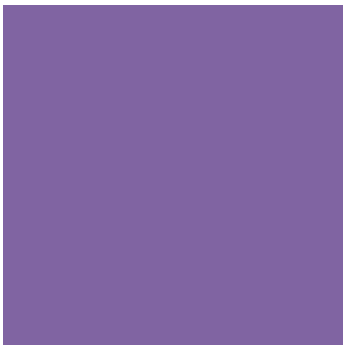

Naloxone

”Naloxone is a great medicine that all people who use drugs should carry in their pockets”

Irma Kirtadze

August 2012

Foreword

This report has been prepared within the framework of project “Overdose: Policy Development, Awareness and Prevention”, implemented by New Vector (Akhali Vektori) NGO with financial support of Open Society – Georgia fund.

The proposals and conclusions, presented in the report, belong solely to the author and can differ from the fund’s position.

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Introduction

Drug use in Georgia is a quickly changeable and diverse problem, which is clearly reflected in the annual national drug situation reports (J. Javakhishvili et al, 2010). Injecting use of opioids has become widely spread over the last two decades (Zabransky, T. et all, 2012), bringing the opioid overdose problem to the forefront. Yet, there are no general statistical indicators of drug overdose death in the country. Registration of drug overdose deaths resumed at the Forensic Expertise Bureau under the Ministry of Justice only in 2008 and only in Tbilisi. Since 2008 throughout the following years the death rate ranged between 15 and 39 cases per year, while the cumulative rate of the period from 2008 till 2011 was 54 (J. Javakhishvili et al., 2011; Georgian Harm Reduction Network, 2011).

In 2011 Georgian Harm Reduction Network conducted a study (Factors Influencing Risky Behavior of Drug Abusers, Georgian Harm Reduction Network, 2011) aimed at scrutinizing the opioid overdose problems. The Study showed that 42.1% of respondents witnessed at least one overdose case during the last 12 months, while 26.7% - during the last 6 months. The age of a majority of patients, who experienced overdose, ranges between 30 and 35 years. The study results clearly show that opioid overdose is a crucial problem in Georgia and that measures need to be taken to minimize drug overdose deaths.

Georgia's drug legislation pertaining to the problem of overdose caused by the use of illicit drugs has been also scrutinized within the framework of the project (Georgian Legislation Analysis, Harm Reduction Network, 2011). The research threw light to the legal barriers that condition low emergency care appealability in case of opioid overdose. One of the barriers is the emergency team's obligation to report to the police of all overdose cases. The issue is regulated by: joint order #1244-278/n of October 24, 2006 by the Minister of Interior Affairs and the Minister of Labor, Health and Social Affairs; Order #239/N of December 5, 2000 by the Minister of Labor, Health and Social Affairs and other internal or interagency verbal instructions. These regulations oblige health professionals to report to the police about "presumptive drug intoxication case, when a patient is unconscious".

This highlights importance of opioid overdose and death prevention for public health. The availability and accessibility of "life saving medicine" – Naloxone - acquires special importance in this light and justifies the development of the "Naloxone" study.

Aim of the study

The main aim of the study is development of recommendations that will be used by harm reduction programs and will help them to reduce opioid overdose deaths. To achieve this purpose, the study sets the following objectives:

- To collect evidence based information on Naloxone and its use practices;
- To present facts, problems and practices used by community members and health professionals in opioid overdose cases;
- To study the existing practices and regulations impeding overdose prevention.

The study focuses on the following issues:

- ❖ Naloxone's pharmaceutical characteristics;
- ❖ Accessibility of Naloxone to people who use (PWU) opioids;
- ❖ Policy of pharmaceutical firms on Naloxone distribution through drugstore chains;
- ❖ Policy of emergency services and ambulance in relation to opioid overdose cases;
- ❖ Harm that use of Naloxone without doctor's prescription can cause to human health and life;
- ❖ International practice use of Naloxone with and without doctor's prescription;
- ❖ Policy of insurance companies regarding insurance of injecting drug users and opioid overdose cases.

