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## QUALITY ASSURANCE SEROLOGICAL TESTS

### USING RAPID TEST FOR THE DETECTION OF ANTIBODIES TO HIV

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In this paper analyzed the learning experience and assessment of knowledge and skills of specialists of the health care practice on the use of rapid tests for detection of antibodies to HIV.

**Keywords:** *HIV infection, antibodies to HIV, rapid tests, training, assessment of knowledge and skills.*

Experts WHO, UNAIDS and CDC (US) emphasize that one of the key components control the spread of HIV is to get individual information about the diagnosis as early as possible. In this regard the increasing importance both abroad and in Ukraine, acquire methods for rapid diagnosis with rapid tests (RT) for the detection of antibodies to HIV (anti-HIV) [1, 5].

In health care facilities (HCF) Ukraine RT to detect anti-HIV have been widely used, since 2010, when it was adopted by MOH Ukraine of 21.12.2010 p. №1141 «On approval of testing for HIV quality assurance and research, forms of primary records on testing for HIV, instructions for filling them out "(hereinafter - Order) [2]. According to this document anticipated, primarily consistent application examined at two RT of most risk of HIV infection (HPR) in establishments TB, substance abuse, STI and infection type. The Order also allowed to use a single RT with subsequent confirmation of positive results during the examination of sentinel epidemiological studies NGOs. Given the fact that RT is most often used without HCP specialists skills in the laboratory, in the context of the widespread introduction of rapid HIV diagnostic important to the effectiveness of training and quality control conducted research.

The aim was to assess the effectiveness of approaches to teaching and assessment skills (TAS) specialists of the health care practice that is used VT to detect anti-HIV in their daily practice.

**Materials and Methods** TAS performed using different approaches: input and output survey for training; Remote survey and research using reference materials. As control materials were used standardized lyophilized sera panel, manufacturing NGO "Diagnostic systems" (Russia). The composition of each panel consisted of four samples, 2 of them containing anti-HIV-2 were negative on said marker.

#### **Results and discussion**

The widespread use of RT in HCF and NGOs needs serious monitoring both in quality training to work with this type of diagnostics so and for their use in daily practice. At one time, to the widest introduction of rapid diagnosis in public health practice, developers Order of consciously trying to avoid strict regulation on training professionals working with RT and special permission for their use. In practice, this has meant that today the country is almost no information on the number of professionals and institutions that conduct testing with RT, as well as where and who carried out training and more.

Given the importance of this problem, SI "Institute of Epidemiology and Infectious Diseases. LV Gromashevsky NAMS of Ukraine "has in 2008 started working with ICF" William J. Clinton "on expanding access HPR and vulnerable groups to counseling and testing using RT in medical institutions of Ukraine TB, substance abuse, STI, Profile infection clinics and family medicine. It was

developed a special program that included lectures on epidemiology and diagnosis of HIV infection; basic principles of pre- and post-test counseling; algorithms testing for anti-HIV via VT; driving report and records in accordance with the Order; development of standard operating procedures when using VT; utilization of biological material; approaches to assessing the knowledge and skills of experts on the use of HCF RT. Particular attention was paid to the training of practical work - the training, each participant had to carry out their own research on two types of VT 4-5. The training program is constantly changing and improving; so, in 2014 launched an additional input and output questioning the participants. The purpose of the questionnaire was to determine the level of knowledge of participants on matters of general and special epidemiology and diagnosis of HIV counseling and testing using RT.

Overall, during the 2011-2014 biennium it was conducted 28 training courses, which trained 302 professionals (social workers, medical personnel and medical units HCF prison). The input and output survey in 2014 was attended by 70 people (participants 5 training sessions), including the results improved 87.2% (61 participants). According to the analysis of responses to the questionnaire, the greatest difficulties caused following:

- list of risk factors for HIV infection. For example, participants study indicated no commercial sex as one of the risk factors;
- HPR list of HIV (respondents often do not know that sexual partners of men who have sex with men, also belong to these groups);
- HIV counseling principles;
- HCF list, where you can apply the algorithm with two rapid tests.

In addition, specialist's practical level it was difficult to learn the theoretical and practical aspects of research using RT, namely that a major operating characteristics tests (not distinguish between the concept of sensitivity and specificity), difficulties caused practical application of

algorithms survey VT (confusion final doubtful result inspection and valid outcome studies using RT, etc.).

The widespread introduction of RT to detect anti-HIV HCF Ukraine actualized the problem of quality control studies on the use of these diagnostic products. International experts offer several methodological approaches to assess the level of practical knowledge and skills of professionals and hence the quality of work of the RT, including "blind" retest adopted in accordance with the algorithm in a particular country examination; the use of standardized reference sera panels; by the so-called "dry drop of blood" and direct observation of the process of testing [3]. To some extent, experts evaluate the practical skills of the health care possible through remote survey [4]. The latter approach also was used in the first stage of implementation TAS in 2010 - a questionnaire 24 participants from 12 HCF Dnepropetrovsk region based on a specially designed sheet-questionnaire, which contained photographs of research results RT and test questions designed to assess the knowledge and skills of professionals practical level health care (7 theoretical and practical issues concerning the practice of using RT). Analysis of the results showed that none of the participants answered correctly on all questionnaires (of 67.0% correct). The maximum number of correct answers (13 of 15) was recorded in two of the respondents, with two specialist managed to answer only 6 issues. In the future, we determined effort to develop approaches to assessing the quality of the specialists VT. As you know, during external quality assessment (EQA) research by ELISA using reference material (RM), which usually is a freeze-dried or diluted serum, and is exploring the prescribed order of a diagnostic procedure. As for VT, the use of any RM to assess the quality of work does not always give an opportunity to verify whether the expert assumed errors in their daily practice, or does it right, because the procedure of research of RM is different from the routine practice of RT in HCF or another institution.

