who do not have this practice.

Naloxone is there (at the raves). It is available for workers and also for peers to use but it is not given out, because the context is different and if you distribute it would imply something different there. Naloxone is connected to those who shoot up.. (M46To)

In the rave and party contexts the drugs that are used are not opiates generally, therefore naloxone would not have a place there (M27To)

The question of the mode of administration appears to be significant therefore. Having **intranasal naloxone** for example, could make a difference:

Yes it would be easier for who doesn't...injecting scares a bit and obviously if you are in an emergency you put the needle in and ok but for sure it is harder. If you don't know how you would ask yourself a few questions before doing it and for sure you don't go looking for a vein.. if it was an aerosol them it would be easier for sure (M27To)

In general, from the viewpoint of participants, if the health services system responded more than what they are doing today regarding **prevention for new types of drugs use by youth**, this would create better opportunities to intervene with respect to preventing OD and the distribution of naloxone in a population that today is unreachable. Services and HR interventions have this potential, especially when there are peer workers present:

There is little to it really. If you want to be in contact with PWUDs you need to be on the same ground as them but above all you have to propose something that they are interested in. For example proposing useful

materials, like tinfoil paper...everyone knows that ordinary ones are bad and nobody gives you what is actually needed to smoke. There is Domopak but after 5years maybe you find yourself with some neurological problem in your brain (M46To)

At the raves when you organize the chill out and analyze the drugs, the young guys come, of course they do. If you are inside the event and they don't have to do much to come and find you and if they bought stuff from someone they didn't know, given that they are intelligent they come and have their dose analyzed. They want to see if they have really bought what they think they have bought in terms of quality, and while you are there you can work with them (M47To)

The information about naloxone could also clearly be on the internet. According to participants social media is a resource to be utilized to get to young people in an effective way:

You need to get to the others, the new ones, and we could do this via the web. We could put lots of information, announcements, a campaign, talk about where we can be found. Here is not the SerD because these people do not go to the SerD (F53To)

Here everyone uses social media. It's not difficult to grasp this (M36To)

THN, the Italian model. It works but needs innovating

The focus groups happened in two cities where HR interventions aimed at users of opiates are operative in a consistent manner for more than 20 years. For both groups, the access to naloxone guaranteed by low-threshold services is an ordinary normal thing. Nonetheless the reflection around the efficacy of the Italian system for THN distribution presents many critical aspects and identifies places for innovation.

The SerD. The great (unjustified) absence on the THN scene

PWUDs confirm what emerged from the research with professional workers and highlight the paradox of the absence in the SerD, or rather, in their day-hospitals, of prevention work through the distribution of naloxone. On the one hand the role of protagonist by low-threshold services in preventing OD is coherent with their mission of HR. On the other hand it is also true that- on the contrary to HR services- the network of SerD day-hospitals is capillary throughout the country and represents a potential that is unexploited today.

I think that the SerD should give it to me but the fact is that the SerD are inattentive today, and have stopped experimenting (F53To)

I need to say that the MNE is the only one who gives you narcan, but the SerD will give you methadone but they will not give you narcan (M37Na)

PWUDs critically analyze this inattention and accuse the fact that the SerD occupies itself with “treatment”, still interpreting this as aimed at abstinence and delegating to the HR services the objective of OD prevention:

It is maybe like condoms- some think that if you give them out you are inviting people to have sex and maybe they think that if you give out a life-saving drug you are inviting them to use, but it's not like that (M47To)
People maybe but a SerD should not reason like that! On the contrary, it is absurd! The SerD have gone backwards and a lot (F53To)

This absence of the services is more serious if it is taken into account that many cities in Italy (most) do not have HR services and expose PWUDs to a higher level of risk. The SerD should in fact become the capillary network for THN distribution:

For a person with a drug dependency, the SerD is a point of reference. You go because you need a substitute drug or something else, but you go. And if you get good information and communications then even better (M27To)

The important role that the SerD could play is one aimed at **families**, which have been identified as not involved and are for the most part very far removed from a HR approach. The HR services have less possibility regarding this area due to the type of work they dowhereas the SerD work of actual care often adopts an approach which involves and meets with family members:

It would be interesting, also as it would create a culture within the service- new and with the times, and also for the families too, because the families are always hooked in by groups with a precise ideology, and this is what is wrong with what happens here in Italy (M46To)

Pharmacies, the other great absence on the THN scene
Access to naloxone by purchasing it in a pharmacy is more than a rare event. Only one participant reported to having bought it in a pharmacy:

Yes, I did yes (bought it). Where I was staying before there were no HR services and I bought it (M46To)
And you found it straight away? They gave it to you?
Yes, immediately (M46To)

Not only do people not buy it in the cities where it is free obviously, but also in places where there are not THN interventions. There are factors or resistance connected to a variety of factors. The **economic factor** for example, is one for PWUDs who are in greater difficulty:

Well, if you use and you have money you use it to buy drugs (M36To)

Some underlines how **contact with pharmacists** is not very easy for a PWUDs. They risk not being appreciated in the shop and not treated well, which occurs when they buy syringes:

With pharmacies...they don't want addicts in the way and they won't give it to you or they say they don't have it and anyway a lot of people don't really even know about this (M36To)

Opposing this is that the pharmacist is seen however as an **agent of health promotion**

They are health workers anyway, right?! They should (M45bTo)
We need to fight a battle. They should have it and they should give it out (M47To)

Pharmacists have a significant potential network in the area that, apart from selling drugs, should and could initiate an action of information and prevention:

They could in fact give out information, pamphlets and other stuff (M45bTo)
Also for communications as well as for distribution, it would be worth it above all in the provinces where there are no HR services that distribute it, where it is not as accessible as in the cities (M46To)

Some participants indicated the automatic distributors as a possible way (such as for syringes), as they are always active and could be another possibility for access, much like the defibrillators that are available in public places now:

There should be the vending machines in the street (F40Na)

The automatic distributors like those for syringes could be an idea (M47To)

The Police Force. An obstacle or a resource?

For some participants, one of the obstacles preventing people from keeping a dose of naloxone on them are police controls and the reactions of policemen. The same people who indicate this limit also indicate the necessity of overcoming this logic. Police officers in the area, who have a very diffuse network, could become agents for first aid once they were trained, according to those who are on the streets:

You need to inform the police, get them to do courses so they can give narcan..(M47Na) (everyone intervenes and they all appear to be in agreement)
All they need to do is to do the Red Cross course like I did, the first aid course! What is more important is to help another person and not say I am not authorized (M47Na)

A life-saving drug, a right (PWUDs around the world....)

At the end of the focus groups, the facilitators described the international situation, informed on the current campaign for THN and asked the participants if, based on their experience, they had a message to send to those PWUDs who are fighting this battle today.
There was some stupor on learning that Italy is ahead in this good practice...

Really? At least in this we are a better country. They don't give it out in other countries? Hey they should tell other countries that this is a life-saving drug! (M37Na)

This is a cultural problem, of climate.. however it is strange in these civilized countries, advanced, whereas us Italians are behind in so many things. For once we are the best! (M47Na)

A key concept that was suggested is that **having access to a life-saving drug is the right** of every person. This is a strong affirmation by peers for the rights of PWUDs and in a particular way when the right to life is in question.

It is a right to be able to take care of your own health and therefore this is fighting for a right. If this was a life-saving drug for an oncological disease nobody would pose the problem of giving it or not. I don't see why there should be a problem for naloxone (M45bTo)
Exactly. You are a person with the same rights as everyone (M45bTo)

There is the need to underline the connection between individual rights and **the responsibility of public health** to guarantee this:

I would say to them that it is their right and there is no motive why this should be negated. Saving lives is something that should be at the base of the health system (F53To)

If they do not want to have deaths on their conscience...the question of narcan is an intelligent and CIVIL thing (M47Na)

Arguments in favor of this: **the efficacy of the drug and the lack of risk in using it:**

It needs to be said that many people would still be alive if they had had this help, this possibility (F40Na)
And it is a normal thing; it doesn't do nothing...(M37Na)

Finally there is the conviction that change is possible and that **the activation of PWUDS** is possible and necessary.

