RUSSIA

Piloting Naloxone for OD Prevention

Foundation Center for Social Development and Information
Executive Summary

Opiate overdose (OD) is a major cause of mortality among drug users, exceeding death from all other causes in many countries. In the United States, it has been the second leading cause of accidental death since 2004, with the vast majority of cases due to accidental opiate overdose. In the European Union, OD is one of the leading causes of death among young people and the top cause of death among people who inject drugs (PWID), exceeding deaths from HIV-related illnesses. In Russia, opiate overdose is the cause of one in every five deaths related to injection drug use with an estimate of over 70,000 deaths per year.

Among treatment choices, Naloxone – a specific opioid receptor antagonist used to reverse an opiate overdose – is highly effective in counteracting overdoses. Costing just under US$1 per dose, Naloxone is highly effective with a success rate nearing 100% for prevention of death during OD. Unlike opiates or other drugs, Naloxone has no abuse potential. As an opioid receptor antagonist, the effect of Naloxone is to reject opiates from the receptors in the brain, negating the effect of the opiate on the drug user. Naloxone has been used for decades in hospitals and by ambulance services around the world to reverse opiate overdose. However, despite low cost and proven effectiveness in preventing deaths, the availability of Naloxone in most countries is limited to medical professionals. Most countries have strict legislative restrictions on Naloxone, a limited number of distribution channels, low awareness of the product among PWID, and/or perceived low profit margins by the private sector pharmacies.

Best practices from many countries indicate that early response to opiate OD is critical in limiting its consequences. Studies show that effectiveness of such response highly depends on such factors as availability of Naloxone, ability of a victim’s companions and co-dependents to recognize an OD and their knowledge of where and when to seek effective help. A number of innovative international overdose death prevention programs include components on educating PWID, their friends, and family members on methods of first aid, correct use of Naloxone and distributing the product to them. Research results show that with proper training, people without formal medical education can correctly identify the signs of overdose and determine the need for Naloxone. This, however, is not always sufficient in addressing longer-term challenges with access to the medication.

Despite the scientific evidence base, Naloxone distribution to reduce opiate overdose deaths is still not commonly included in most public health programs designed for opiate users. In an attempt to address the urgent health need of PWID and with the hope of building the evidence base in this area and increasing the number of programs, globally, that include Naloxone as a regular part of public health programs for opiate users PSI designed a Naloxone project for implementation in Russia in 2008.

NALOXONE

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In order to measure health impact of the program, PSI used the World Health Organization (WHO)-designed disability-adjusted life year (DALY). Each DALY represents a year of productive, healthy life saved. Based on such country-specific statistics as burden of disease and life expectancy, data on PWID and rate of product use and wastage, PSI developed a DALY calculation model that provides accurate estimates of the disease burden reduced in Russia as a result of Naloxone distribution.

Naloxone Disability Adjusted Life Year Generated, Russia

<table>
<thead>
<tr>
<th>Year</th>
<th>DALYs generated</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>1,834</td>
</tr>
<tr>
<td>2010</td>
<td>16,445</td>
</tr>
<tr>
<td>2011</td>
<td>10,904</td>
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C S D I / P S I R U S S I A
From 2008 through 2011, with funding from PSI, PSI Russia had implemented an overdose prevention project aimed at reducing OD-related mortality and identifying effective Naloxone distribution models. After three years of implementation, about 36,000 ampoules of Naloxone were distributed to PWID and their co-dependents, resulting in 29,183 DALYs and 1,238 deaths averted – with an estimated cost of $20 per DALY generated. The project piloted Naloxone distribution models that could be used in countries with highly restrictive legislative and drug control environments.

This report summarizes the three-year program experience and offers replication models for reducing the OD-related deaths in Russia and other countries.

**Opiates In Russia**

Instances of injection drug use have been registered in every region of the Russian Federation (RF). A study conducted by PSI in 2009 among PWID in two Russian cities showed that 21% of PWID had survived an overdose and 74% had witnessed an overdose in the past year. Survivors reported having experienced a case of OD on average twice within their lifetime.¹ The same study showed that 67% of PWID had never heard of Naloxone; 30.6% had heard of it, but never used it; and only 2.4% had previously used it.