The material for the study on the presence of anti-HIV RT using a sample of capillary blood from the finger,

and reproduce such material and the whole procedure of testing of KM impossible. Thus, in terms of assessing the quality of work with RT we can not talk about EQA, as such, ie control routine process of study and evaluation of knowledge and skills, ie the ability to carefully read the instructions, carry out the necessary procedures for the preparation of RM for research and Field evaluate the results. In conducting TAS medical workers KM used as standardized lyophilized panel of blood serum samples. We have prepared detailed instructions on studies using RM, sample panels were encrypted and transferred to the HCF compliance with the cold chain. Piloting program TAS preceded by a training workshop dedicated to the practice of such materials. Research carried out in the Dnipropetrovsk region during July 2011 - January 2012, it was attended by 19 health professionals from 11 HCF region, experience them with RT in an average of 3 years, with the month they spent about 50 inspections for the presence of anti-HIV . In total 18 participants from 19 research results were correct KM (95.0%).

Further to participate in the program were involved 16 health workers who conduct testing for anti-HIV via VT 16 HCF Cherkassy, Poltava and Transcarpathian regions (the study period July - August 2012). Experience with RT professionals averaged one year, and the number of the studies ranged from 20 to 150 per month. According to the given answers, only 14 participants (87.5%) were able to correctly interpret test results RM. In the next stage TAS, held in March 2013, attended by 68 experts HCF and correctional institutions from 11 regions - Donetsk, Dnipropetrovsk, Zhytomyr, Zakarpattia, Ivano-Frankivsk, Kyiv, Luhansk, Mykolaiv, Poltava, Sumy, Kharkiv, with which 20 schools participated in the program again. For the first time in the program attended by health workers 7 prisons and two clinics in general practice - family medicine. Experience with RT participants ranged from 6 months. 2 years number of studies per month - from 5 to 150 tests. In total, 55 participants (80.1%) of 68 were correct, fully answered passport data of the RM. Among the institutions that received the wrong results TB

dispensaries were 4, 3 prisons, Dermatologists and Venereal 1 room, 1 office "Trust". Notably, clinics and specialists of TB clinic, dermatologists and dermatovenerologic office twice participated in the program and made a double error.

The main reasons for errors were:- Violation of preparation technology control panels by the manufacturer;- Violation of the instructions of the VT (making improper buffer, failure time for interpretation of results, etc.);- Incorrect interpretation of (weakly colored test strip was assessed as negative).Overall, during the 2012-2013 biennium. TAS participated in 103 health workers, 87 (84.5%) of them were correct KM research results. When analyzing the results three phases were found TAS inverse relationship between the number of incorrect results and number of tests for a month (the more test, the less errors). The above demonstrates the feasibility of regular monitoring of the quality of the professionals who carry out testing for anti-HIV via VT HCF not only, but also in projects of NGOs.

#### Findings

1. High-quality training and regular testing of knowledge and skills of professionals who use RT in their daily practice is an integral part of getting guaranteed results of testing for antibodies to HIV.

2. In conducting the study, the focus is expedient to give practical skills and interpretation of results using different units.

3. A survey of trainees showed that 87.2% of them improved their knowledge on various aspects of the theory and practice of using RT.

4. Percentage of correct results (84.5%) three stages TAS demonstrates the need for continuous learning and improvement of practical skills of all professionals who carry out testing for HIV antibodies using RT.

Prospects for further research. Despite the widespread use of RT to detect anti-HIV HCF and NGOs, to date, there are no common approaches as to collect information on the use of these diagnostic kits and training to work with them. Urgent need at the national level is to

develop programs and activities of the quality control research using RT.

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#### ОБЕСПЕЧЕНИЕ КАЧЕСТВА СЕРОЛОГИЧЕСКИХ ИССЛЕДОВАНИЙ С ИСПОЛЬЗОВАНИЕМ БЫСТРЫХ ТЕСТОВ ДЛЯ ВЫЯВЛЕНИЯ АНТИТЕЛ К ВИЧ

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В работе проанализирован опыт обучения и оценки знаний и навыков специалистов практического звена здравоохранения по вопросам применения быстрых тестов для выявления антител к ВИЧ.

**Ключевые слова:** ВИЧ-инфекция, антитела к ВИЧ, быстрые тесты, обучение, оценка знаний и навыков.

#### QUALITY ASSURANCE SEROLOGICAL STUDIES USING RAPID TESTS FOR THE DETECTION OF ANTIBODIES TO HIV

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The experience of training and assessment of knowledge and skills of specialists practical health care on the use of rapid tests for the detection of antibodies to HIV were analyzed.

**Keywords:** HIV infection, antibodies to HIV, rapid tests, training, assessment of knowledge and skills.