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FINAL REPORT
ON THE COST-EFFECTIVENESS OF PROVIDING HIV TESTING AND COUNSELING USING RAPID TESTS AT THE PRIMARY HEALTH CARE LEVEL IN UKRAINE

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USAID's Health Finance and Governance (HFG) project will help to improve health in developing countries by expanding people's access to health care. Led by Abt Associates, the project team will work with partner countries to increase their domestic resources for health, manage those precious resources more effectively, and make wise purchasing decisions. As a result, this five-year, $209 million global project will increase the use of both primary and priority health services, including HIV/AIDS, tuberculosis, malaria, and reproductive health services. Designed to fundamentally strengthen health systems, HFG will support countries as they navigate the economic transitions needed to achieve universal health care.

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ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
CD4	Cluster of Differentiation 4 (a type of T helper cells)
CE	Cost-effectiveness
CEA	Cost-effectiveness analysis
CHAI	Clinton Health Access Initiative
ELISA	Enzyme-linked immunosorbent assay
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GOU	Government of Ukraine
HIV	Human immunodeficiency virus
HTC	HIV testing and counselling
ICER	Incremental cost-effectiveness ratio
IRR	Incidence rate ratio
M&E	Monitoring and evaluation
MSM	Men who have sex with men
NMAPE	National Medical Academy for Post-Graduate Education named after P. L. Shupik
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PHC	Primary health care
PICT	Provider-initiated HIV counseling and testing
PLHIV	People living with HIV
PWID	People who inject drugs
STI	Sexually transmitted infection
SD	Standard deviation
ToR	Terms of Reference
UCDC	Ukrainian Center for Control over Socially Dangerous Diseases (Ukrainian Center for Disease Control)
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VCT	Voluntary counseling and testing
WHO	World Health Organization
WB	Western blotting

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[1] The State Service on Control over HIV/AIDS, TB and other Socially Dangerous Diseases was restructured in early 2015, and its functions are being transferred to a new department at the Ministry of Health of Ukraine.

EXECUTIVE SUMMARY

Ukraine has the highest HIV prevalence in Europe. HIV service delivery in Ukraine is a vertically structured system, targeting key populations, but compromising efficiency and access to care. HIV testing and counseling (HTC) service is especially meaningful in Ukraine, where of the total estimated number of 238,000 people living with HIV (PLHIV), only 138,000 were registered for HIV care in January 2015, which indicates both that many PLHIV are not aware of their HIV status and the difficulty of bringing PLHIV into care. Currently, HTC is available mainly at polyclinics, located in rayon (district) centers and cities, in specialized offices for HTC provision (Trust Cabinets), and HIV is mainly diagnosed using ELISA tests. High HIV prevalence in key populations, high levels of losses to follow up after diagnosis, and undiagnosed HIV cases underpin the need to improve access and the existing continuum of HIV care in Ukraine.

Ukraine is embarking on an ambitious agenda of health reform, which the early reform legislation and piloting of reform interventions of (2011-2014), did not include HIV care. At the same time, international donors were indicating that external funding for HIV/AIDS would decline in coming years, thus leading to a desire to seek efficiencies in prevention, counseling, care and treatment. Yet until now information on the effectiveness and cost-effectiveness of HIV testing and counseling strategies is scarce globally and absent for Ukraine. In July 2012, at a meeting of national and regional government and non-government representatives engaged in fighting HIV and AIDS in Ukraine, it was decided to test an integration strategy in order to inform national policy.

The USAID-funded Health Finance and Governance Project (HFG) is a global project designed to strengthen health systems and thereby increase access to care. In Ukraine, HFG worked with the Chernigiv Oblast Administration, the Ukraine Ministry of Health, the Clinton Health Access Initiative, and other partners to design and implement a pilot model of HTC using rapid HIV tests as a service offered at primary care facilities by non-specialized primary care physicians. The program was implemented in 2014 at 30 primary health care (PHC) facilities in the Chernigiv Region of Ukraine. The objectives of the HFG Project were to:

(i) evaluate the effects of the introduction of the integrated model of provision of basic HIV services at the primary health care level,

(ii) analyze the associated costs of providing such services, and

(iii) estimate the cost-effectiveness of the model compared to the current HIV services delivery model.

The pilot implementation and study design

A quasi-experimental comparison study was designed; all PHC ambulatories at four pilot districts of the Chernigiv Region participated in the implementation of the pilot, and 21 other districts where PHC clinics do not provide HTC, made the comparison group. The effects are compared to the ex-ante model of HTC available at polyclinics. The effects and costs are controlled against performance of health facilities in provision of HTC in the year preceding the implementation of the intervention. It was not expected that the implementation of the model would require an increase in human resources at any level of care, but redistribution of functions was expected as recommended in the Appendix E.

Increased infrastructural costs are similarly not envisaged, but all costs that occurred were analyzed, and counted if considered relevant to the implementation of the model.

Sixty-five physician and nurse pairs in the pilot received in-service training in HTC to provide HTC both as a provider-initiated testing for populations with risky behaviors and clinical signs of infection, and as voluntary counselling and testing for patients self-presented for testing.

Data on the number of tested and detected HIV cases in intervention and comparison districts was collected through regular health information reporting. For the cost-effectiveness study, the regular model of HTC provided at polyclinics was costed using simplified step-down allocation of costs of polyclinics and costs of the laboratory procedures. To extract costs of PHC ambulatories related to the provision of services, the study among PHCs was conducted aiming at estimation of average time allocated to standard of HTC service and related procedures (e.g. recording and reporting, etc.), and financial and operational indicators were analyzed.

Findings

For the analysis of the effectiveness of the model, the change between 2013 and 2014 was compared between pilot and non-pilot areas for each of the outcome indicators, using regressions. The results of implementing the model can be interpreted as following:

- There was a 3.52 times increase in the number of HTC per capita in pilot regions compared to non-pilots after the implementation of the program;
- There is about 2 times increase in the number of HIV positive cases detected (per capita) in pilot regions;
- The proportion of people found positive among those tested in pilot areas was just under half that of the comparison areas;
- There is an 8 times increase in the number of people who received HTC from the most-at-risk groups in pilot regions (per capita) as compared to the comparison areas.

All four of these results are statistically significant at $p<0.05$.

The adjusted baseline costs of detecting 1 HIV positive case by the current model with HTC provided at Trust Cabinets was UAH 6,693.94. The total costs per one HIV positive case detected at PHCs was UAH 6,659.44. The resulting incremental cost-effectiveness ratio (ICER) is UAH 4,580.28 per one additional HIV positive result detected after the implementation of the model. This means that the costs for detection of each additional HIV case with participation of PHCs in HTC provision is lower than the cost per case detected in the pilot regions before the implementation of the model, and therefore we may conclude that in general the new model is cost-efficient in terms of detecting HIV cases.

Discussion and recommendations

Although the model is more cost-efficient, affordability issues remain because the PHC integration program costs about 260,000 UAH more than the Trust Cabinet only model per annum. This is because, with the implementation of the new model, the costs per detected HIV case at Trust Cabinets decreased, but the required additional investments on the PHC side more than offset this decrease. With the additional costs, however, the integrated model reaches more individuals with HIV testing and finds more positive diagnoses, in particular among most at risk populations.

The recommendations based on the results of the implementation of the model address the model set-up, its implementation, recording and reporting procedures, organization of the referrals, financial aspects, and recommendations for future studies.

