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HIV non-occupational post-exposure prophylaxis in Ukraine

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Сальнікова А., Шевченко М.В. Постконтактна профілактика при непрофесійних контактах із збудником ВІЛ-інфекції в Україні Школа охорони здоров'я, Національний університет «Києво-Могилянська академія», м. Київ, Україна

Introduction

Ukraine belongs to the countries with the highest burden of HIV-infection in Europe [1]. The occurrence of HIV infection cases is stable with insignificant fluctuations [1–3]. According to the estimates, approximately half of all people living with HIV (PLWH) are unaware of their HIV-positive status. Annually, about one third of all identified HIV-positive cases remain out of the medical care. In Ukraine new HIV cases are usually detected on the late clinical stages of HIV infection. More than 50% of people aged 15 years old and older are newly detected in the III-IV clinical stages of HIV infection [3].

Despite the efforts of the national and international stakeholders, HIV/AIDS epidemic is still ongoing and requires effective approaches to accelerate the epidemic response. Nowadays, HIV-infection is not curable, thus, one of the most effective strategies to fight epidemic is prevention. Prevention component plays significant role in the strategy to accelerate HIV/AIDS response globally, including Ukraine. Complex of HIV prevention measures include HIV post-exposure prophylaxis (PEP).

PEP is a complex of actions that includes special medicines intake (antiretroviral therapy) no later than 72 hours after potentially risky exposure to prevent infection. PEP is considered to be an emergency method and used in case of risky professional and non-professional behavior, practices, and actions in regards to HIV infection. PEP is effective prevention method if adequately utilized. In Ukraine PEP is not widely utilized that can be explained by the PEP specificity, episodic use, side effects, low awareness of this prevention strategy, other factors. According to the latest statistics, annually 1,215 persons applied to the medical facilities to obtain PEP, out of them 692 persons had risky non-occupational contacts [4–6]. The highest number of applications for PEP in Ukraine was observed in Kyiv city [5–7].

In Ukraine HIV non-occupational post-exposure prophylaxis (nPEP) has not been thoroughly examined. However, PEP strategy is the important component within the

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HIV response prevention package. More thorough study, adequate use, promotion of nPEP strategy may contribute to the strengthening and improvement of HIV epidemic response, especially considering the prevalent mode of HIV transmission and undiagnosed proportion of PLWH in the country. The goal of the present study is to explore the state of nPEP use through examining expert opinions in Ukraine.

Materials and methods

The study is explorative and has qualitative design. It consists of the desk and empirical parts. The desk part includes literature review and analysis of the existing nPEP practices worldwide. Literature review is conducted based on the international and national literature sources including articles, reports, guidelines, recommendations, statistics, informational bulletins. Empirical part is conducted via in-depth interviews with experts. Geography of empirical part of the study is Kyiv, Ukraine. Eligibility criteria for participants include professional experience in HIV/AIDS area, expertise and/or experience towards nPEP prevention strategy, consent to participate in the study. Snow ball sampling technique and maximum variation principle were used to sample participants. The experts from different areas were involved in the study in order to capture different prospective: providers of nPEP prevention in medical facilities, experts from nongovernmental sector, national public health professionals, international expert (technical assistance). In total, 8 experts were interviewed. The number of participants is attributable to the specificity of the subject and explorative nature of the study. In-depths semi-structural interviews with participants were conducted. The guides for in-depths interviews were developed. Design of the guides reflects the professional experience and expertise of participants. Guides comprise mostly open questions. Guides consist of 5 main domains: 1) experience and expertise of participants towards nPEP; 2) opinions about potential and actual beneficiaries of nPEP, awareness about nPEP as prevention strategy in beneficiaries;

3) algorithm of delivering nPEP (this domain was mostly directed on the providers of the service); 4) linkage between nPEP and HIV pre-exposure prophylaxis (PreP) strategies; 5) further research directions, perspectives of nPEP strategy use development. The interviews were conducted face-to-face. Duration of interviews ranged from 30 minutes to 1 hour. Interviews were conducted in Ukrainian, Russian, English languages to meet the respondent convenience. Results were analyzed and systematized to meet the study tasks and goal.