Study methodology

Qualitative approach was chosen for the study that was conducted in July 2012, since survey purposes required conducting an in-depth study. Mapping and further collection of information through the work with focus groups and individual interviews were planned. Qualitative information was processed using thematic analysis by applying qualitative information analyzer software NVivo 9.

There is no standard formula for establishing of sample size necessary for conducing a study based on the qualitative method. As a rule, researchers rely on existing experience. The number of in-depth interviews or focus groups depends on whether the obtained information can give the researchers an opportunity for drawing conclusions.

The active phase of the study was preceded by so-called "mapping" during which sources of information valuable for the study were identified and tactic of work with them was defined.

The sources of information:

- ❖ Internet resources;
- ❖ People who use drugs (PWUD);
- ❖ Pharmaceutical companies;
- ❖ Insurance companies;
- ❖ Physicians (emergency care, hospital physicians and addiction specialists).

Information retrieval from reliable sources was conducted via the internet using the following resources:

- ❖ http://who.int
- ❖ http://www.matsne.gov.ge/
- ❖ http://www.ncbi.nlm.nih.gov/
- ❖ https://www.google.com/

Two focus groups (N=10) were planned and implemented with participation of PWUDs, who were recruited for the study with help of New Vector NGO. No financial incentives were offered for participation in the study and as compensation of time.

Representatives of five pharmacological and six insurance companies have been interviewed alongside with informal interviewing of six physicians (including cardiologists, resuscitation specialists, emergency care specialists and addiction specialists) and representatives of the Regulation Agency for Medical Activities and the newly established Emergency Situation Management Center 112.

No general study tool (interview guides) was used. Instead different unstructured open-ended questionnaires were applied for different respondents that covered the themes of concern for the study.

Ethical aspects of the study

The study protocol and corresponding documentation were examined and approved by Maternal and Child Care Union (registered by the US Department of Health and Human Services - IRB00006752 Maternal and Child Care Union IRB #1).

The PWUDs participating in the study were familiarized with the informed consent form that included data on study purposes, rights of study participants and confidentiality commitments. Interviews with the focus group members were conducted only with their written consent. Individual and informal (telephone) interviews with other respondents were conducted with their verbal consent. The discussion in the focus group was audio-recorded, while in all other cases, field recording was applied. Audio materials were then transformed into electronic text format for further analysis.

Study results

Information on Naloxone (Narcan) available on the Internet

Information on Naloxone and Narcan in Georgian has been retrieved from the Internet via Google. The system retrieved 819 information sources about Naloxone and 798 sources about Narcan. The retrieved webpages contained information posted by pharmacological companies, forums, blogs, electronic medical journals and Georgian medical search systems. The sources provide for medicine description (pharmacological group, pharmacokinetics, production form, indications and contraindication, side effects and dosage), case studies, recommendations on how to behave in case of opioid overdose, etc.

We considered it logical to search information by entering “first aid in case of overdose” phrase in Georgia and Google responded with 328 sources. More or less interesting and meaningful information was available mainly in the first three pages.

A similar search on the webpage of the National Drug Agency (http://moh.itdc.ge/) yielded a zero result on Narcan and only 2 results on Naloxone (Figure #1).
According to the available information, Naloxone produced in Poland was re-registered in 2010 and its registration term expires in April 2015.

Figure#1

ნაპოვნია 2 ჩანაწერი — ერთ გვერდზე აჩვენე: 20 ჩანაწერი 1

რეგისტრაციის ნომერი	სავაჭრო დასახელება (ქართ)	სავაჭრო დასახელება (ინგლ)	მწარმოებელი ქვეყანა	რეგისტრაციის თარიღი	მოქმედების ვადა
#r-002122	ნალოქსონი	NALOXON	Poland	26.04.2010	26.04.2015
წს #რ 000265	ნალოქსონი	Naloxon	Poland	16.05.2005	16.05.2010

ნაპოვნია 2 ჩანაწერი — აქტიური — გაუქმებული — ვადა გასდის ორ თვეში — ერთ გვერდზე აჩვენე: 20 ჩანაწერი 1

According to the WHO Guidelines (WHO, 2009), Naloxone is a non-selective, short-acting opioid receptor antagonist that has a long clinical history of successful use for the treatment of overdose. It is an effective antidote for overdoses of short-acting opioid such as heroin.