The following recommendations are based on the results of the study implementation, and were discussed and agreed with counterparts in Chernigiv during the final steering meeting of the HFG Project, and therefore would be useful to consider for the further implementation of the proposed model:

1. **More attention to screening:** PHC practitioners are seeing many patients, and naturally when the HTC service is provided free-of-charge, many patients would be interested to know their HIV status even if they are low-risk. It is desirable that PHC provide opt-out HIV counseling to all their patients, but make decisions to offer HIV testing for patients that are most likely have risks of contracting HIV. Focusing on testing people with risky behaviors or clinical indications may ensure higher yield of HIV cases detected and thus increase the cost-effectiveness of the approach.
2. **Case management for linkage of patients to HIV care:** one of the most time-consuming procedures when the result of HIV test is positive is to refer and make sure that the HIV-positive patient is linked to care. However, it would be desirable to increase the proportion of people who were successfully linked to HIV care. Where possible, the efforts of PHC practitioners should be combined with the case management projects for PLHIV, implemented by HIV service NGOs.
3. **Review the possibility of using HIV rapid tests at Trust Cabinets:** in the model the traditional ELISA testing was offered at Trust Cabinets for people who applied for HTC. Given that the transport expenditures are high for remote regions, and that the HIV rapid tests do not lead to losses of patients while they are waiting for the result of the test, it is desirable to consider the possibility to use HIV rapid tests for HIV diagnostics at Trust Cabinets.
4. **Taking blood samples for verification and CD4 test at once for registration of PLHIV for HIV care:** for the cases when a patient is referred from the PHC unit after two HIV rapid tests were showing positive results, it is recommended to send the blood sample for both the verification ELISA/WB test and the CD4 test in order to make timely decisions on ART initiation. This is also cost-saving, because the transportation costs would be reduced.
5. **Simplify recording and reporting**: a considerable amount of time associated with delivering HTC by PHC personnel is devoted to records and reporting HIV testing and counseling sessions. The current recording and reporting requirements maybe reasonable for Trust Cabinets procedures, where the most amount of time is dedicated to seeing patients coming for HTC; however, for PHC routine care, where the volumes of patients served are much higher, the recording and reporting procedures around HTC have to be simplified to the minimum possible. This simplification may also save costs at the PHC site.
6. **Coding of reasons for HIV testing:** the coding of key population groups needs to be made clear for the staff implementing the model to avoid incorrect coding and have more accurate information of the groups of people who received testing.
7. **Develop standard supervision procedures:** the project has developed procedures for regular supervision of the HTC service provided at the PHC level; however, these procedures were project specific and required certain investment of time from the Clinical Advisor to the project.
8. **Review the terms of reference (ToRs) for the AIDS Center, Trust Cabinets, and PHC to enable and support the provision of the new model.** The current ToRs do not include the needed coordination and implementation functions. The suggested amendments to the ToRs are provided in the Appendix E.

9. **Availability of tests at PHC facilities:** while the project implemented a model with each PHC physician and nurse were trained and equipped for the provision of HTC, and also maintained their own records on HTC-related procedures. From the project prospective, it is recommended to make sure that HIV tests and books for recording of HTC-related procedures are available at PHC facilities, and staff are properly trained and have access to the materials and books to be able to provide HTC when necessary.
10. **Expiry date for HIV test and other materials:** to avoid waste of tests, and unnecessary utilization of tests it is important to supply facilities with the stock of tests with expiry date at least 3 months after the end period of the expected utilization.
11. **Incentives for PHCs:** the incentives for PHCs providing the HTC to their catchment population is to be considered as a part of a broader motivation for health promotion and health risks cessation. However, it is recommended that the capitation payment will be used for PHCs with risk-adjusted coefficients, so that PHCs will get additional payment if it provides care to patients with chronic conditions, including HIV, which will enable appropriate attention and case management of patients with HIV.
12. **Further assessment of the model:** The project was limited in time, and could not assess effects in a longer-term period. It is recommended to repeat the evaluation after the next year of implementation in the Chernigiv region. Also, it is desirable to assess the effectiveness of the model in regions of Ukraine with high HIV burden. The potential HIV prevention effects of the model of HTC service provided by PHCs is not assessed due to limitations of the implementation phase; however, such results could be expected in a long-term perspective, and it would be valuable to assess them.

1. BACKGROUND

Ukraine has the highest HIV prevalence in Europe (0.8%). HIV testing and counseling (HTC) is one of the key services in addressing the HIV epidemic. It opens the door to HIV care and treatment options, and is one of the most effective prevention mechanisms[2]. HTC service is especially meaningful in Ukraine, wheref of the total estimated number of 238,000 people living with HIV (PLHIV)[3], only 138,000 were registered for HIV care in January 2015[4], which indicates that many PLHIV are not aware of their HIV status as well as of the difficulty of bringing PLHIV into care.

The current provision of HTC is organized through three programs, the first of which is a network of 707 Trust Cabinets[5], located in almost every rayon (district) center and city of Ukraine. Trust Cabinets are specialized offices established solely for the testing, counselling, care and treatment related to HIV and AIDS. HTC is also an important part of the nation's antenatal care package of services: the coverage of pregnant women with HTC is 99%[6], and HIV testing is a mandatory element of screening potential blood donors. HTC is a part of HIV prevention programs provided for key populations, primarily funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

In 2013, 2,941,748 people or 6.5% of the total population of Ukraine received HTC, but more than 60% of the total number of tested were pregnant women and blood donors (both populations are required by the health system to be tested)[7]. The remaining number of people tested for HIV amounts to only about 2.5% of Ukraine's population, of them less than one fourth are representatives from the key population groups[8]; more half of those who received the HTC service (if donors and pregnant women are excluded) were people who applied for HTC on their own initiative.

The progress toward universal access to HTC will largely depend on identifying models of HTC delivery that are most technically and culturally acceptable, most cost-effective, and best reach the communities most vulnerable to HIV[9].

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[2] Service delivery approaches to HIV testing and counselling (HTC): a strategic HTC policy framework. World Health Organization 2012 http://apps.who.int/iris/bitstream/10665/75206/1/9789241593877_eng.pdf

[3] The national assessment of the situation with HIV/AIDS in Ukraine as of the beginning of 2013. UNAIDS, 2013. http://ucdc.gov.ua/attachments/article/911/%D0%94%D0%BE%D0%B42-Ocinka%20situaciy%20VIL%20-%20SNID%202013.pdf (accessed 23 March 2015)

[4] Operational data of the number of PLHIV registered for HIV care as of January 2015. UCDC website http://ucdc.gov.ua/attachments/article/1325/%D1%81%D1%96%D1%87%D0%B5%D0%BD%D1%8C%202015.pdf (accessed 23 March 2015)

[5] "Human resources of the AIDS service: current state, challenges and opportunities" workshop organized by HIV reform in Action Project (USAID-funded). Presentation by L. Getman (UCDC) at the HRH workshop on February 12, 2015.

[6] HIV infection in Ukraine: informational bulletin #41. UCDC, 2014

[7] *ibid*

[8] For the purpose of this report the key population groups are defined as PWID, MSM, and high risk groups, including people with STIs, and people with multiple unprotected sexual contacts.

[9] Service delivery approaches to HIV testing and counselling (HTC): a strategic HTC policy framework. World Health Organization, 2012. http://apps.who.int/iris/bitstream/10665/75206/1/9789241593877_eng.pdf (accessed 23 March 2015)

1.1 Why test a new HTC model in Ukraine?

Previous studies by the United States Agency for International Development (USAID)-funded Health Systems 20/20 project and studies by the World Health Organization (WHO) indicate that HIV/AIDS care is delivered in such a way that it contributes to stigmatization of HIV patients by not allowing the primary health care (PHC) system of the Ukraine health system to address even their most basic clinical needs. It is also possible that the vertical systems of HTC and care and treatment represent a barrier to physical access, given the limited number of locations where testing, counselling care and treatment can be accessed. Furthermore, the continuation of a completely vertical HIV/AIDS prevention and care system will come under even more scrutiny considering the likelihood that international funding for the HIV response in Ukraine will diminish in the future. The Government of Ukraine (GOU) realizes that in order to make its response to HIV/AIDS more cost-efficient, it must include PHC more fully as part of the response[10].

In July 2011, the authors presented findings of the policy study *Optimization of HIV/AIDS Services within the Context of Health Care Reform in Ukraine* at a roundtable of stakeholders, including Oblast AIDS Center directors, Oblast Health Administration directors, Ministry of Health, Ukrainian Centers for Disease Control (UCDC), the State Service for HIV, TB and other Socially Dangerous Diseases, USAID, UNAIDS, WHO, the Clinton Health Action Initiative (CHAI), the World Bank and other development partners. During two days of discussions, the group outlined some of the opportunities and threats to greater integration of HIV and AIDS services into the PHC system. The group reached consensus that a feasibility study of the integration model would further inform policy makers on the best way to integrate HIV into the ambitious health reform agenda of the government at that time.