I will continue to fight and insist because this is a good idea and saves lives (M56To)
It is indecent. They should pass a law! (M47Na)
If it is a people's law.. collect signatures from your own town! (F40Na)
Let's use this as a spot " **GIVE VALUE TO LIFE"** (M37Na)

3.2.3 Discussion of the results of the questionnaire and of the focus group with people who use drugs (PWUDs)

a) The strong points of the Italian model from the point of view of PWUDs

- **The peer network as a pivotal resource**

Italian PWUDs use naloxone and they do so in their daily contexts: among those interviewed, 60% had or had had on them a phial of naloxone. Those who had it on them had used it in 67% of cases and 80% of these cases had used it more than once.
Those who use naloxone the most are intravenous drug users. They have the characteristics of being in contact with low-threshold services that distribute naloxone and of being the most expert in the administration of the drug, which today in Italy is available only as an injectable solution.
The network between peers works: according to respondents of the questionnaire, it is the network of relationships between peers which is seen as a pivotal factor in the strategy for fatal OD prevention. Those who intervene the most frequently (in 70% of cases) are in fact, other PWUDs. They respond immediately and appropriately: 75% of those who provided first aid had called the emergency number and had administered naloxone in 63% of cases. This figure was confirmed by the direct experience of those who had had an OD episode and had been aided by a peer. The support, the valorizing and the development of an informal network among PWUDs is considered, according to the results of the research, to be the central point of a strategic action of HR. Those who actively intervene are those who use drugs in open spaces or public places (70%) and are therefore people exposed to the risks of using "on the street". There are also those who intervene and who use inside houses and in groups, as is testified by the accounts from the focus group. Here a consolidated culture of attention and reciprocal care emerges. What also emerged from the focus groups was that even people who do not use drugs intravenously will carry naloxone with them in case they meet someone who needs it. This aspect supports what is an acquired habit these days. This network of relationships appears to be a factor for promotion and incentive: over two-thirds of the episodes of OD experienced personally by the respondents happened while the person was alone, and therefore it is necessary to continue to work with PWUDs so that they place more attention on the importance of using drugs in the presence of others and not alone.

- **Competency and solidarity. Processes of learning and willingness to intervene**

The research confirms that having and perceiving to have the capacity to intervene in an appropriate manner in an OD situation (*self-efficacy*) is necessary for the development of an efficient capillary network for intervention by peers. Solidarity therefore is not only a behaviour and background of single individuals but it is also in function of competencies, feeling secure, and trusting in one's own abilities. The learning process that the PWUDs undergoes towards a major acquisition of skills and capacity to intervene in an OD, has many methods and sources. Above all there is "natural" learning: from personal experience. Many have learnt from a critical episode (76%). They have modified their behaviour of drug use following an OD experience, changing personal strategies that range from modifying the pattern and context of their use to having naloxone with them, or not using alone.
This however is not a solitary learning experience. The learning is correlated with an informative and training opportunity: here also the role of training and communications between peers to increase the level of knowledge and abilities appears crucial. This is relevant above all for older PWUDs (those who state they have used for more than 15 years) and for intravenous drug users. Finally (see following paragraph), there is training that was received from HR services, via informative counselling sessions or training courses. Those who had this opportunity are more aware of risks and have greater knowledge of first aid and how to correctly use naloxone. From the focus groups it clearly emerged that peers are the most cited and valued source of information by PWUDs and also demonstrates how the training opportunities offered by the health system had an added value, which has been verified in many episodes as important.

- **The role of THN in learning processes and the increase in self-efficacy**

According to the results of the questionnaire, in 63% of first aid cases, the PWUDs administered naloxone. This data was reinforced by the experiences heard in the focus groups. Naloxone appears to be a routine tool in the experience of Italian intravenous drug users. The daily availability of naloxone is reflected not only by its actual use in emergency situations but also, according to PWUDs accounts, in other crucial dimensions. Above all this regards the more complex area of perception of risks. Naloxone and its accessibility places the PWUDs in a condition where it is easier-both in the relationship between peers and with HR services- to focalize their attention on causes, risks and ways of avoiding OD. The possession of a phial of naloxone basically facilitates that awareness. Secondly, as already discussed, the possession of naloxone appears to enable the first aid intervention by further contributing to the reinforcement of active behaviours and overcoming uncertainties, fears and obstacles that can prevent aid from being given. Reading the results it emerges that those who have never used naloxone tend to feel they are not "authorized" to intervene in some way. The results of the section of the questionnaire dedicated to verifying the competencies around OD and naloxone identify a median of 66% as giving a correct answer. It should be noted that the elevated percentage regarding naloxone administration ability is higher than that regarding OD in general (for example, symptoms). On the one hand there is widespread concrete experience in daily life and on the other hand this issue merits more training. Knowledge and skills nevertheless refer to personal variables and the history of drug use. The intravenous drug users who have used drugs for a long time are those with the most skills, above all in recognizing cases of overdose. This suggests the need for greater attention towards younger drug users and to question the current system of interventions for this group.

- **Overcoming false myths that limit the use of naloxone**

The research negates, via the words of PWUDs, some false myths with respect to the use of naloxone by peers and contradicts some of the concerns expressed by workers. First of all, the idea that a person who OD's (presumed or real) will be irritated by the administration of the drug, has not been confirmed- if not in exceptional cases- by the data obtained. What is in fact interesting, and this emerged from the focus groups, is that the risk of withdrawal that can follow the administration of naloxone is real but can be limited by administrating it in an expert and competent manner, for example by being attentive to the method (intramuscular versus intravenous) and the dosage. Therefore the myth of the "resistant PWUD" to naloxone is defeated by competency. Secondly, there has also been a process of evolution in this context, with respect to its entry in the 90's. As far as health workers are concerned (the ambulance staff in particular), this practice is no longer considered inopportune and therefore there does not appear to be any evidence of censure or sanctioning behaviour towards those who assist and administer naloxone. Supporting this are the responses to the questionnaire where it was indicated that frequently peers who intervened were thanked by doctors and were asked for further information regarding the episode. This was also confirmed in the focus groups. Finally, the question of the police force was addressed. For some years they were seen as an obstacle as they tended to use finding naloxone on a person as a further reason to search them. This was police practice but today the general opinion is that this has been superseded. This in itself is an important indicator of how THN has been able to "educate the context".

- **The role of HR services for accessibility and training**

Naloxone is accessible to PWUDs. The Italian distribution model, notwithstanding the enormous limits of geographic discontinuity, has however achieved the result of consolidating the behaviour of having naloxone on one's person and of using it, possession and utilization have in fact become routine behaviours. The research suggests that this sort of "normalization" in daily life by those who use drugs, emphasizes its efficacy. PWUDs appreciate this accessibility, even if they routinely criticize it's limits: the availability and the fact that is free is an important factor. Many in the focus groups underlined how buying it would be difficult above all for those who are more marginalized: for "street" PWUDs, who are also more at risk. What is appreciated

above all is training and the information about naloxone that accompanies its distribution. In the network of services that distribute THN, the low-threshold and HR services, health and educational workers are experts regarding correlated risks and in particular in the intravenous administration of the drug. They have an approach which enables efficacious communications which in turn allows for the information to be spread through informal and even sporadic contacts. They often are working in or nearby drug-taking places. What also emerged from the focus groups is the centrality in this training intervention of peer workers or expert peers who collaborate with the services. This is a confirmation of how horizontal communications, typical of peer support and recognized and appreciated by PWUDs, can play a fundamental role not only in natural settings but also when the aim is for a semi-professional action.

- **THN as a right**

At the end of the focus groups the participants were asked to indicate a good reason, coming from their own experience, to support the distribution of naloxone through the THN regime. Other than the pragmatic reasons for saving the life of another human being, which many had experienced personally, what was indicated was the right to life and to health. Once a life-saving drug exists, it was stated, the fact of negating access to this drug for those directly interested, would be a violation of this fundamental right. Connected to this consideration are the pharmacological characteristics of naloxone: it is a safe drug, with zero or minimal undesired side effects. The question of rights is also connected to a public health dimension, the aim of which is to promote health and to safeguard it, also by valorizing competencies that are inherent in society. PWUDs claim the same rights as all citizens, highlighting the need to promote a different culture and a different social perception of people who use drugs.

b) **The weak points of the Italian model of THN and the requests of PWUDs**

- **Criticisms of the limits of the system of THN distribution**

PWUDs appreciate the promotional and training role of HR services and at the same time the huge limits in terms of coverage at a national level are denounced. The discontinuity that occurs from budget cuts and overall the fact that THN - along with other services - is something that is not completely guaranteed to Italian PWUDs. As the distribution of naloxone is not homogeneous throughout Italy, neither is the knowledge nor the competencies of PWUDs. The same opportunities are offered or not offered in different areas. In fact among the respondents of the questionnaire, those who have never received naloxone tend to give a more negative opinion, a symptom of prejudice and scarce information clearly correlated with a scarce or non-existent offer of the drug itself. At the same time, those who do not carry naloxone with them and do not use it, state that it is because there is no accessibility to the drug or information about where to find it. Only a small percentage of people show a lack of faith in their own abilities and in those of their peers and support the need for specific professional skills. These considerations led to a pressing demand by PWUDs for a proper national and regional policy in terms of HR.
Analogous to this, SerDs were criticized. They are present throughout the territory yet they are not utilized- or very rarely- as a place where naloxone can be found. They could take on a key role in the distribution and in increasing knowledge and skills of PWUDs who do not have access to low-threshold services. The SerDs are criticized for a culture more connected to treatment with an *"abstinence oriented"* view rather than health promotion in a wider sense and in harmony with the objectives of the PWUDs. Participants of the focus group were very critical about this "double track", treatment or HR, stating it was already superseded and suggesting a *client oriented* approach, based on the needs and the objectives of the clients.
A specific criticism of PWUDs with respect to the Italian system regards Drug consumption rooms (DCR), which are not admitted nor experimented and which seem important for those who use on the street and are living in marginal conditions. Combining this with the capillary network of naloxone distribution on the one hand and a widespread practice of drug checking (which is only experimental in Italy today) would signify, according to them, the design of a potent prevention system.