According to the Guidelines, in managing opioid overdoses, the primary concern should always be respiration and oxygenation.

Typically, adequate respiration will resume within 30 seconds of Naloxone administration. According to WHO the ideal dose of Naloxone is one that improves ventilation without inducing withdrawal. It also indicates that it is better to err on the side of too high rather than too low a dose. A standard dose for the treatment of suspected heroin overdose is 0.4g intramuscularly or 0.8g subcutaneously, repeated 2 minutes later, if necessary.

Initial use of doses of Naloxone that are too high (>2 mg) can induce severe withdrawal, with the risk of vomiting and aspiration; very high doses (>10 mg) may even be life threatening as it may cause vomiting, nausea, tremor and hyperventilation. Overdoses of long-acting opioids are more difficult to manage. In this situation, the duration of sedation will outlast the effects of Naloxone. The safest method of treating long-acting opioid overdose is likely to be ventilation, if available. Death can occur if there is unnoticed interruption to the Naloxone infusion or if the patient wakes up and discharges himself/herself from medical care. Ideally, patients should be observed for 2 hours after Naloxone administration before they are discharged. The guidelines also note that the use of Naloxone by non-medical personnel is not without risks (van Dorp EL., 2007), and may even be illegal in some countries (WHO 2009).

In some countries, prefilled Naloxone syringes are distributed to patients and family members, in combination with training. According to the WHO Guidelines, evaluation of such distribution systems has been positive, and Naloxone distribution is likely to be an affordable approach to the prevention of opioid overdose, particularly where inexpensive prefilled syringes are available.

In the United States Naloxone is on the list of medications subject to physician's prescription. Similar to other drugs to be administered by doctors only, the non-prescribed use of Naloxone is illegal and punishable. Yet three states (Connecticut, New York and New Mexico) managed to bypass the law and make an exception (lift the liability) for cases when Naloxone may save a life. This approach works well and Naloxone is widely distributed in local programs, accompanied with training in use practices.

The WHO Guidelines discuss only intravenous (IV) Naloxone, saying nothing about the intranasal (IN) form of the drug that is mentioned in 109 articles searched with the PubMed

database (annex 1). Numerous randomized studies evaluating the efficiency of intravenous, intramuscular and/or intranasal Naloxone show that the use of IN Naloxone is more justified as a pre-hospital treatment (on-site) to gain time before professional medical assistance becomes available. Effects of the intranasal Naloxone show later than those of intravenous or even intramuscular Naloxone. Discussions are still ongoing about wide use of IN Naloxone, though its apparent advantages include fast, easy, noninvasive and no-risk administration (with minimum probability of needle-stick infections). Studies of intranasal Naloxone continue, and the US clinical trials database also contains a reference to a clinical trial of Naloxone pharmacokinetics (http://clinicaltrials.gov/ct2/show/NCT01622504). Programs implying the use of IN Naloxone gradually emerge in the United States and are currently available in the states of New-York, New-Mexico, Connecticut, Massachusetts, and North Carolina. Physicians administer intranasal Naloxone to patients facing the risk of overdose. (http://intranasal.net/OpiateOverdose/default.htm).

Information received from IDU focus-group

There were two focus-groups, with a total of 10 participants with average age of 34.7 (ranging from 27 to 53, std=7.4); the average drug-use period was 9.9 years (ranging from 2 to 23 years, std=5.8). Four participants had never been overdosed, whereas others had minimum one and maximum 3 overdoses. Absolutely all participants had ever seen somebody overdosed at least twice, six participants said they had seen overdoses ”many times” or ’numerously’, which finally was evaluated together with the participants as more than 10 overdoses.

All the participants (N=10) had heard about Narcan and 7 knew about Naloxone, and discovered that was one and the same drug during the focus group discussion. Two participants in the group had some medical experience: one was a medical university graduate and the other one had a parent who was an addiction doctor, so those two had more and better information about first aid for drug overdose.