The USAID-funded HS 20/20 project's *Feasibility Study: Integration of HIV/AIDS Services into the Health System of Ukraine*[11] concluded that it would be feasible to create an enabling environment in Chernigiv Oblast for implementing a pilot test of optimizing the delivery of HIV and AIDS services. For the pilot it was suggested to concentrate on delivering specified services through the PHC system and therefore increase the overall cost-efficiency and sustainability of the HIV and AIDS response. In particular, the feasibility study pointed to the probable good uptake of the Oblast AIDS Center of expanded responsibilities to include mentoring and oversight of the PHC and Trust Cabinet-based HIV/AIDS efforts. The major focus of the study was the need to enhance the role of family practitioners in the provision of basic HIV and AIDS services, starting with HIV testing and counseling, to later provision of treatment of basic conditions and some opportunistic infections, monitoring of stable HIV-positive patients for clinical signs of AIDS; and refilling ARV prescriptions.

The authors of the above study recommended providing family practitioners with rapid HIV test kits, because this could improve detection of HIV positive people. It was mentioned that about one in five people who had undergone the counseling aspect of voluntary counselling and testing at the PHC level actually went for testing. Other priority recommendations of the feasibility study included (i) the need to conduct a cost-efficiency study and (ii) the possibility to explore provision of financial incentives for PHCs who will be delivering HIV/AIDS services.

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[10] Cowley, P., Akkazieva, B. Optimization of HIV/AIDS Services within the Context of Health Care Reform in Ukraine. Health Systems 20/20, 2012

[11] Cowley, Peter and Akkazieva, Baktygul. Feasibility Study: Integration of HIV/AIDS Services into the Health System of Ukraine. Bethesda, MD: Health Systems 20/20 project, Abt Associates Inc., 2012.

1.2 Health Care Reform

Under the former government of Ukraine, an ambitious Health Care Reform was launched in 2011, with three regions of Ukraine (Vinnytska, Dnipropetrovska and Donetska oblasts) and two districts of Kyiv city participating in the reform as pilot regions[12], and a strategy of rolling out of the reform activities from the pilot regions to the rest of the country.

The Health Care Reform faced many challenges, and overall was slow in implementation of its core activities. The key priority of the reform was financial and organizational separation of different levels of health care with the focus of the first stage of reform's implementation on strengthening of primary health care.

Although there have been multiple criticisms of the progress of the health care reform to date, many experts agree that the most influential aspect of the reform is related to the development and strengthening of primary health care. As of the beginning of 2014, in all of the pilot reform regions the network of PHC facilities is fully established, staffed and equipped much better than in the other oblasts of Ukraine. The per capita expenditures allocated to the provision of PHC in pilot regions were 1.8-2.3 times higher than the average per capita PHC expenditures in Ukraine[13]. Additionally, the share of the total health care budget channeled to PHC services in pilot regions was 1.5-2.5 times higher than the 8.8% average for Ukraine[14].

The new system of age-adjusted salary payment and the system of coefficients for the volume and quality of service provided introduced in pilot regions allowed testing of the new payment and incentives system at the PHC level, which was seen as an effective financial motivation for PHC staff. However, the effects and cost efficiency of the new payment system were not assessed.

The 2013-2014 Revolution of Dignity and the new government of Ukraine put in place in February-March 2014 set new priorities for national reforms. Health care reform is one of the priority areas of these reforms, and the vision of these reforms is currently outlined in the recently developed Strategy of Health Care Reform (2015- 2025).

At present, there is no clear understanding among key stakeholders about how the new approach to health reform will influence HIV/AIDS services. This is another challenge that is to be addressed in the near future, and one that we hope this study will help to inform.

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[12] The Law of Ukraine #3612 of 07.07.2011 "On implementation of reforming of health care in Vinnytska, Dnipropetrovska, Donetska oblasts, and Kyiv city" http://zakon4.rada.gov.ua/laws/show/3612-17

[13] According to 2013 data, the average per capita expenses in PHC were at the level of UAH 105.6, whereas in pilot regions reaching UAH 185-238. http://moz.gov.ua/docfiles/analytical_reference.pdf

[14] *ibid*

1.3 Need for an integration of the HIV service at the PHC level

Although some progress has been made in the efforts to reduce the number of new HIV infections in Ukraine, HIV surveillance continues registering many HIV cases, leaving Ukraine among most affected countries with HIV epidemic in Eastern Europe and Central Asia. The existing HIV surveillance is mostly reactive in capturing HIV cases, and presently the majority of HIV cases is being detected in the late stages of the disease. High HIV prevalence in key populations, high levels of loses to follow up after diagnosis, and undiagnosed HIV cases underpin the need to improve the existing continuum of HIV care in Ukraine.

The new National AIDS Program for 2014-2018 sets ambitious targets for HIV prevention, care and treatment. The current financial crisis, the anticipated cessation of GFATM funding within the next few years, and other challenges raise the issue of the best use of available resources in the provision of HIV services.

PHC facilities, which are a relatively new entity in Ukraine, are where the major part of primary contact with patients should take place, but they are not yet utilized at full capacity. Some reasons for underutilization of facilities is that there is no clarity on the role and functions of the PHC units, insufficient capacity in terms of training of the PHC staff and supply of material and equipment to deliver the full scope of primary health care services, low level of equipping and provision with suppliers, and legal and financial constraints.

The potential effectiveness and cost-effectiveness of engaging the PHC level into the provision of HIV/AIDS services had not yet been properly studied in Ukraine. The first move in exploring these directions was taken within the USAID-supported HFG Project in Ukraine.

1.4 HFG Project Ukraine Program

To better understand the opportunities and challenges of engaging PHC facilities to provide basic HIV services, USAID has supported a pilot project in one of Ukraine's regions, Chernigiv Oblast, within the global Health Finance and Governance (HFG) project. Abt Associates, Inc., the lead implementing organization of the HFG project, in close consultation with USAID mission, national and local partners developed and agreed on the Project's concept, goals and objectives.

HFG in Ukraine worked closely with country counterparts to test new ways of managing and financing basic HIV services that are fully aligned with the government's current health reforms. The piloted activities included HIV testing and counseling through their integration into the primary health care (PHC) centers in selected towns and districts in Chernigiv Oblast.

Given that the current reforms in Ukraine aim to improve health services, the purpose of this work was to explore the following questions:

- What are the costs and benefits of providing integrated HIV testing and counselling at PHC centers, as compared to the current vertical model of provision based on specialized Trust Offices and AIDS Centers?
- What are the impacts of the integrated HIV care model on HIV testing rates, counseling uptake, and timely AIDS treatment?

Table 1 lists the activities of the HFG Ukraine Project.

Table 1. HFG Ukraine Activities

Activity 1: Develop a model for managing and delivering integrated HIV services at PHC clinics
Activity 2: Develop institutional and human resources capacity for providing HIV/AIDS services at PHC facilities
Activity 3: Propose health financing framework for the integration of HIV services into PHC facilities
Activity 4: Economic evaluation of an innovative model of integrated HIV/PHC services

In the next sections, the results of the HFG Ukraine project implementation are presented and discussed.

2. DEVELOPMENT OF THE MODEL

This chapter reviews the traditional organization of HTC provision and referral system in Chernigiv Oblast, the proposed algorithms for the new model, the required and provided capacity development at different levels, the organization of the supply of necessary materials (e.g. HIV rapid test kits), and recording and reporting lines suggested for the new model.

2.1 HIV epidemic and HTC provision in Chernigiv region

Chernigiv Oblast is located in the north of Ukraine. It has a total population of 1,066,826 people[15]. HIV prevalence in the oblast is 0.3% of total population. Chernigiv Oblast is among the regions of Ukraine with a relatively moderate level of HIV burden, but in 2013, the share of HIV positive cases among blood donors (0.25%) and pregnant women (0.49%) were higher than the average for Ukraine (0.14% and 0.39% respectively).

Delivery of HIV/AIDS services is organized through a network of health facilities, social services and NGOs. The Oblast AIDS Center provides overall leadership of HIV control efforts in the region. The oblast has a network of Trust Cabinets, working in each rayon and city of Chernigiv Oblast, mainly to provide HTC services to the population. There are only a few NGOs working with key populations and PLHIV in Chernigiv, and their activities are mainly concentrated in the oblast's capital city, Chernigiv. Of the total of 1,101 patients receiving anti-retroviral therapy (ART) in the oblast, 96.4% patients are receiving ART at the Oblast AIDS Center and only 3.6% courses were provided outside the capital at the ART site in Pryluky city. Decentralization of HIV/AIDS services, in order to increase access to prevention, care and treatment for the population, is among the key challenges for the oblast's HIV control efforts.