- **Widening the distribution network**

As much as naloxone is a drug that does not require medical prescription and the cost is contained, it is practically never acquired in pharmacies by PWUDs (1% of respondents of the questionnaire and only one case in the focus groups). For people who live in areas where free and informed access is guaranteed by HR services, this is obvious. For those who live in areas where this offer is not available, they are confronted by three obstacles: lack of information regarding the accessibility and its use (and here a return to the gap in the SerDs for this lack); economic factors for marginal people and those in the greatest difficulty; the behaviour of pharmacists who often tend to ostracize PWUDs clients as undesired and annoying (which also happens when they attempt to buy sterile materials), which is a disincentive to PWUDs to go to them. Regarding this aspect, those interviewed strongly underlined the potential role of pharmacies. They could present themselves not only as a commercial venture that selects their clientele but as public health workers who encourage good practices from citizens. A clear intervention request emerges from this: a campaign for example, to close the gap by involving and activating pharmacies to work with drug dependencies and the HR network and associations.

The scenario that PWUDs describe regarding the involvement of family members in the first aid network is complex. Only 8% of the sample had informed their partner that they had on them or in the house, a life-saving drug. The focus groups clarified that they were talking about partners, not the nuclear family, parents, brothers or sisters. It seems this is not connected to an issue of better communications rather than to a more problematic issue of the perceptions the family has of drug use and the expectations that they harbor. These are generally connected to ideas of remission rather than to good practices of limiting damage and risks. The dominant Italian cultural model in families and above all parents, centered around abstinence, is called into question here. This makes it very difficult for PWUDs to be explicit about their actual behaviour, even when drug use is controlled and safer, and therefore difficult to face the topic of a possible emergency. At the same time a deeper criticism is aimed at the treatment services. They often have the possibility of working with families and do not use this opportunity with a HR perspective. Here the request of the PWUDS is very explicit and aims at a different approach, as was already mentioned regarding the distribution to users.
The focus groups also indicated the need to make those who were seen until a few years ago as an obstacle- the police forces in the area- a resource, by giving naloxone to every patrol car and providing the training necessary to police officers.

- **An outstanding question for collective training**

The questionnaire highlighted a constant and diffuse offer of information and training about OD and naloxone by HR services on an individual counseling level, but a scarce offer of group courses. In the experience of PWUDs these group experiences are moments of significant learning. If the most widespread basic training remains that among peers, the training received from professionals is seen as an added value for a broader set of skills. This is important above all with respect to first aid maneuvers but also for naloxone: to have a serious “protocol” of use, as the group reported, equals knowing how to avoid undesired consequences, such as the risk of withdrawal following administration. PWUDS explicitly ask health services for more training.

- **Young PWUDs and new styles of use**

As has been discussed above, the competencies around OD and naloxone and the use of naloxone is concentrated on people who have used drugs for a long time, who choose and have chosen for years to use opiates as their drug of choice and do so by injecting. This is connected to the time it takes to learn and to experience, including the frequent experience, active and passive, of OD in the arc of a lifetime. It also includes relationships among peers, which are a characteristic of this generation. They are regular users of HR services and use intravenously (given that in Italy naloxone is available only as an injectable substance).
However heroin and other opiates are also used by the younger generation and in Italy in increasing numbers. Styles of use are however different according to the drug, due to culture and the objectives of use and methods of assumption. The view of older drug users is that the younger generation appear to be less expert and less aware of the risks, including that of OD. The reasons given are varied: there is an actual real minor risk of OD in taking drugs not intravenously. Direct or indirect experience of OD is rare for these PWUDs and

therefore occasions for learning by experience are also rare. There is also however no investment by services regarding information and training aimed at them and above all regarding peer training, considered by adult PWUDs as very important. There are no occasions, if not sporadic, for inter-generational meetings that could help transmit skills. Even if the molecules are the same, the drug culture and the places of using are not.

PWUDs envisage three different directions to fill this information and training gap for younger users. The first is to bring the HR services up to date by calibrating them to new styles of use: a better offer (for example straws or tinfoil that is not toxic, when syringes aren't what is used). Above all a service of drug checking would serve to create contact and offer occasions to work on OD risks and invite them to use naloxone- which would need to be provided in the intranasal format e/o in mono-doses ready to use (a ready-to-use syringe). The drug checking aspect- giving the PWUDs knowledge of the drugs they are about to use- appears to be crucial: 25% of the respondents to the questionnaire stated that the uncertainty, the variability, and not knowing the quality of the drug is the highest risk factor for OD. This factor was also emphasized by the PWUDs in the focus groups, who put the illegal market in first place among that variables that lead to OD.
The second direction is to activate them intentionally as peers, aimed at reaching the younger users and building occasions for meeting and exchange. This would activate a real responsibility as peer experts, and also connect with services and PWUDs associations that intervene in natural settings where young users meet.
Thirdly, the greater and better use of internet for awareness campaigns about naloxone and indications regarding access to the drug. The internet is seen as a source to privilege for information and knowledge for younger PWUDs. These younger people are not seen at all by older users as hopeless but in fact capable of in-depth research about drugs they intend to use, and therefore potentially capable of also accessing information about prevention.

4. Conclusions and recommendations

It is possible to extract some recommendations and apprehension from the results of the research to enable an efficient practice in distributing naloxone and to optimize this in the wider arena of policy and practices for the prevention of deaths from opiate overdose.

The recommendations are divided according to area: operative, research, political, and each area proposes a focus on the Italian context.

4.1 Recommendations for the operative model and practices

a) Guarantee access to naloxone. The classification of naloxone as an over-the-counter drug that does not require a medical prescription, is a crucial factor. It allows for any staff member, even non-health workers, any drug user, and any citizen to have access to it and to become an active protagonist for a strategy of preventing deaths from opiate overdose. The transfer of these competencies to civil society is in line with the health promotion approach which invests in "doing health" for the entire community in an alliance between professionals and citizens. The characteristics of naloxone are such that managing it at a community level is significantly safe. Naloxone should be obtainable, available and accessible in diverse methods of assumption, both as an injectable drug and for intranasal use.

b) Invest in Harm Reduction (HR) services as strategic promotors of THN. Due to their mission and approach, HR services are the most competent for promoting and supporting the distribution of naloxone among PWUDs. They operate in the vicinity of the drug scene and the natural settings of drug use and therefore have access to PWUDs who are not in contact with services (some of whom have never been in contact and never will contact drug services). They also know the patterns of use of their clients and the correlated risks, and interact with the dynamics between peers and are able to valorize this with the objectives of solidarity and peer support. HR works according to a health promotion approach which places value on the skills of users, putting them on par with other citizens. The free offer of naloxone by the public health system, above all to the group of PWUDs who are more fragile, is a facilitating factor. When looking at the synergy between services, the distribution of naloxone is more efficient where HR services have multiple intervention modes that are simultaneously active (drop-in, needle exchange, other outreach services, drug consumption rooms, drug checking), all of which multiplies the distribution network points and widens the options for intervening in cases of OD, both on a prevention level and that of first aid.

c) Combine the distribution of naloxone to PWUDs with information and counselling. The crucial role of HR in THN distribution is correlated with a necessary and continuous action of information, training and counselling offered to the PWUDs regarding the correct use of the drug, first aid techniques, the ability to recognize an opiate OD and to act correctly in that context. Proper training guarantees the prevention, or at least the reduction, of the impact of eventual undesired side-effects, such as a withdrawal crisis for the person assisted. It also guides the people providing aid towards standard behaviours of surveillance and support in the post-intervention phase, even when the subject in OD does not wish to go to hospital.