When asked what they did upon seeing a person suffering from overdose, respondents gave diverse answers: salt water injection, artificial respiration, external cardiac massage, beating, pouring cold water, bloodletting and Naloxone injection. Only one of 10 respondents had Naloxone use experience, and he described it as follows:

”Naloxone is a great medicine that all drug users should carry in their pockets. I’ve got it at home and when I saw an overdose I called my mother. Before this I did artificial respiration and then I needed to do Naloxone too. So I did everything very calmly without being nervous at all”.

Respondents gave the following reasons of not using Naloxone:

- Lack of information about the medicine;

”…I didn’t know that Narcan and Naloxone were one and the same drug”;

- Superficial (hearsay) information about the medicine;

"...I surely heard of it, but I never used it, others did";

- Lack of the medicine;

"…I didn't have it at that time (when the overdose occurred), but I knew about Narcan";

- Lack of information about proper use of the medicine;

"…We couldn't get in the vein and I didn't know whether it was ok if we did it intramuscularly;

- Inability to assess overdose adequately;

"…. We didn't need it (Naloxone); we did artificial respiration and then took him to hospital"

"….We beat him up so hard we brought the poor thing round; he had all ribbons broken";

"…We thought we brought him back to consciousness, but then he suddenly felt worse and died".

All participants have experience of use of emergency care services. When asked what they would do on witnessing an overdose case, a majority responded they would call an ambulance after unsuccessful attempt of help;

"…If you can't help on our own, you have to call an ambulance";

"… If I see that I can't help, I'll rush him to hospital even if they put me in jail for 20 years";

Some hesitate and think that the ambulance can only transport a patient to hospital:

"…the country where you call an ambulance and they don't have Naloxone... they always had it in Edika's [Eduard Shevardnadze] time, now they don't. It's the law. You have to warn them beforehand that it's an overdose and they bring it along and a different team arrives… because it is the minister of internal affairs code, it's such law – don't take Narcan along! I saw it lots of times – they came and they didn't have it."

"…If you don't warn them they come only with an ordinary artificial respiration device…"

"… Yes, I just through about it, yes, they do the transfusion and then take them to hospital."

"…Doctors ask: "What's the matter with him?" You say: "The man's sick," and they say: "We don't have any Narcan…""

According to some respondents, if their first aid attempts failed, they called the ambulance and left the scene to avoid encountering the police which doctors had to call. They said the police used to prosecute not only the patient, but also people who were with him. However, certain changes have become evident lately and doctors don't call the police because of overdose.

"… They haven't been calling (the police) lately."

"…Last time they didn't call the police... The election campaign is on, so they don't call the police... Do they hope I'll cast my ballot for them?"

"…They haven't been calling lately, during the last month."

"… It depends on doctor … The doctor was a brick. He told the police he couldn't promise that the patient wouldn't die on the way if they took him, so the police left us alone and went away."

"… So what, they would get him the next day anyway. Remember, I told about the man, whom we nearly lost. We called the ambulance and they made adrenaline injections three times and then revived him with electric shock? So no police arrived then, but they found him the next day and fined him with GEL 2000."

None of the respondents has ever tried to buy Naloxone or Narcan in a drugstore.

"…Is it available?"

"…I think it's impossible to buy it."

"…By the way, I never thought of buying it."

None of the participants had experience of using services of the newly established Emergency Situation Management Center (112).

Information obtained from pharmacological companies

The study involved five pharmacological companies: PSP, Aversi GeoPharma, GPC, ABC Pharmacia and Gea. The companies have a well-developed drugstore chains in Georgia, known under the names of: GPC, PSP, Pharmadepo, Pharmacenter, Narinjisperi Aptiaki (Orange Pharmacy), Tsiteli "A" (Red "A") and Gea Pharmacy.

Gea LLC is the only importer of Naloxone in Georgia, responsible for its import and registration. Other chains buy the medicine at the domestic market and sell it almost at an identical price, ranging between GEL 3.19 and 3.22 per 0.4 mg/ml ampoule. We experimentally purchased two Naloxone ampoules in each drugstore except the PSP's one, where they did not have Naloxone. In all other drugstores it was available without the need to produce any medical certificate, prescription or some other documents.