Although not legally restricted to the following three channels, accepted practice in Russia is for Naloxone to be kept in supply and administered only through: 1) ambulance service (staffed by a licensed doctor) 2) drug treatment services and 3) toxicology clinics. Doctors administering Naloxone for OD are obligated to then report the overdosing individual so that s/he can be officially registered as a drug user with drug treatment services. Consequently, many PWID fear the resulting stigma and discrimination of revealing their identity and addiction to the authorities and refuse to seek medical help. ⁶ In addition to the three channels cited above, Naloxone is also available at cost of under $1 USD at a small number of municipal and private pharmacies through prescriptions from drug treatment specialists. Supply through this channel is limited because of the prevailing stigma towards PWID and reluctance of pharmacies to sell Naloxone in retail quantities. In addition, low demand from PWID means that pharmacists are often reluctant to stock the product.

**Russia’s Naloxone Program**

Addressing the root causes precluding PWID from using Naloxone in cases of opioid overdose, the program worked to create informed demand for the medication and increase supply through pharmacies offering it at retail prices and medical specialists prescribing it. On the demand side, program activities focused on working with PWID and members of their families (mostly parents); and on supply side – with medical workers (drug treatment specialists, medical toxicologists), pharmacists, and staff of partner organizations.

The program aimed to reduce overdose deaths among PWID through:

- Improving awareness among PWID about what to do in case of overdose
- Increasing informed demand for Naloxone among PWID
- Facilitating Naloxone supply for PWID and family members who had been trained on OD prevention
- Creating an enabling environment for OD prevention programs, including Naloxone supply
Program Models

Based on the context of each of the implementation sites (existing relationships with the authorities), changing political and legislative environment in Russia, drugs consumed and a variety of other variables outside of the control of the project team, PSI Russia designed and piloted three product distribution models. Depending on program priorities, resources available and existing relationships with and among stakeholders, each of these models can be replicated in similar contexts outside Russia.

Model One: Free Distribution
Model Two: Sustainable supply through Private Pharmacies and Drug Treatment Clinics
Model Three: Comprehensive OD Prevention Model

Targeting two sites, the cities of St. Petersburg and Yekaterinburg, the project worked through:

- Nine peer educators (former PWID) responsible for conducting outreach with PWID
- Three drug treatment specialists/narcologists who issued prescriptions for Naloxone and provided trainings on identifying signs and symptoms of OD and methods of addressing them (cardiopulmonary resuscitation and Naloxone) with PWID and members of their families
- Two trained program managers liaised with 16 pharmacies conducting mini-trainings and roundtable discussions with pharmacy staff and owners

After three years of implementation, the project built PWID’s willingness to pay for Naloxone in St. Petersburg, with PWID participating in focus groups at the end of the project reporting that they were willing to buy Naloxone for 100% of the retail cost. In Yekaterinburg, PWID were willing to pay 50% of the cost.

The number of pharmacies that sell Naloxone at retail prices in Yekaterinburg increased from two to 12.

RESULTS

20,000 PWID reached with inter-personal communication (IPC) activities (outreach, peer education, telephone hot line)
29.5% PWID who used Naloxone last year*
72.4% PWID who know that a Naloxone injection should be administered in case of an OD*
83.5% PWID who know how to provide first aid in case of an OD*

9,000 PWID and 715 co-dependants trained on providing first aid and using Naloxone in case of OD
35,794 ampoules of Naloxone distributed
9 drug treatment specialists trained
8,000 PWID referred to HIV prevention or drug treatment services (HIV/STI counseling and testing, TB counseling, detoxification, etc.)

*data from the end-line survey
Model 1: Free Distribution

In this implementation model, priority is given to saving lives if PWID and reaching high health impact within a short period of time. It was implemented in Yekaterinburg. Partnering with a local organization of PWID in remission, the program focused on creating awareness of the OD and methods of preventing it, building up demand for Naloxone. Partners focused on reaching PWID with inter-personal communication (IPC) during outreach, individual and group mini-training sessions, using information, education and communication (IEC) materials and on distributing the ampoules of Naloxone among PWID free of charge.