Study results and discussion

Algorithm of HIV nPEP delivery

Majority of the experts do not mention flaws in the legal framework of nPEP. Experts who directly provide nPEP point out on the volume of information to collect in line with the registration form. International expert notes that bureaucratic component in the HIV field overall may be simplified, however, the volume of relevant forms may be necessary to protect the patients. None of the experts notes significant shortcomings in the nPEP regulation, although the definite stages of the nPEP complex could be improved. Experts agree that on such stages of nPEP as risk assessment and initiation of medical post-exposure prophylaxis (MPEP), additional tool to simplify decision-making process for the medical provider is appropriate. Currently, decision about nPEP initiation is made in line with the information available in the registration form, knowledge and experience of the medical provider in the field of HIV/AIDS, international recommendations and guidelines. Public health expert notes that complementary tool for decision-making for provider would be relevant and convenient, and it has not been created yet perhaps due to the small amount of patients seeking for nPEP prevention.

According to the experts at the stage of MPEP prescription and therapy initiation, antiretroviral drugs are available and accessible for the patients. MPEP medications are provided in specialized medical facilities (facilities that provide medical care services for HIV-positive patients) on a 24-hour basis 7 days per week. All experts point out that in case of delegating nPEP component to other types of medical facilities (given ART delivery delegation to the primary health care chain in the framework of public health reform), the obligatory condition is to ensure continuous access of patients' to the medication within the nPEP complex.

All the experts mention the importance of the adequate MPEP intake phase. Adequate intake of MPEP course, which includes complete course of drug therapy (within 28 days) in line with the doctor's recommendations, may significantly decrease the odds of infection occurrence [8]. None of the experts on the service provider's level notice the failure of nPEP if taken "properly" by the patient.

However, according to the national statistics and experts opinions not all the patients successfully completed drug therapy within the nPEP prevention [5–7]. The most common barrier to the MPEP adherence is drugs side effects.

«Persons to whom nPEP is prescribed are not always responsible... They may have different gastrointestinal disorders and they start missing it (medicine) and the odds of infection to occur increase...». Motivational counseling, social workers involvement in the patients' support process, prescription of the drugs with mild side effects and simpler regimen (for instance, tablet once a day) are highlighted by the experts as the measures to improve adherence to the antiretroviral therapy. Experts on the level of service providers and public health specialists emphasize the importance of the collaborative work of medical and social workers, in particular on the stages of monitoring and evaluation and in the course of the MPEP therapy. Involvement of the social worker may facilitate the patients' adherence to the treatment and other aspects of adequate MPEP intake, thus, contribute to the successful completion of MPEP phase.

«...Counseling should be carried out by the medical worker and social worker towards the medications, side effects, instructions of how to get tested, when to arrive, phone contacts ...».

International expert emphasizes the importance of the adherence and proper completion of MPEP course. On the individual level, non-adherence and/or incomplete course of drug therapy increase the risk of infection occurrence due to the prevention effectiveness reduction; the public health concern is in the risk of the antiretroviral drugs resistance occurrence.

«.. The most important things would be follow-up and adherence. That's the vital thing... If you start taking it (MPEP), you need to complete it in 28 days...».

Another expert view towards adherence of the patient to MPEP is that patient is motivated enough to be committed to the MPEP completion, given person has already applied to the medical facility to obtain the service.

Consumers of HIV nPEP prevention complex

According to the experts, the most common reasons to apply for the nPEP are the risky sexual contacts and contacts with the used syringe/needle. Experts – nPEP service providers note that the significant proportion of the risky sexual contacts accounts for "single", "occasional", "one-time" sexual contacts with non-permanent partners with unknown or positive HIV status: «...often the contact was lost, it was single sexual contact...». At the same time, discordant couples applied to obtain nPEP in "emergency cases" like sexual intercourse without condom or if the condom was damaged. Also, experts notice existence of multiple applications to obtain nPEP from the same persons. The main consumers of the nPEP prevention are represented by the persons from different groups who had risky sexual contact with the partner with unknown or positive HIV status, men having sex with men (MSM), discordant couples, victims of sexual violence, parents of children, who had contact with used syringe or needle. According to the nPEP provider, 70% of all nPEP applications that were received among adults belonged to MSM group, the rest of the cases belonged to different groups. Other expert with nPEP delivery experience indicates that prevalent proportion of received nPEP applications is associated with the sexual contacts with the partner whose HIV status is unknown or positive. A small percent of cases relates to the sexual violence. The expert who works with the children and adolescent population highlights the seasonality of applications – the peak is in spring. The majority of cases

belong to the contact of child with used syringe/needle. The appeal of the adolescent population to receive nPEP is rare, the reasons for that are unknown.