d) Recognize, legitimize and valorize the competencies of PWUDs and their social networks. PWUDs are those who most frequently assist in an OD, therefore representing a potential network of first aid assistance which is widespread and timely. It is necessary to operate on many levels in order to increase and value both the skills for intervening and the solidarity and communication dynamics between peers. This means supporting them in recognizing their own abilities, in increasing their own self-efficacy and also- in reference to the context- in breaking down the socio-cultural barriers and the social stigmas that are still too frequently describing them as incapable and irresponsible subjects. This itself immediately invalidates the potentiality of their actions. Self-organization of PWUDS promotes their responsibility and capacity to play a social role, reinforce trust in their own skills and knowledge and support their civil rights. The associative and citizenship processes which work in opposition to the stigma and social prejudices, reinforce a positive protagonist role

that also reflects on the peer role in the area of health promotion and limitation of risks. An alliance and collaboration is desirable, in a dialectic dimension, between PWUD organizations and the services in the area.

e) Elaborate strategies, methodologies and instruments capable of increasing information and competencies. Civil society associations, HR and treatment services, other educational and prevention services and PWUD organizations, must work in synergy to construct useful ways and materials for enhancing and complement the skills that PWUDs already acquire from their own personal and collective experiences. It is opportune to elaborate the training and information materials together with the recipients of these materials and target them to the specifics of single groups and diverse methods of drug use. The role of HR workers could be significant in this area.

f) Place responsibility on the entire drug addiction services system. The central role of HR services should not mean not recognizing the part played by treatment services both in preventing deaths from OD and with respect to the THN model. Drug addiction services follow opiate users who continue to use even during treatment, and who access the OST therapy, not with the aim of remission but for control/regulation of their use. In fact one of the outcomes of substitute drug therapy is the reduction of death from OD. With this profile, drug addiction services must operate in a continuum with those of HR services. Drug Addiction services are spread throughout the area, intercept a significant part of PWUDs and can therefore have both a capacity for risk assessment regarding OD during the entire therapeutic phase and also be a distribution point for naloxone and for information and advice on how to use it. These services also have more possibilities that HR services to intervene with families of PWUDs, to inform them and make them aware, even through the eventual consignment of naloxone. With respect to residential detoxification centers and therapeutic communities, it is important - given that the moment of discharge exposes the client to the greatest risk of OD due to altered levels of tolerance - that they elaborate ad hoc modalities of information, even predisposing the adoption of naloxone on release. This approach becomes even more urgent when the PWUD is released from a period of time in prison.

g) Elaborate innovative strategies of THN aimed at diverse drug using styles and contexts and at younger users. For styles of drug use where opiate are not the first choice of drug nor is injecting drugs contemplated, OD risk is perceived in a very light way. While it is true the risk is less, it is nevertheless present and the current trend of an upswing in opiate use in the younger population of poly-drug users, identified in many countries, suggest urgency in adopting interventions such as information and distribution of naloxone in new natural drug user scenes and with new outreach methods. Furthermore this population could be correctly informed of the availability of naloxone in pharmacies or from services through the internet. Training could also be provided on-line. Other than *combination interventions*, the practice of drug checking-already present in many entertainment and drug use contexts as a prevention tool- could provide useful information regarding the composition quali-quantitative of the drug acquired and be an appropriate occasion to inform about THN. It appears crucial that intranasal naloxone be made available for this population who for the most part do not inject.

h) Invest in the friendship and family networks. If the PWUD network is utilized, a good THN praxis is to also invest in their closer network of friends and family. To expand the information campaign, both media and on-line, and to create together opportunities for meeting, information and training, the involvement of the service networks, including those for treatment and associations of civil society are important. Particular care needs to be attributed to information and awareness of partners. It is also important to provide for support and to listen to family members who deal with the experience of OD of someone close to them.

i) Widen the network of subjects to be included in THN distribution (1). General Practitioners. General practitioners (GPs) are present throughout the territory and each citizen- PWUD or not- is in contact with one of them. This therefore is a potential capillary network and professionally competent. GPs could be actors for OD prevention-through counselling and information- and for naloxone distribution in cases where their clients use opiates or have a family member who uses. They could be consultants and a network point for the distribution of naloxone. It is useful to propose training modules and concrete modes of participation in

prevention campaigns for death from OD (informative materials, contacts, referrals to specialized services, and with PWUDs associations).

l) Widen the network of subjects to be included in THN distribution (2). Pharmacies. In countries where naloxone is for sale in pharmacies as an over-the-counter drug and not requiring a medical prescription, pharmacies can be thought of as not just a sales point but as a network point in the health system. They could be the center of an information campaign and one to promote the acquisition and the use of naloxone by citizens directly or indirectly involved in opiate use. Particular attention needs to be paid to the relationship with the PWUDs, who not uncommonly is the object of distrust, stigma and alienation.

m) Widen the network of subjects to be included in THN distribution (3) Police Force This issue needs to be dealt with in two different directions. On the one hand, the police who are present throughout the territory need to become allies in THN, overcoming the attitudes that often on the drug scene made them agents of dissuasion. They identify possession of naloxone as proof of drug use and/or possession of drugs and transform it paradoxically into an incentive for repressive control. Here the role HR workers can play in their community interventions is important. Secondly, it is possible to provide the police themselves with naloxone and the competencies for its correct use.

n) Awareness and training of social and health workers. Wherever naloxone is available, all staff members, health or otherwise, must be able to use it, distribute it to PWUDs and administer it in case of emergency. In the national contexts where it is not an over-the-counter drug, services can -while respecting current national legislation- adopt guidelines ad hoc that allow socio-health workers to use naloxone. The non-health workers must have adequate training, knowledge and methods of use, and all workers, health, social and educative, must have training as to how to correctly inform PWUDS and their close network contacts. First aid workers should be made aware on how to interact with PWUDs who have perhaps already intervened with naloxone. They could ask for useful information and reinforce and legitimize their intervention and thus create a network of diverse but integrated competencies.

o) "Socialize" naloxone. A media information campaign for the general public. The Health promotion approach that underpins THN recognizes the diffuse social skills that "make health". As has happened in recent years for other first aid or prevention practices which have "exited" from professionals-only areas, to valorize the interventions in and of the community- (the diffusion of defibrillators in public places and the invitation to people to use them in case of emergency, for example)-the same could apply to naloxone. It is opportune to think of a media and social media campaign to inform the general public and to bring this life-saving drug out of its "niche" for use only by specialists in that particular field, and make it known, accessible and an everyday word. The activation and the assumption of responsibility process of the community towards preventing OD deaths should be both a cultural and a concrete process. As it happened for PWUDs, so it must be for citizens, to have at their disposition a pragmatic efficacious and easy to use instrument. This can only occur through the reinforcement of attitudes of solidarity, reducing fears and concerns and increasing perceptions of self-efficacy.

Recommendations for the Italian context

- **The current regulatory framework is clear and sufficient.** Notwithstanding that the classification of naloxone and the Italian regulatory framework regarding first aid in emergency situations is clear and sufficient to guarantee and protect whoever intervenes with naloxone in an emergency, it has happened, and still happens, that in some regions workers and services are not authorized by their regional authorities or by their own drug addiction services to neither distribute naloxone to their clients nor to administer it in the case of OD. While it is true there exists a policy gap (for example regarding guidelines), it is also true that the above cited regulatory framework permits intervention in any case. The absence of THN programs in certain areas of the country do not therefore appear justified from a legislative perspective.

- **Every service can and should distribute naloxone.** Each public and accredited private service, for

treatment or HR, should include among their services, the offer of naloxone to their clients and their close contacts. With current resources, and while waiting for politicians to assume responsibility regarding this theme, even regions completely lacking or with very few HR interventions, could activate THN practices. They would need to act with the viewpoint of integration and networking among all the services and all the health workers in the territory. The economic impact of naloxone is very limited, and should not represent a real problem for the budgets of the public addiction services.

- **Provide incentive for the peer support approach, collaboration between peers-services and support PWUDs associationism.** The first resource of THN are the PWUDs and their competencies. In Italy there is still a strong cultural resistance against recognizing PWUDs as citizens and as experts of themselves. Professionals, above all those in HR, need to include in their operative models, the in-depth knowledge of natural protection strategies adopted by PWUDs, their valorization, their development and peer support, group training, support for associationism and PWUDs as civil protagonists. In Italy this approach has a long tradition and some areas of excellence but this is not equally distributed throughout the country.

- **Initiate programs aimed at families.** In Italy there exists a consolidated tradition that has consigned families of PWUDs to a culture centered on a dual dependency-abstinence binary, where parents and partners are induced to not see objectives such as less riskier use or methods of control and regulation of drug use, as acceptable or appreciable objectives. This "all or nothing" approach inhibits a prevention culture and often impedes an open dialogue between the PWUDs and the family. In order for the family to become a valid player in the prevention strategies for deaths from OD, it is necessary to promote a culture of risk limitation, informing and making family members aware and accompanying them in this process. The service system has all of the competencies and resources to promote this cultural innovation.