In 2013, when the implementation phase of the HFG Ukraine project was planned, almost 10% of the oblast population had received HIV testing and counseling. Of this number, about 19% of tested population was blood donors and 11% were pregnant women who received HTC within the antenatal care program. About 42% of people received HTC on their own initiative.

Among the total population who received HTC, 661 HIV cases[16] were detected in 2013, or 0.65% of the total number of tested. More than 96% of total HIV cases were detected among the following populations[17]:

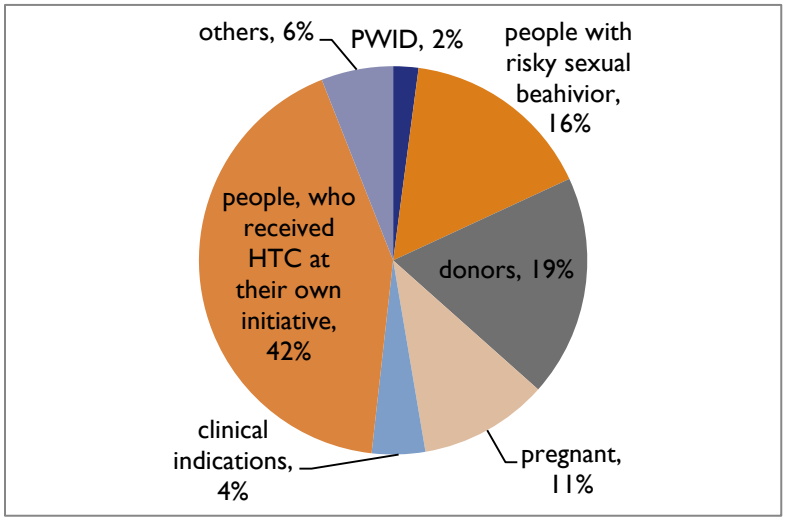
- Sexual contact with registered PLHIV (5%);
- People who inject drugs (PWID) (15%);
- People with risky sexual behaviors (22%);
- Blood donors (5%);
- Pregnant women (8%);
- Imprisoned population (6%);[18]

[15] Demographical yearbook "Population of Ukraine in 2013". State Statistics Service, 2014.
[16] From the total number of detected cases, unconfirmed HIV cases among children born to HIV-infected mothers were excluded (103 children born to HIV-infected mothers in 2013).
[17] The mentioned categories reflect the official coding of people who received HTC

- Tested due to clinical indications (10%);
- People who asked for testing at their own initiative (24%).

The prevalence among these groups varied in 2013: from 0.2% of HIV cases among donors, imprisoned population, tested due to clinical indications, and people who applied for testing on their own initiative, to 0.5% among pregnant women, 0.9% among people with risky sexual behaviors, 4.7% among PWID, and up to 8.5% among those with sexual contacts of registered PLHIV.

Figure 1: Share of population by categories who received HTC service in 2013



2.2 New patient pathway

With the idea to test the possibility of HIV service integration at the PHC level, partners identified the need to develop the new model that would reflect new functions and referral lines after HTC service becomes available at the level of primary health care delivery.

Using the available testing algorithms described in the MoH order #1141, the project, in consultation with the national partners (including the State Service of Ukraine on HIV/AIDS and other socially dangerous diseases, CHAI, and the Oblast AIDS Center and Trust Cabinets) developed a new pathway for patients receiving HTC using rapid tests at the PHC level.

Schematically this pathway is presented in the diagram below.

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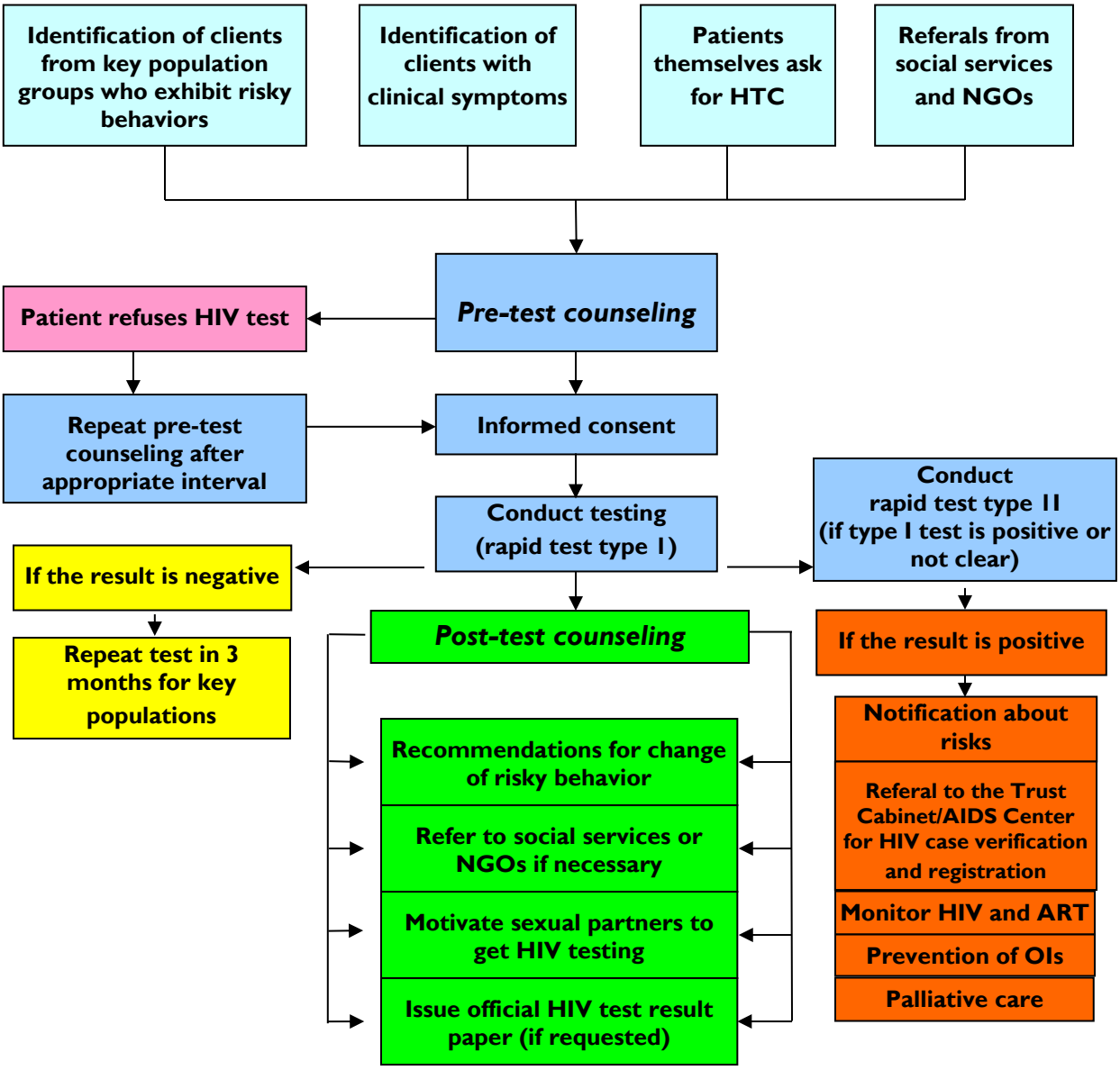
[18] Currently the assignment of the code is arbitrary to the physician who is conducting HTC, so the same prisoner could be coded differently depending on the situation: if s/he was donating blood- as a blood donor, if had TB signs –as tested due to clinical indications, if drug addiction suspected – as PWID. The system of coding was long criticized by many experts, but this is the current classification, and this is how data is organized. The most recent UNAIDS report (2014) estimated HIV prevalence among prisoners to be 12%.