We discussed in detail the origin of the medicine with Gea LLC representatives, who explained that their company cooperates with pharmaceutical companies in Poland, which makes it easy for Gea to import Polish medicines in Georgia. It was noted that Naloxone produced by Ukrainian company Darnitsa used to be imported in Georgia several years ago. The price of the medicine was much lower (GEL 7 per 10 ampoules) than that of the Polish drug. Unfortunately, the Gea representatives did not know why Darnitsa's medicine was unavailable in Georgia, but they noted that Naloxone sales were stable without any growths or declines. When asked

whether Gea would be interested in importing some alternative forms of Naloxone, for example intranasal, company representatives responded that intranasal Naloxone was unavailable in Poland. Yet, they said, if it was registered in any other country and we could prove that it was necessary, the company could consider importing and registering the medicine in Georgia after a thorough assessment of anticipated expenses and profits. They also noted that the new medicine was rather expensive and the alternative form would be simply a luxury. We eventually concluded that Gea representatives did not see any prospects of selling intranasal Naloxone in Georgia.

According to the Regulation Agency for Medical Activities, any individual or legal entity is entitled to import and register medicines in Georgia in compliance with corresponding procedures, regulated by Law of Georgia "On Drugs and Pharmaceutical Activities".

Article 11^2 of this law categorizes pharmaceutical products for advertising or retail purposes as follows:

a) First group: pharmaceutical products subject to special control;

b) Second group: pharmaceutical products that can cause a serious harm to human health and life if used inappropriately and that can be administered by prescription only;

c) Third group: pharmaceutical products that can be used by directions without any prescription.

Under the law, the Minister shall make a list of medicines of the first and third groups. The third group shall be composed based on international experience and shall automatically include all medicines available in the Georgian market, except for those referred to the first and second groups.

Upon the registration, pharmaceutical products are included into the Agency's registry with indication of the registration number, interested person, producer country, trade name, international nonproprietary name (if any), form, dose, concentration (when appropriate), date and period of registration as well as electronic image of packaging and labeling. Registry's public documents and information are accessible through the internet.

There is no need to register repeatedly the pharmaceutical products that already authorized for use in Georgia only because they are imported in a new package or with a new labeling. Such products can be imported based on the legal notice procedure with provision of the following information:

a) Authorized Georgian version and original version of directions for use, as established by the ministry;

b) Electronic image of medicine's package and labeling;

c) Certificate issued by an entity authorized to sell the pharmaceutical product in a corresponding country, confirming that a corresponding foreign or international regulatory body for pharmaceutical products permitted the sale of the pharmaceutical product with this

package and labeling in the market under its jurisdiction. Identification information of the entity having the right to sell the product shall be attached to the certificate;

d) Unique (authorization) number of pharmaceutical product's permit in the corresponding market.

Upon receiving the notice, the Agency shall verify information provided by the interested person. In case of reasoned denial of importing already authorized medicine in Georgia with new package and labeling, the Agency shall notify the interested person in writing. Lack of a response from the Agency shall be automatically regarded as permission to import a medicine, already authorized in Georgia, using a new package and labeling. If the Agency permits import of a pharmaceutical product already authorized in Georgia with new packaging and labeling, it shall add the corresponding information to its register within five days after the receipt of the notice.

A pharmaceutical product can be imported in Georgia bypassing two market access regimes (official registration recognition regime and national regime) for the following noncommercial purposes:

a) pre-clinical and clinical research;

b) as a sample for registration;

c) private needs of an individual;

d) demonstration at exhibitions, symposiums, conferences, forums and congresses;

e) re-export;

f) storage in a customs warehouse/terminal and/or transit;

g) as unpacked pharmaceutical product intended for domestic production;

h) humanitaruian purposes in states of emergency (natural disaster, massive damage to the population, epidemics, rare diseases) and in special interests of the state with the ministry's consent.

Information obtained from insurance companies

The study involved six insurance companies: Aldagi BCI, Imedi L, Archimedes Global Georgia, Vienna Insurance Group Irao, GPI Holding and Alpha.