The experts' opinions of nPEP utilization are different. Service providers mention probable underutilization of the prevention strategy, for example, among persons who had risky contact with used injection tools, persons who participated in fights, other risky behavior.

«...There is no guarantee that all emergency cases applied, ..., when HIV infection occurs, especially if the infection transmission cannot be determined, often we consider sexual transmission, but it is not always the case, fights (when "bloody")... it also may be the option to apply for nPEP...».

International expert supports opinion towards the PEP underutilization, besides, expert made focus on HIV antiretroviral medicines being underutilized as a PEP component and overall within HIV treatment: «ARV drugs are underutilized including in post-exposure prevention for sure».

Another expert view on the use of PEP is the lack of necessity "to expand" the prevention strategy at the moment. The expert notes that in case of risky contact, individuals are able to determine the presence of risk and/or find necessary information about medical facility to apply for prevention. According to the expert, nPEP prevention strategy is not a priority at the moment given specificity of the prevention and present challenges/tasks to manage in HIV/AIDS field in the country.

Awareness of nPEP among beneficiaries of service

The majority of experts agreed that awareness of nPEP in population is low. The lack of awareness may act as a barrier to seek for nPEP service. Moreover, adequate use of PEP implies early appeal to initiate MPEP to specialized medical facility, thus, persons not only should be aware about prevention but also know its specificity for early initiation of the drug therapy.

«I think many people do not aware about this prevention existence. They do not even suspect that they may seek for it, read about it, and apply somewhere...».

«.. If information is communicated to the population, they know in which cases and where to apply... if this information is missing, nobody knows...».

Despite the low "overall" nPEP awareness, experts have opposite view towards knowledge of the key populations.

«Those who are at risk, they already have information, their knowledge is good, unfortunately, they do not always practice what they should, but they know. They have more information than the rest of the population.»

"Concentration" of knowledge in key population may be explained with the variety of the programs, projects etc. targeted onto these groups. Majority of experts had common position that basic knowledge and awareness in HIV/AIDS area, especially about prevention component (including PEP) are relevant for the broader audience. Otherwise, persons who do not belong to the key populations may neglect the risk of being HIV infected, consider "being outside the key groups" as a guarantee of not being at risk.

«General population does not consider themselves to be at risk, there are stereotypes and myths that this disease is in risk groups... Therefore, it is very difficult for socially secure people to accept diagnosis, ...».

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In addition, experts on the service providers' level make focus on the lack of awareness of population not only in the nPEP topic, but also in basics of HIV infection prevention. For example, patients still have difficulties in detecting risk of HIV infection:

«.. There are still patients who say: «I was lying nearby and then I found out that my partner has HIV, ..., what risk do I have in percentage...»

The findings of the study indicate that the guidelines of nPEP delivery is absent, in case of application to receive nPEP from the persons, provider collects information in accordance with the registration form approved by the MOH order. For professional HIV risky contact guidelines are developed [9]. According to the expert interviews and studies in different countries guidelines of nPEP delivery may facilitate the nPEP initiation by the medical provider [10] and adequate targeting nPEP prevention [11-14]. The nPEP guidelines in some countries contain tools to effectively implement nPEP and simplify the decision-making process for the medical provider. WHO guidelines include information about potentially risky in terms of HIV infection biological materials and contacts and conditions when initiation of PEP is not recommended [15,16]. Canadian guidelines on HIV pre-exposure prophylaxis and non-occupational post exposure prophylaxis contains tablebased tool to assess the risk of nPEP initiation [17]. CDC Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV provide the algorithm (chart) to assess the risk and feasibility of nPEP initiation [8]. UK Guideline for the use of HIV Post-Exposure Prophylaxis Following Sexual Exposure (PEPSE) includes formula to calculate the risk of potential transmission of HIV infection and interpretation of the results [18].