- **Adopt THN in prison and post-prison contexts**. In Italy HR does not enter into prison. Currently the distribution of sterile materials and condoms is not provided for. Neither are specific actions for OD prevention. Methadone therapy is often on a sliding-scale only, even for people who enter already on a maintenance program. While certain political and specific actions are first necessary to begin HR interventions in the penitentiary sector, some actions could be implemented "from the grassroots", regarding ordinary service interventions, especially if they do not impact directly on internal management. For example, the consignment of naloxone to PWUD on discharge from prison, considering that an altered tolerance for drugs after a period of confinement is one of the most important factors of risk for OD, and the period immediately following prison discharge is in fact where the major part of overdose episodes are concentrated

4.2 Recommendations for government and policy makers

a) Explicit support for the politics of HR. HR has need for explicit, motivated support, based on evidence, by government. This support guarantees the continuity of the intervention, access to services, and economic support for these services. It has already been proven by the vast literature on the subject that a lack or weak support and clarity in politics is a factor for failure and for the scarce efficacy of the interventions. Policy-makers must therefore engage in dialogue with the experts, with workers, with civil society, with PWUDs and decide, while limiting the influence of ideologies, and base their choices on a double criteria: evidence-based (what science and experience say) and human rights (what human rights and first of all health rights, say). THN should be part of the routine HR interventions.

b) Make naloxone accessible in all possible pharmacological forms. Where naloxone is not accessible as an over-the-counter drug and requires a doctor's prescription, or where even it can only be used by health staff, a reform of the national pharmacopoeia is necessary. There is much evidence that government could use to demonstrate that naloxone is a safe drug and there are very low risks correlated to its use. In countries where it is not yet available, actions must be implemented at all levels necessary to have accessibility in the shortest time possible, to intranasal naloxone.

c) Elaboration of operative guidelines for THN. Government should give a clear mandate to agencies predisposed to elaborating operative guidelines that include THN. They should be oriented towards services and to the actors involved, as a guarantee of the quality and the appropriateness of the practices and their efficacy. The guidelines, while respecting the relative autonomy of the services at regional and local levels, should stabilize criteria and standards that guarantee everywhere, the availability of naloxone and the need for counselling and training of workers and PWUDs. The elaboration of guidelines should receive a contribution from all the competent actors and involve and include organizations from civil society and from PWUDs.

d) Adopt the "combination intervention" approach. In order to have major efficacyand efficiency of interventions, THN needs to be considered not as an isolated intervention but within an integrated system. Prevention of OD and deaths from OD must be able to use all of the interventions that have been shown to be effective. It is opportune that where HR interventions such as OST with HR goals, drug consumption rooms and drug checking are not active, government assumes the urgent obligation to innovate and support a better intervention system.

e) Modify context factors that increase OD risk. There are social, regulatory and cultural context that maximize the risks correlated to drugs, and context that instead play a positive role in limiting damage and risks. Political policy-makers influence this alternative under different profiles: the regulatory profile, that can aggravate or not the condition of being clandestine, a factor which directly influences the risk of OD; the politics of territorial control, which concretely influences places and methods of use; those regarding systems of service, that can be more or less responding to real needs, more or less accessible, more or less appropriate. Regarding protection from the risk of death from OD, a context that is not criminalized and not punitive for those who use drugs, and where resources are invested more in health and support than in repression and control of the phenomena, facilitates this protection.

f) Intervention for a different social perception of drug use and drug users. On a political cultural level, an action that promotes a different social perception and a different "common sense" around drugs, users and correlated risks, is necessary. This means removing the PWUDs from the stigma that nails them or the pathology or deviance, or both. They represent a condemnation to "a bad ending" while they have contact with drugs. This is a vision which marginalizes people and also suggests the impossibility of containing the risk through adequate policies.

Recommendations for the Italian context

- **To have an up-to-date policy and action plan on drugs.** Italy does not have a clear drug policy nor an up-to-date national action plan, which explicitly includes HR as a pillar of national strategy. Alternating governments with diverse agendas have bought repeated discontinuity with respect to an approach on drugs, and scarcely based on evidence. Currently Italy does not have even a member of government delegated to deal with this issue. It is therefore urgent that the subject of drugs is back on the agenda, that Parliament proceeds with modifying the laws on psychotropic drugs and on services. These laws have been lying in the drawers of various commissions, and a redefinition of the national drug plan to include HR is necessary. It is also necessary that this process is participative- as indicated by the European Drug Strategy- open to contributions from all competent and involved subjects. The triennial national Conference on drugs - established by law- needs to be revived as it is the seat for the evaluation of policies and for necessary innovations (a Conference that has not been called for more than 8 years).
- **To release guidelines for HR.** In 2000 and again in 2008 tow commissions of experts, workers and members of civil society elaborated guidelines for HR that explicitly included THN among the practices. These were to be guaranteed throughout the national territory in an effort to overcome the extreme unhomogeneous nature of the operative models between regions. In both cases, changed in government coalitions impeded the guidelines from becoming mandatory and operative. It is necessary to adopt new guidelines that include and define, among other interventions, the practices of THN. Prisons also need to be

included in these guidelines, with the same interventions and services of HR as is guaranteed outside prison walls.

- **Include THN in the LEA- Essential levels of Assistance.** In January 2017 the LEA were redefined, and for the first time they include HR, therefore allowing HR services to be implemented in all regions and not, as currently happens, only in some. During 2017 the HR services will be defined and it is necessary that THN is included. This represents a guarantee for the diffusion of naloxone throughout the national territory.

4.3 Recommendations for research

a) Organize an efficient monitoring model for deaths from OD. An efficient system for recording deaths from OD needs to be established in order to have full knowledge of the phenomena, necessary to orientate interventions and political decisions.

b) Elaborate a monitoring and evaluation model for THN. Monitoring and evaluation are essential for the elaboration of the best guidelines for intervention, to evaluate the efficacy and efficiency of the operative models and THN services. They would also provide workers with a solid base for managing and innovating their own practices. An evaluation model would also support policymakers in their choices. This means therefore that THN must be included in the data collection system of processes and results inherent to HR. The monitoring and evaluation system must be realistic and manageable, and must take into account the needs and restrictions that workers have in data collection when this often occurs in informal contexts such as the street or natural settings.

c) Knowing drug use patterns and strategies of PWUDs. The distribution of naloxone "enters" into the daily life of PWUDs and their networks and makes use of their relationships, their skills and their behaviours. This implies having good knowledge about both drug use patterns and individual and group strategies in managing drug use, as well as the life contexts and their influence. It is therefore necessary to develop qualitative and ethnographic research which are able to orientate operative models.

d) Valorize and involve workers and PWUDS in research. Those who work in the field and who live drug use in the first person are "privileged antennae": research on risk factors for OD, prevention strategies and first aid, must place value of these informal "observers" and create occasions for collaboration and synergy with researchers and the organizations undertaking research.

e) Promote action-oriented research to practices. It is necessary that whatever type of research is undertaken concerning strategies and operative intervention models, that it provides knowledge aimed at action. It must be explicitly applicable in terms of strategies and models for intervention, and be oriented to support policymakers. Regarding interventions, particular attention should be paid to propaedeutic research for elaborating efficacious models of risk assessment for OD for health services.

Recommendations for the Italian context

- **Include THN in the institutional monitoring system.** Today, thanks to the lack of clear guidelines for HR, the monitoring system for interventions managed by SIND- The Ministry of Health- does not include data on HR services and therefore also not on THN practices. These interventions need to be included and a regional and national system of data collection set up. This is more urgent now that HR is included in the LEA- Essential levels of Assistance.

- **Develop qualitative research, change perception about PWUDs.** Qualitative and ethnographic research on drug use in Italy is particularly penalized due to the current cultural, scientific and economic

profile. A decisive step is required to re-orientate research policy (and relative investments) in this direction. All competent subjects need to be involved and the DPA- National Drug Agency Department should be asked initially to include a specific dedicated section to this in a new (hopefully) national Action Plan.

- **Develop evaluation studies for the processes and outcomes of THN.** In order to support evidence-based policy decisions, as well as providing necessary feedback to those working in the field, it is necessary to promote and support evaluation studies on the outcomes of policies and practices relating to the prevention of OD and deaths from OD, including a specific focus on THN.

- **Greater synergy between information systems and the death registries to monitor cases of OD.** In Italy data on drug related deaths and from OD arrive from diverse sources and within different times. They are also collected using different codifications, making the reading of this data difficult, not complete nor timely. It would be opportune to intervene to render the system more efficient and to enable greater cooperation between the departments involved.