Figure 2: Algorithm of Actions for Family Practitioners to Provide HIV Testing and Counseling (HTC)



The clients at PHC facilities who may need to get HTC were divided into four main groups: identification of at-risk patients from the catchment populations of PHC ambulatories, patients who have clinical symptoms and manifestations that may be explained by HIV infection, patients who ask for HIV testing on their initiative and clients referred from social services and NGOs. For these four groups, PHC physicians were advised to provide pre-test counseling, and if the client ever had risk of contracting HIV, motivate them to get HIV testing. If for some reasons patients refuse to get HIV test, but belong to an at-risk group and continue practicing risky behaviors, PHC physicians were recommended to repeat pre-test counseling after appropriate time interval (e.g. at the next visit of the patient).

HIV testing is to be provided using rapid tests: a type I test with high sensitivity, and, if the result of the type I test is positive, a type II test with high specificity. All patients after testing their blood for HIV using rapid tests should receive standard post-test counseling, which should include counseling for change of risky behavior (if applicable), motivation to bring sexual partners for HTC, referral to social services and NGOs, if necessary, and provision of the medical paper with HIV test result (if requested). If the result of the HIV test is negative, but the patient belongs to a most-at-risk group, the patient should be recommended to repeat HIV testing after a 3 months period.

If the result after two rapid tests is positive, the patient should be referred to the nearest Trust Cabinet or AIDS Center (per the patient's choice) for verification of HIV status and registration for HIV care. The PHC physician should closely communicate with Trust Cabinet to ensure that HIV positive patients are linked to HIV care. Potentially, PHC staff may further conduct monitoring of HIV infection and participate in anti-retroviral (ARV) treatment by providing ARV refills, provide treatment of opportunistic infections, and provide palliative care as needed, although this was not implemented in the time period covered in this report.

The new model of providing HTC at the PHC level also influenced the patient's pathway at Trust Cabinets. Instead of the traditional procedure of taking blood for both screening and a verification ELISA test, patients referred from PHC level after a positive result on the second HIV rapid test, blood is drawn for the verification ELISA/WB test, and where possible, CD4 count.

2.3 Essential oblast government support

The HFG Ukraine Project initiated the signing of a three-party Memorandum of Understanding (MoU) to support the implementation of the pilot model in Chernigiv oblast. The MoU was signed on October 2, 2013. The parties to the MoU were the Chernigiv Oblast Administration, the State Service of Ukraine on HIV/AIDS and other socially dangerous diseases, and Abt Associates Inc., the implementing organization of the HFG project in Ukraine.

For the purpose of the model's implementation, a project steering group was established as a working group at the Oblast HIV Coordination Council, and approved by Protocol #3 of the Coordination Council meeting held on October 30, 2013.

An additional enabling document for the implementation of the pilot model was the order of the Oblast Health Administration, which supported the implementation of HTC at PHC level in Bobrovytsky, Chernigivsky rayons, cities Pryluky and Nizhyn starting on January 20, 2014.

2.4 Selection of pilot sites

For the purpose of the effectiveness and cost-effectiveness analysis, the HFG Project suggested random selection of 4 rayons/cities from the total of 22 rayons and 3 cities in Chernigiv Oblast. However, when the implementation of the model was planned, only 2 rayons and 2 cities had completed the process of establishing a PHC facilities network: Chernigivskyi and Bobrovytsky rayons, cities of Nizhyn and Pryluky. In consultation with the Oblast Administration and AIDS Center management, the decision was to implement the pilot model in these 4 territories. Since there are a finite number of PHC units in the select territories, the project, in consultation with partners, aimed at covering all PHC facilities in the chosen rayons/municipalities. There are 30 total ambulatory PHC sites, and all of them participated in the pilot. At these 30 sites, 65 family physicians and 65 nurses were providing services to designated catchment populations, and all 65 units were asked to participate in the pilot to achieve universal access for the population to HTC service.

2.5 Capacity development

To enable implementation of the new model, the need to build additional capacities arose at different levels of HIV service. The staff of PHCs that were to start providing HTC service required training on counseling, testing using rapid tests, recording and reporting, storage of materials, and utilization of waste. Trust Cabinets staff required training to understand the new model of HTC provision, and to provide mentoring and supervision to PHCs participating in the pilot. The capacity of the Oblast AIDS Center was to be improved for overall coordination of the pilot activities, monitoring and evaluation (M&E) and supervision of the implementation stage, planning of commodity distribution, training of PHC practitioners on HTC, and operational troubleshooting.

2.5.1 PHC staff

Capacity of PHC physicians and nurses to provide HTC is one of the key prerequisites for the implementation of the proposed model. At the time of planning the model implementation, there was an agreement that both PHC physicians and nurses need training in HTC provision.

To train PHC physicians, HFG Ukraine partnered with the National Medical Academy for Post-Graduate Education named after P. L. Shupik (NMAPE) to develop the thematic improvement in-service course, using already available 2-weeks course on HTC provision using rapid tests, and updating it with more focus on primary care specifics, counseling skills, stigma and discrimination issues, referral lines and recording/reporting requirements. The two-week (78 hours) certificate course was developed by the Faculty of Virology of NMAPE in collaboration with two faculties from the Institute of Family Medicine at NMAPE, and in consultation with the State Service of Ukraine on HIV/AIDS and other Socially Dangerous Diseases. After the approval of the course at the Scientific Council of NMAPE for continuing medical education credits, the Faculty of Virology, with participation of HFG Ukraine Project specialist on counseling, stigma and discrimination, conducted a training of trainer's course for the faculties of family medicine, and then the three engaged faculties were ready to provide training to PHC physicians.

During the period November 2013 to February 2014, 72 persons received training during 4 courses organized by NMAPE (65 PHC physicians and PHC manager, 4 Trust Cabinet physicians, and 2 representatives from the AIDS Center). Two trainings were led by the Faculty of Virology, and the other two were led by the Institute of Family Medicine at NMAPE, although staff from both faculties

were engaged during all four courses. All training was evaluated through pre- and post-training knowledge assessments, and participants of all courses demonstrated increased knowledge in all themes of the course content.

The training for 76 PHC nurses was organized in 5 rounds of two and tree-day trainings. The first two trainings, conducted by CHAI, were conducted at the Institute of Epidemiology and Infectious Diseases named after V.L. Gromashevsky. The next 3 trainings were organized at the Chernigiv Oblast AIDS center, with engagement of the Clinical Adviser from the HFG Project, and the Chief of the Laboratory. All trainings for PHC nurses were organized with a focus on practical skills of HIV testing using rapid tests, bookkeeping, and stock management.

All trainings for PHC physicians and nurses were completed by February 2014.

2.5.2 Trust Cabinets

The capacity building for Trust Cabinets included joint training with PHC physicians to fully understand the algorithm for the new model, and additional instructions to provide mentoring and supervision support to PHC staff on the provision of HTC. The additional capacity of the Trust Cabinets in the pilot regions included oversight over data collection and reporting, and support in linking people with HIV detected at the PHC level to HIV care.

2.5.3 AIDS Center

To implement the model, the Oblast AIDS Center required additional capacities in the overall coordination of the model's implementation, provider-initiated testing, training for the use of rapid tests, assessment of the need for test kits and other materials, planning of the distribution of medical suppliers and control over their stocks, supervision and monitoring of the implementation, and evaluation of the results of implementation.

2.6 Supply of materials

The HFG Ukraine Project supported the Oblast AIDS Center in the assessment of the need for suppliers to provide HTC using rapid tests. It was estimated that each pair of family physician and nurse would provide 8 to 10 HTC services to their catchment population per month. For this quantity, the following calculation of the requested materials was prepared (Table 2).

Table 2. Planning of the suppliers for the model implementation

Category	Specification	Per 1 pair of family physician/nurse	Required quantity	Total need (with additional stock)	Total received
HIV tests	Type I (high sensitivity)	1 per HTC, about 100-120 per year	7,800	8,200	7,965
	Type II (high specificity)	Up to 5% of the quantity of type I test	390	410	495
Medical gloves	Nitrile, size M/L	1 per HTC	7,800	8,300	8,300
Disinfection	Capacities for disinfection, for 3L	One per pair	65	70	70

	Disinfectants for HIV disinfection	1 Liter	65	70	70

To ensure supply of the required materials, the HFG Ukraine project partnered with CHAI to implement the pilot with 32 pairs of PHC physicians and nurses, where CHAI initiative provided rapid tests and medical gloves: 3,200 tests Type I, and 160 tests Type II. Medical gloves were included with the test kits with the Type I tests, constituting 3,200 pairs.