Representatives of all these companies were surprised upon hearing the proposal to insure PWUD. All noted that such insurance products were exceptional and were not included into individual or corporate packages. All admitted that they never received such orders, but promised to clarify whether it was possible to create such products. They underlined that it would depend on calculation of expenses, risks, number of persons to be insured and general profitability. Two companies expressed readiness for negotiations and promised to give an exact

answer after discussing details with their managers. However, later everybody confirmed that first aid in overdose situation or treatment of other relevant cases could not be insured, expenses could not be covered.

"… This (insurance) is impossible. Drug abuse is an offence and no expenses can be recovered in this connection".

"… The law envisages deliberate self-injury and drug abuse is self-injury. This is a violation of law and also a violation of contract terms, so it cannot be financed."

"… Not speaking of drug abuse, if our customer gets injured because of gun mishandling, we won't compensate treatment since the injury was due to carelessness."

"… If one gets run down by a car when crossing a street on a red light, we won't compensate treatment since the injury was due to carelessness."

For example, article 2.2.2 of the corporate insurance agreement of Georgian Harm Reduction Network, listing expenses not compensated by the company, reads as follows:

"Expenses related to treatment of diseases caused by deliberate self-inflicted corporal injuries; expenses related to treatment of diseases caused by cases when ensured person deliberately incurs danger, except when he/she acts this way in order to save other people's lives; expenses related to alcoholism, drug and toxic substance abuse; expenses related to treatment of injuries received when driving under the influence of alcohol, drugs, toxic or psychotropic substances."

Information obtained during individual interviews with physicians

Six physicians, including cardiologists, resuscitation and addiction specialists, have been interviewed. Average clinical experience of the respondents is 10.2 years.

We asked the addiction specialists whether it was advisable to prescribe Naloxone to a patient, who often experienced overdose. Patient gets to an addiction specialist either for outpatient consulting or inpatient treatment; hence, the specialist does not prescribe Naloxone. However, if the specialist deals with frequent overdose cases, he/she can recommend that the patient should have Naloxone along and use it when necessary. Naltrexone, which is an opioid receptor antagonist, is sometimes used for supporting treatment after inpatient detoxication in addiction treatment centers. It gets in contact with all opioid receptors and reverses the effect of both endogenous and exogenous opioids (narcotic analgesics and their substitutes).

Naltrexone has a similar, but longer effect than that of Naloxone (24-48 hours). Naltrexone is prescribed for complex treatment of opioid dependant patients to reverse the effect of opioids. The medicine shall be prescribed only after terminating withdrawal syndrome and shall be taken by patients daily as tablets or capsules.

We asked the emergency care and hospital physicians about routine practice of opioid overdose management and policy of informing the police about overdose cases.

Upon arrival at a corresponding address, the emergency care physician diagnoses a patient and administers a corresponding first aid. As a rule, the physician records patient information (including ID data) and the address, as well as a detailed report of administered aid, including the list of used medicines. Hence, if Naloxone is used, it will be also included into the list of used medicines.

Two emergency care physicians said calls for overdose cases have reduced significantly, but the third physician on the contrary said the number of such calls has increased.

"…The number of such calls has decreased significantly. I haven't encountered overdose cases for months. I can't even remember whether I've got Naloxone in my box";

"… I had one case during the last six months. Three years ago they often called us to Digomi and Vake districts, now they don't";

"… I had six calls for overdose reason during the last six month. Of these, only two were diagnosed to narcotic coma for they don't actually use narcotics, they use some poison… so they were diagnosed to coma of unclear etiology";

Before 2012, upon diagnosing narcotic coma, an emergency care physician had to notify the dispatcher's service, which in its turn notified the police. The practice has changed lately and physicians do not have this obligation any more. Physicians do not know which law regulates this practice, but all admit that there was such order and that physicians who broke it, risked to get in the focus of police's interest themselves.

"… It's about one year since they stopped informing them (the police); there's a special order that this is not mandatory any more";

"If a patient comes round and runs away, a doctor can be accused of complicity."

"They don't punish drug users any more, they simply register them. They used to impose fines – GEL 500 for the first time, GEL 1500 for repeated commission, and so on."