<table>
<thead>
<tr>
<th>NGO Staff</th>
<th>Outreach Worker</th>
<th>PWID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtain prescription from drug treatment specialist</td>
<td>Engages PWID as clients</td>
<td>Get peer counseling</td>
</tr>
<tr>
<td>Procure Naloxone from pharmacies</td>
<td>Provides peer counseling and mini trainings for PWID on OD prevention</td>
<td>Participate in the training on first aid</td>
</tr>
<tr>
<td></td>
<td>Distributes Naloxone and IEC materials</td>
<td>Get Naloxone</td>
</tr>
</tbody>
</table>

9,922 DALYs (34%) produced by the project were generated through this model.

LESSONS LEARNED

Audience centered approaches to development of communication strategies are critical to utilization

Building demand for Naloxone, even when it is distributed free of charge, requires targeted communication tools. Initially, materials developed by the program did not consider special needs of the PWID. Based on feedback from clients and a marketing planning exercise, the program changed format and content of the IEC materials, increasing the relevance among PWID. For example, original program flyers were sized at A5 and were marked “for PWID.” Based on complaints from the clients about the difficulties with carrying the large sheets and the unnecessary police attention that they often gathered carrying them, program staff designed a small brochure (size A6) and labeled it “for individuals who are close to PWID.”

“Key Influencers” within the PWID community can be an important channel

Program experience shows that some of the outreach workers started identifying “key influencers” – natural leaders among the PWID with limited exposure to the program, trained these individuals as peer educators and gave them product in bulk to distribute further within their networks. Follow up focus group discussions and data verification demonstrated that, while these numbers are very low (about 0.1% of the total Naloxone distribution), this channel was very effective in increasing the awareness of the OD and Naloxone among PWID.
<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
<th>Recommendations</th>
</tr>
</thead>
</table>
| ▪ Direct services for PWID  
  ▪ It’s possible to bring the intervention to scale within a short period of time  
  ▪ It’s not resource intensive | ▪ It’s a short term fix because NGOs cannot always be where someone needs Naloxone when they need it, no sustainable supply  
  ▪ Did not create linkages to sustainable supply of Naloxone  
  ▪ In countries like Russia, may be deemed illegal because Naloxone is only permitted to be distributed by key personnel (medical professionals, pharmacy, etc.)  
  ▪ Need to constantly monitor shelf life of the product | ▪ This model can be implemented in countries where availability of Naloxone is not regulated by medical prescriptions  
  ▪ It can also be recommended for programs prioritizing immediate health impact (i.e. lives saved) and as a first step of building demand for the products  
  ▪ Would be stronger if demand creation and product knowledge efforts over the short term are combined with longer term linkages with sustainable supply chains for Naloxone |

*Model 1 can be implemented as a stand-alone intervention and as a first step of Model 2 below. While it focuses on building demand for the product among the PWID, Model 2 includes extensive work with supply side.*
Model 2: Sustainable Supply through Private Pharmacies and Drug Treatment Clinics

This model focuses on involving private sector pharmacies and drug treatment clinics in providing Naloxone and building PWID’s demand and willingness to pay for the product over the life of the program. This can be done through a combination of free of charge and subsidized distribution. This model was piloted in St. Petersburg where two program partners had strong connections with the municipal medical institutions.

**Drug Treatment Clinics**
- Include OD prevention and management into regular counseling sessions
- Prescribe Naloxone
- Provide coupons or vouchers for getting Naloxone from the private pharmacies (for subsidized distribution)

**PWID + Co-dependents**
- Registering with the drug treatment center
- Attending regular consultations
- Accessing Naloxone either from private pharmacies or drug treatment centers

**Pharmacies**
- Sell individual ampoules of Naloxone at retail prices
- Provide Naloxone to PWID based on coupons or vouchers (for subsidized vouchers)

**NGOs**
- Provide trainings for drug treatment specialists on OD prevention and motivate them to prescribe Naloxone
- Provide trainings for pharmacists on OD prevention and stigma reduction
- Conduct outreach and IPC with PWID building demand for drug treatment services and the product
- Train narcologists on use of Naloxone

16,342 DALYs (56%) produced by the project were generated through this model.