The International HIV/AIDS Alliance with the approval from the GFATM provided the rest of the required materials: 4,765 rapid tests Type I, and 335 tests Type II, 5,100 pairs of medical gloves, and disinfection (70 capacities and 70 liters of disinfecting solution).

The supply of the materials from CHAI was organized in January 2014, and the materials procured by the International HIV/AIDS Alliance were supplied in February 2014. The AIDS Center distributed the materials to PHC Centers according to the distribution plan.

Due to the difference in supply dates, 32 PHC units were equipped to provide HTC in February 2014, and the remaining 33 units were able to provide HTC starting March 2014.

2.7 Recording and reporting lines

The recording and reporting procedures concerning the provision of HTC services were organized according to the current legislation, specifically MoH Order #1141. For convenience, the HFG Ukraine Project developed short guidance for PHCs with the list of forms and journals required (see Tables 3 and 4, below).

Table 3. Forms and Journals for HTC record keeping

Daily (morning and afternoon): Form **510-5/0** "Temperature log for storage of rapid tests"	
Pre-test	
Form **503-1/o**	"Informed consent to get HIV test"
Form **503/o**	"Journal of pre-and post-test counseling sessions related to HIV testing"
Post-test	
Form **510-4/o**	"Journal (stocks register) of diagnostic kits, reagents, medical suppliers used for screening of HIV-infected"
Form **510-7/o**	"Journal of the protocols of rapid tests conducted"
Form **510-6/o**	"Journal of rapid tests results"
A. The result of the test is negative	
Form **503-4/o**	"Certificate of the negative results of tests for p24 antigen and/or antibodies to HIV"
B. The result of the test is positive ***Second test (test kit from the other manufacturer) is also positive***	
Form **503-3/o**	"Notification for persons infected with human immunodeficiency virus (HIV)".

	2 copies *(one is given to the patient, one is stored at the ambulatory clinic)*
Form **503-5/o**	"Certificate of the presence of HIV antibodies based on the results of rapid tests"
Form **249-4/o**	"Referral for the confirmatory test after 2 positive results of HIV rapid tests" *patient is being referred with this paper to the Trust Cabinet or AIDS Center*

Table 4. Forms for HTC reporting

Frequency	Type of report
Quarterly	Form **58** "Report on the number and results of tests conducted for the detection of antibodies to HIV using rapid tests"
Yearly	From **2** "HIV/AIDS report"
Monthly	Projects' M&E sheets

The PHC units had to submit quarterly and annual reports to their respective Trust Cabinet, which aggregated this data into the joint form for the rayon or city.

The project developed a form for monthly data collection on the numbers of people tested for HIV, number of HTC delivered to women, representatives of key populations – including PWID, men who have sex with men (MSM), people with risky sexual behaviors – and HTC provided to people per clinical indications. The pilot sites were also requested to provide the number of positive results detected, and indicate the remaining stock of HIV tests. The monthly data was submitted by PHC units to either the PHC manager or the Trust Cabinet physician (depending on the local leadership), and further collected by the project Clinical Advisor. The analysis of monthly data allowed timely monitoring of the pilot implementation, identification of PHC units that require additional support for initiation of the HTC service (if the PHC did not report HTC conducted within a month period), referral (if HIV case(s) detected), stock management, and data quality.

3. IMPLEMENTATION STAGE

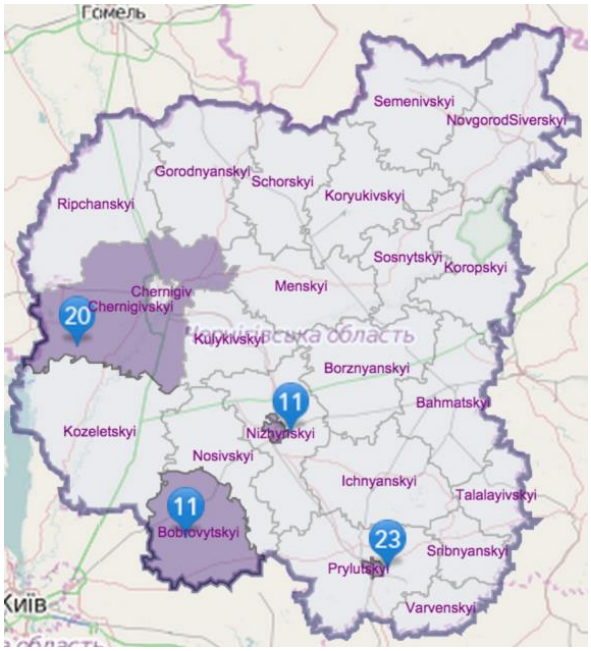
The model was implemented by 65 PHC units composed of a family physician and a family nurse(s) in Bobrovytsky, Chernigivsky rayons, cities of Nizhyn and Pryluky (Figure 2)[19].

Before implementation, all family practitioners received the training on HIV testing and counseling using rapid tests, and were instructed to provide both provider-initiated testing and counseling for catchment populations with risky behaviors, and also to provide HTC upon patient's request, if the patient had risk of contracting HIV.

At all PHC ambulatories, a poster with information about the availability of free-of charge HIV testing at the ambulatory clinic was displayed, with information about the Oblast AIDS Center phone and National hotline on HIV (see Appendix A).

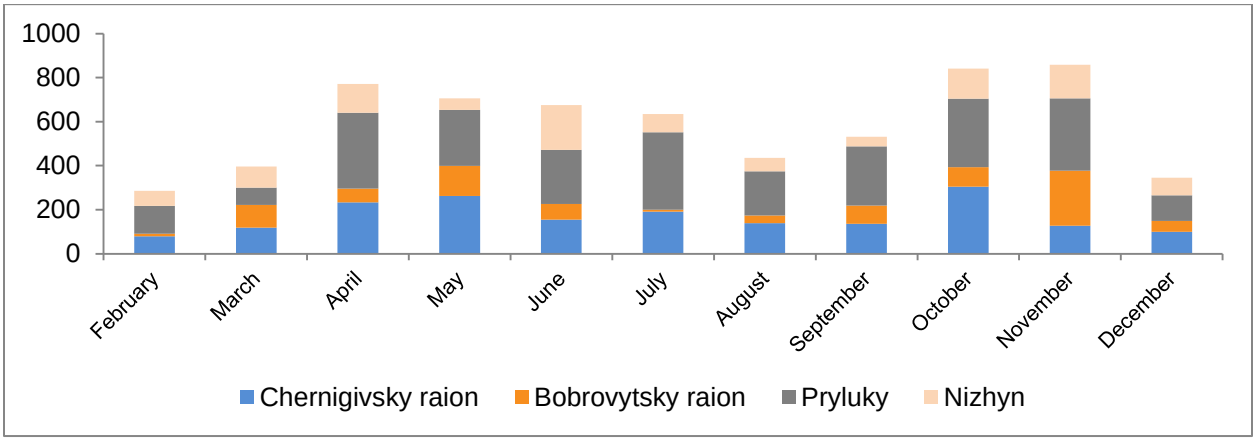
The implementation stage of the model was planned to last 12 months; however, due to the project's timeframe, the implementation phase was limited to the 2014 calendar year. Given that the actual implementation of the model started after the first part of HIV tests was received in mid-January 2014, and the second part received the end of February 2014, the duration of the implementation phase was limited to February-December 2014, or 11 month for 32 PHC units and 10 months for 33 PHC units.

Figure 3: Rayons and cities in Chernigiv Oblast, where the model was piloted, with an indication of the number of PHC units in each rayon/city



[19] Map developed in ArcGIS online application, OpenStreetMap contributors, see www.arcgis.com

Figure 4: The number of people receiving HTC at PHC level in pilot regions (monthly data)



In total, 6,428 people were tested for HIV by PHC sites during the implementation period. As Figure 4 above shows, during the months of February and March 2014 the number of people who received HTC was lowest, which were the first months of the program, when it is possible people were only just learning that the service was available. Also, in some regions, the testing only began at the end of February given the training schedule. Some decrease in the number HTC provided is also seen in August and September; it can possibly be explained by vacations of PHC staff, as well as vacations of population served, and seasonal work in gardens.