APPENDIX

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With the support of the Foundation Open Society Institute and the contribution of Indivior Italia Srl

Research on the distribution of Naloxone
Questionnaire Health Service Workers

We ask for your collaboration in this research project, by responding to the questionnaire on the subject of naloxone and in particular on Take-Home-Naloxone (THN).

This project is promoted by Forum Droghe, in collaboration with the Public Addiction Services Dept. Naples 1, the Public Addiction Services Dept. Turin ex 2 and Turin 3, and the Research and Training Institute Eclectica.

Your contribution will be useful in identifying both the strong and weak points of the interventions in this area, understanding the changes that are occurring and identifying new perspectives.

It is estimated it will take 10-15 minutes to compile the questionnaire. If the compilation is interrupted before completion, it can be saved and returned to at a later moment.

On completion of the questionnaire, we ask for some personal data and a contact email (optional) to be able to ask for ulterior information if necessary. All data will be diffused in an aggregated and anonymous format and conserved in accordance with the current regulations concerning privacy.

We thank you for your collaboration!

1.What are the strategies of the service for preventing episodes of overdose and mortality from overdose of heroin? (multiple replies are possible).

□ Informative materials
□ Individual counseling
□ Information/training of groups
□ Distribution of naloxone to people who use drugs (PWUDs)
□ Giving naloxone to peers, family or friends of PWUDs
□ Street outreach projects and intervention in settings of use
□ Identifying subjects who are most at risk and activating specific protective interventions
□ Modulating the dosages and the consignment of opiate-antagonist drugs
□ Physical presence of socio/health workers with naloxone and a defibrillator in places of drug use
□ Peer support and/or involvement of opinion leaders
□ Observation of PWUDs mobility in the city and the variations in settings of use
Other (specify)_____

2. **With reference to your experience and regarding your clients, what are the principle causes of opiate overdose?**

□ Variation in the purity of the drugs
□ Different and unknown composition of what is used to cut the drugs
□ Compromised health status
□ Changed tolerance levels (e.g. Use after a period of abstinence, prison or rehabilitation)
□ Intentionality of the PWUDs
□ Insufficient pharmacological cover (low doses of opiate-antagonists)
□ Insufficient access to treatment with opiate-antagonists
□ Multiple/poly drug use
Other (specify)

3. **With reference to your experience, what are the predictive factors for a positive outcome from an overdose?** (maximum three answers).

□ Promptness of first aid intervention
□ Promptness and efficiency of ambulance services
□ Availability of naloxone from people present
□ Availability of naloxone from the PWUD in overdose
□ Knowledge of first aid techniques by peers
□ Proximity of a low-threshold service/needle exchange
□ Proximity of a pharmacy
□ Proximity of a hospital emergency room
Other (specify)

4. **What are the operative indications from your service to staff for managing an overdose episode?** (multiple answers possible)

□ Request information from people present
□ First aid techniques (including Basic Life Support)
□ Call the ambulance

□ Administer naloxone intravenously/intramuscularly
□ Alert and inform other PWUDs
□ Activate ways of collaboration between PWUDs and services regarding alert/information system and monitoring
Other (specify) _____

5. **Are these indications shared with non-health workers and peers on the team**?
□ Yes
□ No
□ Don't know

6. I**n your service, who is authorized to administer naloxone in an emergency**? (multiple answers possible)
□ Doctors
□ Nurses
□ Psychologists
□ Educators
□ Social Workers
□ Peer Workers
□ Volunteers
□ All socio-health workers present at the time
Other workers (specify)_____

7. **Does the service in which you work distribute naloxone directly to clients** (THN)?
□ Yes
□ Not now, but in the past yes (go to question 7b)
□ No, never (got to question 7e)

7a. If yes, for how many years has it been distributed? (got to question 8)
7b. If not now, in what period was it distributed? From year_____ to year____
7c. Who decided to interrupt the distribution?
□ The Regional government
□ The Health Agency
□ The work team
Others (specify)_____

7d. For what reasons? (multiple answers possible)
□ Budget cuts
□ Change in administration
□ Reduction in team members
□ Reduction in the needs of PWUDs due to changes in drug use
□ Resistance by PWUDs
□ Resistance by socio/health workers
Other (specify) _____ (Go to question 8)

7e. If naloxone was never distributed, what are the reasons (multiple answers possible)
□ Lack of resources
□ Inappropriate intervention
□ Lack of proven efficacy

□ Iatrogenic effects of naloxone
□ Unaccepted by socio/health workers
□ Scarce presence of opiate users among client base
Other (specify) _____

(go to question 14)

8. **Were there obstacles to the introduction of THN?** (for those who replied to 7a and 7b)
□ Yes
□ No

8a. If yes, what kind of obstacles?

□ Lack of support at a regional level
□ Lack of support at management level
□ Difficulty in being accepted by team members
□ Difficulty in being accepted by health workers (e.g. emergency services doctors)
□ Difficulties with the police force
□ Organizational difficulties
Other (specify) _____

9. **Who usually gives out the THN?** (multiple answers possible)
□ Doctors
□ Nurses
□Psychologists
□ Professional Health Educators
□ Social workers
□ Peer workers
□ Volunteers
Other health workers (specify) _____

10. **Who is given (or was given) or made available to THN** (multiple answers possible)
□ Individual PWUDs
□ Leader PWUDs/ reference person for a group (go to question 10a)
□ Partner
□ Family member
□ Friends
□ Left accessible at the drug scene
□ Left available in public places
Other (specify)_____

10a In what way was it given to the PWUDs? (multiple answers possible)
□ Individual information session
□ Training course on naloxone and first aid
□ Together with informative materials
Other (specify) _____

10b With what indications was it given? _____

11. **Over time, have there been changes in the number of phials distributed**?
□ Yes, a reduction (got to question 11a)
□ Yes, an increase (go to question 11b)
□ No

11a. The reduction was due to: (multiple answers possible)
□ A reduction in clients using heroin
□ Arrival of new clients less aware and less competent
□ An increased resistance by clients
□ Different attitudes/resistance by health workers
□ Budget reductions

11b. The increase was due to: (multiple answers possible)
□ An increase in clients using heroin
□ A reduction in resistance by PWUDs
□ An increased awareness and competency by heroin users
□ A more intensified offer by health workers
□ Continuity/increase in the budget

12. **Over time, have there been changes in the interventions connected to the distribution**?
□ Yes, an intensification
□ Yes, a reduction
□ No

12a. In what way has been an intensification? (if this occurred) (multiple answers possible)

□ Individual counselling and information
□ Distribution of informative materials
□ Training courses for groups
□ Activation of peer experts and opinion leaders
□ Distribution to family members, partners, friends
□ Distribution in places of drug use and other public places
Other _____

12b. In what way has there been a reduction? (if this occurred) (multiple answers possible)
□ Individual counselling and information
□ Distribution of informative materials
□ Training courses for groups
□ Activation of peer experts and opinion leaders
□ Distribution to family members, partners, friends
□ Distribution in places of drug use and other public places
Other _____

13. **According to you, what are the most useful characteristics of naloxone**? (multiple answers possible)
□ It is accessible as an over-the-counter drug
□ Easy to use
□ Absence of collateral effects

Other (specify)_____

14. **What are the limits of naloxone?** (multiple answers possible)

□ The dose given may be insufficient
□ Risk of using non-sterile material
□ Lack of sterile material (from peers) to administer it
□ Induces withdrawal symptoms
□ After the first dose, signs of overdose can reappear
Other (specify) _____

15. **What are the three main advantages of THN for the social and health system**? (indicate in order of importance: 1 = maximum importance; 3= minor importance)

□ Promotion and support of solidarity between peers
□ Availability of an informal capillary network of first aid
□ Involvement of family members
□ Increase in trust in services
□ Reduction in deaths from overdose

16. **In what order of importance would you place these three advantages for the PWUDs?** (1=maximum importance; 3= minor importance)

□ Increase in knowledge about risks
□ Increase in self-efficacy in knowing how to deal with a crisis
□ Increase in practical skills for intervening

17. **What are the three main risks of THN?** (indicate in order of importance: 1 = maximum importance; 3= minor importance)

□ Inappropriate use
□ Used against the will of the subject
□ Insufficient dose with respect to the drug assumed
□ Induced abstinence
□ Increased controls by Police Officers for PWUDs found possessing naloxone
□ Risk of further assumption and further overdose
□ Use of non-sterile materials
□ Increase in drug use
□ Disincentive for prevention behaviours
Other: _____

18. **How are the risks of naloxone and THN managed**? (OPEN QUESTION)

Not relevant, THN has never been practiced (go to question 22)

19. According to you, has this intervention model increased competencies and capacities of PWUDS in preventing overdose?

□ Yes
□ No
□ Not relevant, THN has never been practiced.