While both partners started with building awareness of the OD and demand for Naloxone among PWID, they gradually expanded intervention to include work with the pharmacies and narcology centers. One of the partners, Fund Humanitarian Action, focused on strengthening relationships with the municipal medical institutions. Faith-based organization Diakonia, the second partner of the program, focused on working with family members of PWID, establishing support groups for mothers and providing trainings on OD prevention.
LESSONS LEARNED

*Narcologists are an important target group and should be targeted early with a comprehensive BCC strategy*

Narcologists, often being a primary point of contact for PWID, are unaware of the methods of first aid during an OD. While they rarely have an opportunity to provide first aid or administer Naloxone injection, they are well positioned to provide consultation on Naloxone use to the PWID who are at risk of an overdose. This lesson was learned by the end of the project. However, the trainings conducted were highly effective and well received by the specialists.

*Working with family members of PWID can be an effective strategy for engaging private sector pharmacies*

Because of the low cost and small profit margin of the product, pharmacies are reluctant to stock the product and do not educate their staff on its use. Moreover, stigma towards PWID and potential impact of such clients on business preclude pharmacies from actively engaging in distribution of Naloxone even when they choose to stock it. Working with family members of PWID on building demand for Naloxone proved an effective measure to engage pharmacies and ensure that the product is available through private sector. Pharmacies were much more willing to fill a prescription and provide consultations when approached by mothers of PWID as opposed to individuals using drugs.

*The life saving properties of Naloxone are an effective entry point with pharmacists*

Approaching pharmacies with a proposal to stock Naloxone was much more successful when the program staff emphasized the importance of saving lives, as opposed to beginning the conversation with the product. Pharmacists were much more open to discussing their role in Naloxone distribution as part of their social contribution but were very suspicious of commercial product promotion.

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
<th>Recommendations</th>
</tr>
</thead>
</table>
| ▪ Has potential for sustainability  
▪ Legally acceptable | ▪ Takes time to establish provider networks, change behavior and generate demand  
▪ Requires extensive work with pharmacies and narcological clinics  
▪ Initially poses challenges for reach and scale because of the initially low uptake  
▪ Does not solve the problem of PWID's reluctance to get registered with the narcology clinics  
▪ Involves intensive BCC with family members | ▪ Longer (up to a year) start-up period that would allow for establishing relationships with the key stakeholders, pharmacies and implement communication strategies with family members  
▪ Engaging local partners with existing relationships with PWID, work through FBOs that have trust of PWID family members and can establish support groups  
▪ Short term supply from FBOs/NGOs could improve demand while supply side structures are being developed |
Model 3: Comprehensive OD Prevention Model

By the last year of the project, PSI Russia integrated an OD component into the framework of a larger USAID-funded HIV prevention program and began piloting a model involving all stakeholders interacting with PWID, introducing distribution of Naloxone into existing scopes of work of each of the parties involved. Implemented in St. Petersburg in the later part of the Year 3 of the project, this model gradually evolved based on the experiences of the project and a larger USAID-funded HIV-prevention program, which focused on creating a continuum of various healthcare services for PWID.

Although this model generated 2,918 DALYs (10%) within this project, it received a lot of interest and recognition from the government stakeholders and donors and will continue to function as a component of the Recommended Package of Services for injection drug use (RPS-IDU).
LESSONS LEARNED

A comprehensive program offers a broader range of access points for OD prevention

Program experience shows that in order to achieve involvement of multiple stakeholders, OD prevention should be implemented as a component of a larger comprehensive HIV-prevention program. Moreover, because effective coordination and monitoring of all program activities requires involvement of authorities at the highest level, building of this model requires a minimum of three years. However, this model is more effective in expanding the access to product for PWID and co-dependents, and illuminates the requirement of being registered as a drug user with the government.

Provider behavior change on drug addiction and stigma reduction is critical to engagement of healthcare professionals

Medical specialists from other fields (HIV, TB, primary healthcare, etc.) demonstrated interest in getting involved in saving lives of their patients who are at risk of OD. This commitment, however, can be secured only through interventions aimed at provider behavior change on drug addiction and stigma reduction.