The greatest numbers of people tested occurred in November and December 2014. These peaks are partially explained by the increased flow of patients in these months due to seasonal illness (e.g. influenza); the other likely reason for these peaks is that for part of received tests the date of expiry was in early December 2014, and the PHC physicians were more pro-active in providing HTC to use the tests before they expire.

Among all HIV tests provided, the share of women who received HTC was 56%. Pre-implementation, the researchers hypothesized that the share of women might be even higher than what was observed because women seek care at family practitioners more often than men[20].

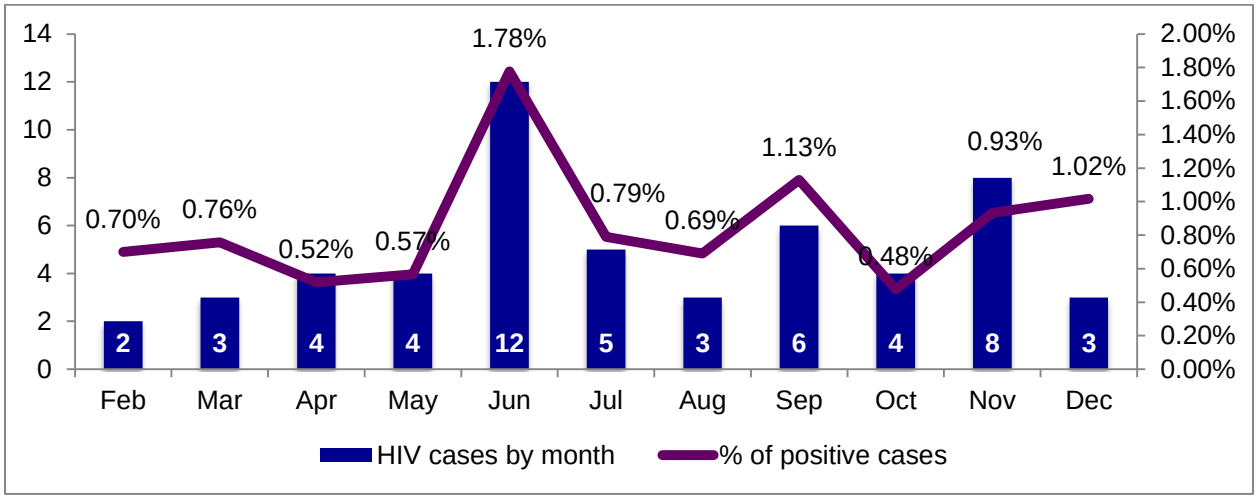
Among all people who received HTC at PHC ambulatory clinics, 59% were coded by PHC staff as people from most-at-risk groups: PWID, MSM, people with sexually transmitted infections (STIs), and people with risky sexual behaviors. The vast majority (3,695 people) in this group are people identified as those who had risky sexual behaviors, with only 59 PWID, 8 MSM, and 40 people with STIs.

Another large group of people who received HTC were people with clinical manifestations associated with HIV infection. The number of people in this group was 515, or 8% of total people tested.

[20] Tudiver F, Talbot Y. Why don't men seek help? Family physicians' perspectives on help-seeking behaviour in men. J Fam Pract. 1999 Jan;48(1):47-52.

The total number of HIV cases detected by PHCs providing HIV rapid testing was 54 cases, representing 0.84% of people tested. The highest number of HIV positive cases detected per month was registered in June 2014(12 cases), representing 1.78% of people tested in this month (see Figure 5).

Figure 5: The number of positive HIV cases detected by PHC participating in the pilot, and the percentage of positive results in the total number of people tested



During the implementation stage, the number of people receiving HTC and positive results at PHC facilities differs for the rayons and cities participated in the pilot of the model (see Table 5).

Table 5. HTC statistics by pilot rayons and cities

Pilot region	Total number of people tested	% of catchment population in the age 15-49	% of women among tested	% of people from most-at-risk groups	Total number of HIV cases detected	% of HIV positives among total tested
Bobrovytsky rayon	898	10%	44%	84%	8	0.89%
Chenigivsky rayon	1832	9%	58%	71%	18	0.98%
Pryluky	2628	10%	59%	36%	16	0.61%
Nizhyn	1070	6%	56%	76%	12	1.12%
Total	**6428**	**9**	**56%**	**59%**	**54**	**0.84%**

Among the 54 cases detected, the proportion of HIV positive women and men were almost equal at 48% and 52%, respectively. The average age of HIV positive persons was 38 years, ranging from 23 to 59 years. The main reason for HIV testing was risky sexual behavior: this reason constituted the majority of HIV cases among women (58%), and explained almost one third of HIV cases among men. One fifth of all HIV cases were attributed to risky injecting behaviors, and all these cases were detected among men.

For women, 6 HIV cases (23%) were detected due to provider-initiated testing when clinical signs were present, while only one such case was detected among men.

The project studied the results for the linkage to care for HIV-positive people detected at the level of PHC as well as the HIV cases detected by PHCs. About 74% of all positive cases were registered for HIV care, which is slightly better than that for the whole Oblast in 2014 (70%), and much higher than the national average of 68% (2013). The share of HIV-positive women linked to HIV care is 85%, which is considerably higher than that for men (64%). It worth mentioning that among all cases linked to HIV care, 43% were successfully referred to Trust Cabinets the same or next day after the HIV case was detected, while 22% were registered within 10 days after detection. Four additional HIV-positive people registered for HIV care within one month after their case was detected.

Of the total of 40 HIV-positive persons detected at PHCs that further registered for HIV care, 83% received results for CD4 count. Only 33% of registered cases were categorized as Stage I-II of HIV, likely indicating that the majority of detected HIV cases are not recent infections. For almost half of all registered HIV-positive persons, ART was initiated as of February 2015.

The summary of characteristics for detected HIV cases is presented in the Table 6 and Table 7.

Table 6. Statistics of HIV-positive cases detected

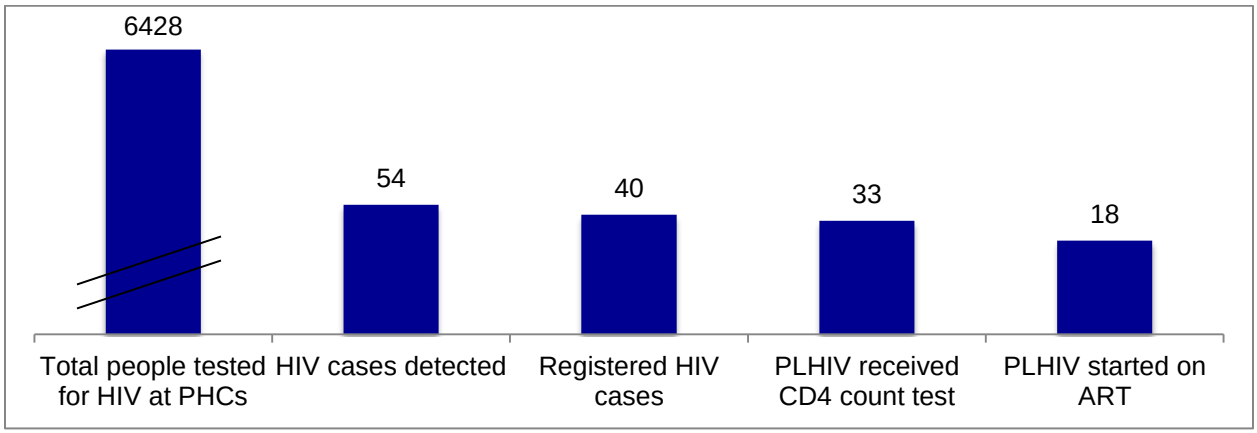
	# of HIV + cases	Average age (min-max)	Reasons for HTC provision, number of cases (% of cases)					Referral time, number of cases (% of cases)			
			Part-ners of PLHIV (101)	PWID (102)	Risky sexual behaviour (105)	Clinical indica-tions (113)	Un-known or anony-mous	same day or one day	3-10 days	one month	refuse or did not show up
Men	28	38 (27-52)	-	10 (36%)	10 (36%)	1 (4%)	7 (25%)	9 (32%)	6 (21%)	2 (7%)	10 (36%)
Women	26	37 (23-59)	2 (7%)	-	15 (58%)	6 (23%)	3 (12%)	14 (54%)	6 (23%)	2 (8%)	4 (15%)
Total	54	37 (23-59)	2 (4%)	10 (19%)	25 (46%)	7 (13%)	10 (19%)	23 (43%)	12 (22%)	4 (7%)	14 (26%)

Table 7. Results of linking PLHIV to HIV care

	# of HIV + cases	**Registered cases (% of total diagnosed)**	**HIIV care, number of cases (% of registered)**		
			Received CD4 count analysis (% of registered)	**I-II stage (% of registered)**	**on ART (% of registered)**
Men	28	18 (64%)	14 (78%)	5 (28%)	7 (39%)
Women	26	22 (85%)	19 (86%)	8 (36%)	11 (50%)
Total	54	40 (74%)	33 (83%)	13 (33%)	18 (48%)

The cascade of HIV care at PHC level is shown in Figure 6 below.