19a. Why? (specify)

20. **Does your service collect data regarding the distribution of naloxone**?
□ Yes
□ No
□ Not relevant, THN has never been practiced

21. **Has research been conducted in your service regarding the methods of naloxone use by clients**?
□ Yes
□ No
□ Not relevant, THN has never been practiced

22. Do you wish to add any comments or information?

Service data

Type of Service:
□ Mobile needle exchange
□ Drop-in
□ Outreach intervention in natural setting
□ SerD (Public Addiction Service)
Other _____

City:

Province:

Person who responded to the questionnaire
Age:
Gender:

Profession:
□ Doctor
□ Psychologist
□ Professional Nurse
□ Educator
□ Social Worker
□ Peer Worker
Other _____

Role in the Service: _____

Email for eventual information requests:

with the support of the Foundation Open Society Institute and the contribution of Indivior Italia Srl

Research on the distribution of Naloxone
Questionnarie to PWUDs

This questionnaire is the research tool which allows us to know the Italian situation regarding the distribution of naloxone.

THE QUESTIONNAIRE IS ANONYMOUS and the data will be gathered in a confidential manner.

We ask you to respond to each question with one answer only, unless otherwise specified.

The questionnaire is divided into 5 sections:

- Section 1: socio-demographic data and use of drugs. If you have not used a narcotic drug (not prescribed by a doctor), reply to the first 4 questions only.
- Section 2: personal experience of overdose or of others, where you can only answer the questions if you can do so from personal experience.
- Section 3: availability and use of naloxone (narcan)
- Sections 4 and 5 refer to the information you have concerning narcan.

It will take about 15-20 minutes to reply to all of the questions

THANK YOU FOR YOUR VALUABLE CONTRIBUTION

SECTION 1 SOCIO-DEMOGRAPHIC DATA AND DRUG USE

1. Age (years to date): |__|__|

2. Gender: ☐ M ☐F

3. Province where you live: _____

4. Have you used an opiate at least 10 times in the past 12 months (heroin/morphine/opium/methadone/ buprenorphine) NOT prescribed by a doctor?

❑YES ❑NO ⟶ THANK YOU THE QUESTIONNAIRE IS FINISHED.

4.2 What is your usual method?

- ☐ Injected
- ☐ Smoke/inhaled
- ☐ Oral
- ☐ Sublingual

5. How old were you when you tried an opiate for the first time, NOT prescribed? |__|__|

6. In the last month have you used an opiate/opiates NOT prescribed?

❑YES ❑NO (if you answered **"NO" , go to question 8** on **this page**)

6.1. If yes what (mostly or exclusively)? _____

6.2. How frequently?

- ☐ Less than once a week
- ☐ Once o more a week
- ☐ Every day
- ☐ More than once a day

7. Is the opiate/narcotic, NOT prescribed by a doctor, your first choice of drug?

- ☐ □ YES (if you answered "Yes" go to question 8 section1 of this page)
- ☐ □ NO

7.1. If it is not an opiate, what is your drug of first choice?_____

7.2. How frequently do you take it ?

- ☐ Less than once a week
- ☐ once or more a week
- ☐ every day
- ☐ more than once a day

8. What drugs have you used in the past month? (multiple answers)

- ☐ Heroin
- ☐ Cocaine
- ☐ Amphetamine
- ☐ Cannabis
- ☐ alcohol
- ☐ LSD
- ☐ ecstasy/mdma
- ☐ opium
- ☐ Ketamine
- ☐ Drugs not prescribed
- ☐ _____

9.Do you usually use different drugs in the same day? ☐ YES ☐NO

Section 2 Personal experience of overdose and of others

1. Have you ever had un overdose from opiates?

❑YES ❑NO **(if you answered "NO" go to question 2 section2, p. 4)**

1.1 If yes, how many times in your life? |__|__|

1.2 **When did the last overdose occur?**

- ☐ Less than 6 months ago
- ☐ 6-12months ago
- ☐ more than 1 year ago

1.3 **With reference to this last episode, what was the main reason, according to you?**

- ☐ I mixed more than one drug
- ☐ I hadn't used for a while (just out from jail, rehab)
- ☐ The drug was too pure and I didn't know
- ☐ I changed dealer
- ☐ I really wanted to exaggerate
- ☐ Don't know
- ☐ Other

1.4. Where were you?

- ☐ At home
- ☐ At someone's place
- ☐ In the car
- ☐ Outdoor (park, square)
- ☐ Outdoor (hidden/ concealed place)
- ☐ Public house
- ☐ Other_____

1.5. Who were you with?

- ☐ Alone
- ☐ Partner/friend
- ☐ Acquaintance
- ☐ Unknown person
- ☐ Don't remember

1.6 Who was the first person to help you?

- ☐ Peers/friends
- ☐ Passerby
- ☐ police
- ☐ Emergency staff
- ☐ mobile needle exchange/drop-in
- ☐ Public Drug addiction service workers
- ☐ None. I helped myself
- ☐ Don't remember

1.7 Do you know what the person who helped you did? (multiple answers)

- ☐ Called for the ambulance
- ☐ cardiac massage
- ☐ mouth to mouth resuscitation
- ☐ injected narcan
- ☐ put me on my side
- ☐ don't know

1.8 Did you take precautions after having an overdose?

☐ YES ☐ NO **(if you answered "NO", go to question 2 section 2, page. 4)**

<u>If yes, what</u>? (multiple answers)

- ☐ I always have narcan on me
- ☐ I never use alone
- ☐ Try first (take a small dose to see the effect and then the rest)
- ☐ If I change pusher I always ask the others
- ☐ I don't mix drugs
- ☐ If I haven't used for a while, I take less
- ☐ I started or restarted treatment with methadone / buprenorphine
- ☐ Other

1.8.1 At that time were you having substitute pharmacological treatment(methadone/ buprenorphine)? ❑ Yes ❑ NO

2. Have you ever witnessed someone else in overdose?

❑YES ❑NO **(if you answer "NO", go to question 1 section 3, page. 5)**

2.1 **If yes, how many times?**

- ☐ Once
- ☐ 2-3 times
- ☐ more than 3

2.2 **Who was the last person you saw in overdose?**

- ☐ Partner/relative
- ☐ friend
- ☐ acquaintance
- ☐ unknown

2.3.Where did this happen?

- ☐ At home
- ☐ At someone else's house
- ☐ In the car
- ☐ Outdoor (park, square…)
- ☐ In a public place
- ☐ Other_____

2.4. What did you do? Write 1 for the first thing, 2 for the second and so on. If you just did one thing write 1 for that

I called the ambulance	
Cardiac massage	
Mouth to mouth resuscitation	
Injected naloxone	
Put the person on their side	
Looked for help from others	
nothing, I wasn't able to do anything	

2.5. What was the outcome?

- ☐ the person got better while you were there
- ☐ the person got better only later, at the hospital
- ☐ the person died
- ☐ don't know/don't remember

Section 3 Availability and use of naloxone (narcan)

1. **Have you ever had phials of naloxone on you?**
   ❑YES ❑NO →

If no, why? (multiple answers) [after replying go to section *4, page. 6*]
- ☐ I don't know what it is
- ☐ Nobody ever offered it to me
- ☐ I wouldn't know how to get it
- ☐ Costs too much
- ☐ Brings bad luck
- ☐ They don't have it in the pharmacy
- ☐ Better to call for professional help
- ☐ No -one would want me to give it to them
- ☐ I get more problems when the police stop me
- ☐ I don't know when to use it

2. **If yes, how do you normally get it?**
   - ☐ Distributed by the needle exchange/ drop in
   - ☐ Distributed by SerD
   - ☐ I buy it in the pharmacy
   - ☐ Through friends/acquaintances

3. **Have you ever used it to help someone ?**
   ❑YES ❑No **(go to question 4 on this page.)**

   3.1. How many times have you used it?
   - ☐ 1
   - ☐ 2-5
   - ☐ 6-10
   - ☐ >10

   3.2.How many phials did you use the last time? |__|__|

   3.2.1 Where did you inject?
   - ☐ In a vein
   - ☐ In a muscle
   - ☐ Under the skin
   - ☐ Other

   3.2.2 Did you have a sterile syringe/needle on you? ❑ YES ❑ NO

   3.2.3 If the person came around, were he/she angry to have been given an injection of narcan? ❑YES ❑NO

   3.2.4 Was the ambulance called? ❑YES ❑NO ❑DON'T KNOW

   <u>If the ambulance was called</u>, how did the ambulance workers react to your intervention with naloxone?
   - ☐ They thanked me
   - ☐ They said I was not authorized
   - ☐ Other_____

4. **Have you ever bought naloxone in a pharmacy?** ❑ YES ❑ NO
5. **Where do you usually keep it?**
   - ☐ Always with me
   - ☐ In the car
   - ☐ Where I usually use

6. **Do other people know you have naloxone on you?** ❑ YES ❑ NO

   <u>If yes</u>, who are they?
   - ☐ Peers/friends
   - ☐ Partner/family
   - ☐ Others

SECTION 4 Information about narcan

1. Have you ever received information about using narcan? ❑ YES ❑ NO
(if you answered **"NO", go to question 2 on this page)**

<u>If yes, from whom</u>?