Carefully managing initial promotional product distribution with longer term sustainability is critical

The distribution system of the product needs to be clearly thought out. Most effective ways may include a combination of free distribution at the initial stages of the program and introduction of the subsidies in the long run. These stages, however, must be carefully managed. In one of the program sites, PWID refused to use pharmacy channels because they were convinced that the product will continue being available free of charge through NGO outreach workers.

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combines direct services provision and builds long-term sustainability</td>
<td>Is resource intensive, requires a minimum of three years to start up period</td>
<td>It is important to build a network of committed service providers before referring clients to it, which may result in longer start-up period but help the system gain sustainability in the long term</td>
</tr>
<tr>
<td>Emphasized ownership of government medical facilities from the beginning</td>
<td>Depends on relationships and links between multiple stakeholders</td>
<td>In order to be able to monitor program trends and effectiveness, development of a comprehensive M&amp;E system and a comprehensive program mapping should be conducted in the beginning of the program with necessary adjustments after the start up period once the partners are determined</td>
</tr>
<tr>
<td>Supports private sector access to Naloxone, therefore addressing concerns of PWID related stigma</td>
<td>Requires careful consideration of the M&amp;E needs</td>
<td>It’s important to consider the impact of short term free distribution on longer term sustainable supply</td>
</tr>
<tr>
<td>Expands numbers of points of access to the product for PWID</td>
<td>Is legally acceptable in the context of Russia</td>
<td></td>
</tr>
<tr>
<td>Is legally acceptable in the context of Russia</td>
<td>Solves the issue of registration as a drug user</td>
<td></td>
</tr>
<tr>
<td>Solves the issue of registration as a drug user</td>
<td>Offers multiple incentives for PWID</td>
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</tbody>
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"It’s important to build a network of committed service providers before referring clients to it, which may result in longer start-up period but help the system gain sustainability in the long term."
Key Indicators to Measure Performance and Progress

For the pilot project, data gathered by outreach workers was plugged into a monitoring information system (MIS) to produce regular reports on:

- Number of Naloxone ampoules distributed
- Number of PWID reached with IPC interventions (outreach, peer education, etc.)
- Number of PWID seeking HIV prevention or drug related services (HIV testing, referrals)

This allowed for further analysis, which produced information on program trends: quantities of ampoules distributed per person (minimum, maximum and average); number and frequency of repeated requests for refills by project clients who volunteered to distribute the ampoules among their friends and acquaintances; and monthly changes in client flow and project staff workload.

This data was also used to calculate health impact of the project based on the DALY model.

In addition, the project used a behavioral survey administered on a respondent-driven sample of PWID in the two project sites. The survey provided data necessary to determine immediate project outcomes featured throughout this report.

Distribution of Naloxone Per Project Year

The project gradually increased amount of product distribution as more channels were established in Y2. In year 3, the project focused on building PWID’s willingness to pay and tried to reduce the numbers of naloxone ampoules distributed free of charge, allowing private sector pharmacies to start filling the void in supply side.
Conclusion

The three year project provided a wealth of information and lessons learned for PSI Russia and PSI at large. While having produced 29,183 DALYS and saved more than 1,200 lives, it helped to establish positive dialogue between PWID and their family members, representatives of the official medical establishments, NGOs and private sector. Most importantly, it laid the groundwork for implementation of a sustainable distribution model described as Model 3 above. By the end of the project, in 2011, PSI Russia secured commitment of USAID, funder of a five-year program focusing on addressing HIV prevention needs of most at risk populations (MARPs), to include OD prevention and Naloxone distribution into recommended package of services for Injecting Drug Use (RPS-IDU). The Model 3 is currently being introduced in three new sites and is expected to be scaled up and replicated in other Russian regions.

Experience of the project shows that OD prevention programs can be implemented at scale even in such heavily regulated and harsh environments as Russia. This leaves us with confidence that models described in this document can be replicated in other countries as well.

END NOTES


6. In Russia, PWID presenting to health authorities must be registered by the drug treatment service and the police which tremendously decreases the chances for this person to get a job or enter an educational establishment.

** Detailed information on the program activities and targets reached is available in the Program Final Report.

*** More detailed recommendations for replication of the models in the context of Russia is available in the Program Evaluation Report (in Russian).