The challenging phase of nPEP prevention complex is MPEP. Complete course of drug therapy implies 28 days therapy intake in appropriate regimen. Inadequate intake of medicine, including non-adherence and/or interruption of the therapy course issues, may lead to the failure of MPEP and drug resistance. Adherence to antiretroviral therapy (including in PEP component) is widely studied worldwide and described in relevant recommendations [19,20]. In addition, safe behavior in terms of HIV infection during MPEP is the necessary condition of successful nPEP outcome [8]. The social worker role is highlighted by the experts in all the phases of nPEP, especially during MPEP intake phase when social worker acts as an informational and motivational supporter to the patient to be adhere to MPEP in line with the medical worker recommendations and practice safe behavior in the course of therapy intake and further.

According to the findings of the current research and previously conducted studies in different countries, the most common consumers of nPEP are represented by the persons who had risky sexual contact (with partner of unknown or HIV-positive status), MSM group representatives, victims of sexual assault [12,13,21,22]. Nevertheless, nPEP may be considered underutilized strategy in HIV response actions [10,28,29]. Given the prevalence of HIV infection transmission mode

(risky sexual contacts) and undiagnosed proportion of all HIV estimated cases in Ukraine [2,3], nPEP prevention sufficient use, coverage of potential beneficiaries, factors of underutilization are important topics to explore further. The reasons for the possible nPEP underutilization may include the specificity of the prevention, lack of awareness, lack of instruments (guidelines, protocol) to provide prophylaxis [19]. The results of the present study and studies in other countries indicate that nPEP awareness among beneficiaries is low or insufficient [23–29]. However, in line with the present study, awareness about nPEP in key populations may be better than in general population, that may be caused by the various programs and projects directed onto the key populations [30-32]. Representatives of key populations apply for nPEP service more frequently among adult population, that may be associated with both awareness of prevention or more frequent risky behavior practice. Experts point out on the appropriateness to increase knowledge and awareness about prevention in HIV/AIDS area in different populations.

Findings of the present and previous studies demonstrate the existence of cases when same persons appeal to obtain nPEP multiple times [22]. In such cases, if persons regularly practice risky behavior, PreP prevention may be more relevant. Strategy nPEP usually implies emergent cases, single contacts, whereas PreP strategy is recommended in case of "repeated" risky contacts or behavior. Linkage and algorithm of reference between these prevention strategies is important so that to apply the most beneficial and effective strategy. In some countries, PreP component is included in nPEP guidelines [17], in this way contributing to the decisionmaking of provider to target more adequate and beneficial strategy the situation given.

Limitation of the study include restricted area of study (Kyiv city) and limited number of participants. The number of participants may be explained by the specificity of the subject and explorative nature of the study.

Research perspectives

Directions for the further research include: low awareness of nPEP, tools to raise effectiveness in nPEP delivery, beneficiaries, consumers and utilization of nPEP, linkage between nPEP and PreP prevention strategies.

Conclusions

1. According to the study results, in order to increase effectiveness of nPEP delivery it is appropriate to analyze the best practices of nPEP guidelines and design/adapt relevant supplementary tools on different stages of nPEP complex (risk assessment tool, the guidelines to deliver nPEP).

2. According to the experts, the most frequent reasons to apply for the nPEP are risky sexual behavior and contact with used syringe or needle. Prevention strategy nPEP may be underutilized. Utilization and potential beneficiaries of nPEP are the directions for the further study.

3. Study findings demonstrate low or insufficient nPEP awareness in beneficiaries.

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Aim. To assess the state of non-occupational HIV post exposure prophylaxis (nPEP) use in Ukraine through exploring the service delivery algorithm, consumption of service, awareness of beneficiaries.

Methods. The research has explorative and qualitative design. In-depth semi-structural interviews with experts were conducted. For recruitment snowball sampling technique is used. Geography of the study is Kyiv, Ukraine.

Results. Legislative framework of nPEP is established in Ukraine. NPEP is provided in specialized medical facilities with continuous access to the prevention. In order to increase effectiveness in nPEP delivery particular stages of nPEP complex have potential for improvement. Risky sexual behavior and contacts with used syringe or needle are the most common reasons to apply for nPEP. Applications for nPEP include emergency single contacts and cases of multiple appeals from the same persons. Prevention strategy nPEP may be underutilized and require further examination. Awareness of nPEP is considered to be low or insufficient in beneficiaries.