- ☐ Peers
- ☐ Needle exchange /drop in workers
- ☐ Personnel at SerD
- ☐ Internet
- ☐ Other_____

1.1 Have you ever followed a course ad hoc, or courses and/or support groups between peers? ❑ YES ❑ NO

2.What is your opinion overall regarding the naloxone distribution in your city?

☐ **Very Bad** ☐ **Scarce** ☐ **Good** ☐ **Excellent**

SECTION 5 KNOWLEDGE

Answer the questions by identifying ONLY those answers you regard as correct (each question may have more than one answer)

1. Which of the following are indicators of an overdose from opiates?

- ☐ Blood -shot eyes
- ☐ Slow – shallow breathing
- ☐ Lips hands feet turning blue
- ☐ Loss of consciousness
- ☐ Doesn't respond to stimuli
- ☐ Collapsed/slumped over
- ☐ Deep snoring and/or gurgling sounds
- ☐ Constricted pupils
- ☐ Behaving in an agitated way
- ☐ Rapid heartbeat

2. What should be done in the case of an overdose from opiates?

- ☐ Call the ambulance
- ☐ Stay with the person until the ambulance arrives
- ☐ Inject them with a saline solution
- ☐ mouth to mouth resuscitation
- ☐ Give them stimulants (cocaine o coffee)
- ☐ Lay the person on their side
- ☐ give naloxone
- ☐ Throw really cold water on them
- ☐ Check for breathing
- ☐ Check if their airways are free (nose and mouth)
- ☐ Put the person to bed to sleep

3. Naloxone is useful for per:

- ☐ Giving up drugs
- ☐ Reversing an overdose from opiates
- ☐ Reversing an overdose from cocaine
- ☐ Reversing an overdose from amphetamines
- ☐ Don't know

4. The recommendations on administering naloxone state that is should be given:

- ☐ Intravenously
- ☐ Intramuscularly
- ☐ subcutaneously
- ☐ swallowed
- ☐ don't know

5. Naloxone should be injected:

- ☐ outside of tights or arm
- ☐ In a vein
- ☐ In the heart muscle
- ☐ It should be given by mouth
- ☐ Don't know

6. How long does naloxone take to have an effect?

- ☐ 2-5 minutes
- ☐ 5-10 minutes
- ☐ Up to 20 minutes
- ☐ Up to 40 minutes
- ☐ Don't know

7. How long do the effects of naloxone last?

- ☐ Less than 20 minutes
- ☐ From 20 mins to 1 hour
- ☐ from 2 to 3 hours
- ☐ up to 12 hours
- ☐ don't know

THE QUESTIONNAIRE HAS FINISHED. THANKS AGAIN FOR YOUR COLLABORATION

III. **The Research Group**

Franca Beccaria: sociologist and doctor of research in Alcoholism; founder of Eclectica, a Turin research institute, in1997. She teaches the Sociology of Health at the Faculty of Medicine at the University of Turin and at the *European Masters on Drugs and Alcohol Studies* program-EMDAS- at the University of East Piedmont. She is also a member of the Scientific Permanent Observation Laboratory on Youth and Alcohol. She has published numerous articles in scientific reviews both national and international. Her most recent book is *"Alcohol and Generations"* published by Carocci in 2010 and in 2013, Giunti Editors published " *Alcohol and Youth. Think before you use".*

Antonella Camposeragna: psychologist and social researcher, she has worked in research and the implementations of harm reduction (HR) interventions for over 20 years. In 1994 she participated in the first HR program in Rome, measured with indicators of efficacy. Since then she has conducted research both nationally and internationally, concerned with describing HR in both these contexts, monitoring of processes and outcomes.

Angelo Giglio: doctor, psychiatrist, he has worked in the area of pathological dependencies in Turin since 1983. He has been in charge of outreach services for the Public Health Department since 2000 and from 2002 has been managing the Ser.D of the Department of Pathology of Dependencies ("C. Olievenstein" ASL ex TO2-Turin). He was instrumental in initiating HR interventions through the creation of the Itinerant Project for Active Drug Addicts " CAN GO" (a mobile needle exchange), active since 1995. In 2009 he created the Itinerant Night Project-"PIN"- in Turin. This is a risk limitation project aimed at reducing risks connected to alcohol consumption and other illegal substances in local places of entertainment.

Paolo Jarre: doctor, psychotherapist, he has worked in the area of diverse types of addiction since 1983. From 2001 he has managed the Public Addiction Department (ASL TO3) in Piedmont. For more than 20 years he has dedicated part of his work to studying the activation and management of HR interventions regarding problems in substance use. He initiated a Mobile Needle Exchange with his colleagues in 1996 and a night Survival Unit in 2002, a Drop-in in 2007 and a residential low-threshold program in 2013. He coordinated the regional HR group in Piedmont from 2006-2009.

Sara Rolando: doctor of research in sociology, she has worked at Eclectica (Torino) since 2007 as a researcher on national and international projects regarding life-styles and at-risk behaviours, in particular addictive behaviours (alcohol, drugs, gambling). She is an expert in qualitative research methods.

Susanna Ronconi: expert in qualitative research, she is a trainer and supervisor in the drug-addiction field as well as HR, urban marginalization and prisons. She has worked in the past as a coordinator of outreach services for drug users and sex workers. She promoted ITARDD- the Italian network of Harm Reduction- with others and is a member of Forum Droghe, for whom she is the Italian delegate for the Civil Society Forum on Drugs in Brussels. Among her latest publications: "*Not only Molecules. Biographic evidence and chemical stereotypes*" in G.Zuffa (editor) *"Cocaine*. *"Controlled Use"* published by Gruppo Abele, 2010; *"Recluse. A look at female differences in Prison* ", published by Ediesse, 2014 (with G.Zuffa); "*Unequal Health*" in Società Informazione, A report on Global Rights, 2016, Ediesse publishing.

Stefano Vecchio: psychiatrist, Director of Public Addiction Department (ASL NA1), Naples. He has been particularly active in public initiatives, meeting, seminars, research and civil society campaigns in favour of HR and has contributed to the instituting of intermediate structures and innovative services such as mobile needle exchanges, work teams for entertainment venues, drop-ins and the project MamaCoca in the city of Naples, obtaining recognition for these services at an institutional level, giving them equal status with other services. The Department he manages is oriented to HR with the logic of self-regulation by the users. He promoted ITARDD, the Italian network of Harm Reduction and is a member of Forum Droghe's board. Among his publications: items *"Remission/Recovery"* in Addiction Atlas, ed. G. Abele, Torino, 2014; *Turning the tide of addiction services in Italy,* "Salute e Territorio", Pacini editore, Pisa, 2014; *Towards a flexible, nomadic and mixed system of drug and addiction services for PWUD*, Medicina delle Dipendenze, vol. 5, n. 19, Cagliari, 2015; *Drugs and addcition services, in* " Lo stato della città" ed monitor, Napoli, 2016

Grazie Zuffa: psychologist, she works mostly in the area of drug use and addiction. She was a Professor of the Psychology of Addiction at the University of Florence, Dept. of Psychology (2000-2006). Currently she manages the research sector of Forum Droghe, her current research regards patterns of use in natural settings. From 1987 until 1994 she was a Senator in the Italian Parliament, involved above all with gender issues, reproductive health and the rights of people incarcerated. She was a member of the Scientific Committee and the National Consultancy Board on drugs, and today is a member of the National Bioethics Committee. Among her most recent publications are: *Cocaine. The controlled use*, Ed Gruppo Abele, 2010; "*Cocaine: towards a self-regulatory model. New developments in Harm Reduction"*, in TransNational Institute- Series on Legislative Reform of Drug Policies, nr. 24, February 2014 (pp.1-12); with Meringolo, P. Petrini, F. (2014) "*Cocaine users and self-regulation mechanisms*" in Drugs and Alcohol Today (Emerald, vol.14, issue 4, pp.194-206), (ISSN: 1745-9265).

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