In case of acute respiratory failure and coma, glucose and/or Naloxone injection shall be made. If the patient emerges from coma after the Naloxone injection, the physician shall verify the diagnosis and record it as narcoma. If the patient fails to emerge from coma despite all efforts, he/she shall be transported to hospital with diagnosis formulated as coma of unknown (unclear, unverified) etiology. If the diagnosis is confirmed as narcoma at hospital, local administration is obliged to report to the police (Georgian Harm Reduction Network,2012).

"You could write before – coma of unknown etiology and that's all. But who dares to do it now? Drug abuse is a crime, so they'll ask you why you concealed information and will accuse you of perpetration."

Naloxone shall not be subject to strict registration regime at hospital. Used ampoules shall not be stored as unlike narcotic substance ampoules. Naloxone shall be registered in the same way as any other medicine.

The emergency care physician shall hand to the hospital manager maps (information on first aid administered) featuring the diagnosis and addresses. The measure is aimed at epidemiological monitoring, timely identification and response in case of an outbreak. A corresponding notice shall be sent to the Epidemiology and Disease Control Service. Maps of overdose cases can be sent to the police in the same way.

"Sometimes you get a call and have no concrete address - we administered assistance in the street too - then you record the address of the place, where the assistance was administered to the patient... If the patients lack IDs, we write down their domiciles as indicated by them or don't write them at all. The Mayor's Office sets a strict requirement that personal numbers and names of all patients should be recorded, as the emergency service covered by state budget."

Representatives of the newly established Emergency Situation Management Center 112 said during an interview that if a citizen calls an ambulance, even if he/she reports that it is a narcoma case, only an emergency team arrives at the scene, i.e. the police are not notified any more. They failed to name the law, regulating this practice, but explained clearly:

"…A citizen will get all necessary assistance".

Findings

Study results show that medical information about Naloxone, Narcan and first aid (artificial respiration and external cardiac massage) is widely available in Georgian internet resources. The information is mainly intended for medical professionals and/or public in general and not for drug abusers.

Injectable Naloxone (ampules) is available at drugstores for individuals and legal entities, of which PWUDs are unaware. A drugstore can run out of supplies or there can be Naloxone shortage in the country for one simple reason – expiration of import permit.

PWUDs have no experience of using services of the newly established Emergency Situation Management Center 112. Consequently, they do not know that if called the emergency team arrives on the scene without informing the police.

Insurance companies do not compensate any expenses related to drug abuse (e.g. cost of medical assistance in case of overdose).

Recommendations

1. **Raise PWUDs awareness about signs of opioid overdose, first aid and Naloxone use**, by publishing detailed and up-to-date information in the internet (texts, images, knowledge evaluation tests). The information should be easy to understand and oriented towards opioid drug users rather than medical personnel or general public. Particular attention should be paid to discussion of widespread 'myths' and their adverse effects with PWUDs.

2. **Develop practical skills among PWUDs for providing first-aid for opioid overdoses.** Active first aider trainings should be conducted for Harm Reduction Program beneficiaries, with further evaluation of the training quality and outcomes.

3. **Improve access to Naloxone** and provide users with correct information on Naloxone, explaining that it is not on the list of strictly controlled and registered drugs and may be bought from any drugstore. In order to improve availability of intranasal Naloxone, one of the harm reduction program coordinators (e.g. the Harm Reduction network) could commit to introduce it to the Georgian market. In parallel, consideration could be given to international practice of administering intranasal Naloxone preventively in patients facing the risk of overdose. This would permit low-threshold programs to legally distribute Naloxone and Naloxone use instructions.

4. **Provide and disseminate information on Emergency Response Service 112.** Information about the newly established service should be provided to users. It would be also advisable to prepare a special training module about the emergency service detailing when and how (e.g. ready-to-use phrases) the medical emergency should be called.

5. **Develop a strategy for working with insurance companies.** In order to provide client-oriented services and develop new products, insurance companies may agree to cooperate and some agreement may be achieved. Consideration should be given to respective international experience, as the insurance companies might refuse to change insurance terms even after future decriminalization of drug use, because of their policy towards unintended (accidental) self-harming.

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