Conclusions. 1) It is recommended to analyze the best practices of nPEP delivery and design/adapt supplementary tools in order to increase effectiveness in service delivery. 2) Prevention strategy nPEP may be underutilized. Utilization and potential beneficiaries of nPEP are the directions for further study. For the nPEP adequate targeting purpose, the linkage between nPEP and PreP prevention strategies ought to be established. 3) Low awareness of nPEP and its factors is the topic for further examination.

Key words: HIV/AIDS, post-exposure prophylaxis, non-occupational contacts.

Мета. Оцінити стан впровадження постконтактної профілактики при непрофесійних контактах із ВІЛ-інфекцією в Україні шляхом вивчення алгоритму надання послуги, споживачів послуги, обізнаності бенефіціарів щодо послуги.

Матеріали та методи. Дослідження має розвідувальний якісний дизайн. Було проведено глибинні напівструктуровані інтерв'ю із експертами. Формування вибірки відбувалось методом доступних випадків. Географія дослідження – м. Київ, Україна.

Результати. Компонент нПКП є врегульованим в Україні. НПКП надається в спеціалізованих медичних закладах, безперервний доступ до профілактики забезпечено. Для підвищення ефективності надання послуги нПКП деякі етапи її реалізації мають потенціал для покращення. За типом контактів найбільша кількість звернень належить небезпечній щодо інфікування ВІЛ статевій поведінці та контактам із використаним шприцем, голкою. Звернення щодо нПКП включають як поодинокі аварійні контакти, так і повторні звернення щодо отримання профілактики від осіб. Профілактичний компонент нПКП може бути «недовикористаною» стратегією й має потенціал для подальшого вивчення. Обізнаність щодо НПКП є низькою або недостатньою серед бенефіціарів.

Висновки. 1) Рекомендовано провести аналіз кращих практик та розробити/адаптувати відповідні допоміжні інструменти з метою підвищення ефективності реалізації комплексу. 2) Профілактичний компонент нПКП може бути «недовикористаною» стратегією. Використання і потенційні бенефіціари нПКП є напрямками для подальшого вивчення. З метою адекватного таргетування послуги, зв'язок та перенаправлення між профілактичними стратегіями нПКП та ПреКП має бути врегульованим. 3) Низька обізнаність щодо нПКП та фактори низької обізнаності є темами для подальшого вивчення.

Ключові слова: ВІЛ/СНІД, постконтактна профілактика, непрофесійні контакти.

Цель. Оценить состояние внедрения постконтактной профилактики при непрофессиональных контактах с возбудителем ВИЧ в Украине путем изучения алгоритма оказания услуги, потребителей услуги, осведомленности бенефициаров об услуге.

Методы. Исследование имеет разведывательный качественный дизайн. Проведены глубинные полуструктурированные интервью с экспертами. Выборка формировалась методом доступных случаев. География проведения исследования – город Киев, Украина.

Результаты. Компонент нПКП урегулирован в Украине. НПКП предоставляется в специализированных медицинских учреждениях, непрерывный доступ к профилактике обеспечен. Для повышения эффективности предоставления услуги нПКП ряд ее этапов имеет потенциал для улучшения. По типу контактов наибольшее количество обращений за нПКП принадлежит рискованному сексуальному поведению относительно инфицирования ВИЧ и контактам с использованным шприцем, иглой. Обращения за нПКП включают как одиночные аварийные контакты, так и повторные обращения за профилактикой. Профилактический компонент нПКП может быть «недоиспользованной» стратегией и имеет потенциал для дальнейшего изучения. Осведомленность о стратегии нПКП низкая или недостаточная среди бенефициаров.



Выводы. 1) Рекомендовано провести анализ лучших практик и разработать/адаптировать соответствующие вспомогательные инструменты с целью улучшения ефективности реализации комплекса. 2) Профилактический компонент нПКП может быть «недоиспользованной» стратегией. Использование и потенциальные бенефициары нПКП – направления для дальнейшего изучения. С целью адекватного таргетирования услуги, связь и перенаправление между профилактическими стратегиями нПКП и ПреКП следует урегулировать. 3) Низкая осведомленность о оПКП и факторы низкой осведомленности являються темой для дальнейшего изучения.

Ключевые слова: ВИЧ/СПИД, постконтактная профилактика, непрофессиональные контакты.

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