Figure 6: The cascade of HIV care at PHC level



3.1 Regulations and coordination

To ensure the smooth implementation of the model, the project in coordination with the oblast AIDS Center supported regular meetings of the project steering group. Participants of such meetings included PHC managers and physicians from the Trust Cabinets from each pilot rayon and city, representatives from the Oblast Health Administration, Oblast AIDS Center, Clinical Advisor of the HFG Project, the HFG Technical Advisor, and the Project Manager from CHAI initiative. In a few meetings other project partners and stakeholders participated.

To prepare for the implementation phase, and in the beginning of implementation, the group convened more frequently: once in one or two months. After the implementation was well on the track, the meetings of the group were held once per quarter. At each meeting, the results of the implementation were presented and analyzed, challenges were discussed, and the joint decisions were made on how to address the specific challenges.

The last meeting was conducted on March 11, 2015. The results of the project were discussed with local partners, and the ideas for the expansion of the pilot were shared. The general feedback and conclusions from the summary meeting are embedded in the conclusions and next steps sections of this report.

3.2 M&E and supportive supervision

The Clinical Advisor of the Project coordinated the monitoring and evaluation of the implementation process. One form was used to collect data from the level of PHC units. The Clinical Advisor herself filled out the second form, and this form was used to organize data on the number of HIV cases detected that were linked to care.

The monitoring data on HTC was collected using a template developed by the HFG project, with the list of PHC units, and a number of required fields. The required fields included the number of people tested, whether those tested constituted PWID, MSM, people with STIs, people with risky sexual behaviors, or

people with clinical indications, the number of women tested, the number of positive results, and the remaining quantity of HIV test kits type I and type II. This form was filled out monthly; data was first collected by either the PHC manager or Trust Cabinet physician (depending on the leadership in the project regions), and sent to the Clinical Advisor of the HFG Ukraine Project. The received data were checked for completeness and correctness, and aggregated by the Clinical Advisor into one form, which was sent to the Technical Advisor, who checked the forms for potential mistakes and identified outliers, which were further verified with respective units.

The second form was developed by HFG and used to record the number of people tested positive at the PHC level who entered in care at the Trust Cabinets or AIDS center. The form was also used to record if these PLHIV received a CD4 count test and the number of people who needed and received ART. This form was used to update information quarterly. Previous to this data collection and review, the information system was only collecting aggregated data, which made tracking the cascade of care and follow up difficult.

To support the implementation of the model and to ensure that implementation was in accordance with the current legislation and quality standards, supportive supervision and mentorship was provided by the Clinical Advisor of the project in the first months of the implementation phase, and later by the physicians of Trust Cabinets and PHC managers. The supportive supervision was performed by individual visits to PHC ambulatory facilities, where the Clinical Advisor and PHC staff did a joint review of the key procedures around HTC. A specially developed template was used to record observations during supportive supervision visits (Appendix B).

The results of the supportive supervision visits were analyzed and discussed at the project steering and coordination group meetings. When typical or frequent mistakes were observed, specific guidance was developed and disseminated through PHC managers and Trust Cabinet staff.

3.3 External quality control

CHAI developed recommendations and organized the procedures for the external quality control for the rapid testing service PHC facilities providing HTC. The procedures aimed at verification of PHC staff's skills to correctly use rapid tests, and properly identify the results of the reaction on HIV contaminated or HIV negative samples.

External quality control processes were organized in December 2014. They included supplying individual packages to each PHC physician and nurse, which included dry blood samples and required tools for conducting testing for HIV using rapid tests. Each PHC practitioner, including both physicians and nurses, was expected to test four received samples using rapid tests, and identify the results of the tests. The results were recorded and mailed back to the reference laboratory of the Institute of Epidemiology and Infectious Diseases named after V.L. Gromashevsky.

All 65 PHC pairs of family physicians and nurses participated in the external quality control procedure. According to the analysis of the results provided by CHAI, there were a total of 136 participants. Of this number, 132 forms were accepted as properly submitted, and 93% of them were submitted with correctly identified HIV-positive and HIV-negative samples. Incorrect results were received from four physicians and five nurses. There are certain limitations in the analysis of the mistakes, one specific limitation is that these participants had the materials to test the received materials using only one type of HIV tests kit; it is possible that the number of mistakes would have been lower if two tests could have been used, because use of the second test could have helped to verify the result of the first test.

4. EVALUATION OF THE MODEL

Prior to the project described in this document, CHAI supported efforts to integrate HIV services, mainly HTC, at the PHC level in Ukraine at selected PHC sites in Dnipropetrovsk and other oblasts. Stakeholders for this project were aware of these prior experiences; however, a formal evaluation of the outcomes of the prior efforts was not conducted. Thus, there was little evidence to support countrywide decisions with respect to the integration of HIV services into the PHC level.

The HFG Ukraine Project initiated a study of the pilot model described above in order to inform broader, country-wide decision-making concerning the expansion of provider-initiated testing and counseling and voluntary counseling and testing at PHC facilities. The study was designed to evaluate the effects of integration of HIV services at PHC, and to assess the cost-effectiveness (CE) of the service delivery model.

The new model's effectiveness and cost effectiveness are compared to the status quo, that is, where HTC is mainly available to the population through the network of the Trust Cabinets. The study assesses the additional effects and costs produced when HTC services becomes available and provided as a regular medical service to the catchment population at the level of PHC.

We conduct an economic evaluation of the intervention using cost-effectiveness analysis (CEA). CEA is the comparison of the costs and effectiveness of two or more alternatives using a CE ratio: the difference in costs divided by the difference in effectiveness.[21] Mathematical models are further used to simulate final outcomes and costs from available data on intermediate outcomes and costs collected from the intervention sites throughout the Chernigiv oblast. CEA can be a helpful tool for decision-makers in allocation of resources and defining priorities among a range of interventions.

The use of CEA to evaluate HIV interventions is only emerging in Ukraine. A PubMed search with key words "cost" AND "effectiveness" AND "HIV" AND "Ukraine" produced a result of only six studies (as of March 2015). Of these six studies, four are relevant to the topic, but only two contain CEA analyses conducted specifically for Ukraine. Both of the CEA studies focused on harm reduction programs.[22,23] The other analyses are reviews or systematic reviews of pre-exposure prevention measures, based on

[21] Drummond M, O'Brien BJ, Stoddart GL, Torrance G: Methods for the economic evaluation of health care programmes. Oxford: Oxford University Press; 1997.

[22] Alistar SS, Owens DK, Brandeau ML. Effectiveness and cost effectiveness of expanding harm reduction and antiretroviral therapy in a mixed HIV epidemic: a modelling analysis for Ukraine. PLoS Med. 2011 Mar;8(3):e1000423. doi: 10.1371/journal.pmed.1000423. Epub 2011 Mar 1.

[23] Vickerman P, Kumaranayake L, Balakireva O, Guinness L, Artyukh O, Semikop T, Yaremenko O, Watts C. The cost-effectiveness of expanding harm reduction activities for injecting drug users in Odessa, Ukraine. Sex Transm Dis. 2006 Oct;33(10 Suppl):S89-102.

the CEA analyses of harm reduction interventions. Thus, there is very limited information on the cost-effectiveness of HIV interventions in Ukraine.

Furthermore, the studies found in a UNAIDS-supported systematic review of the global evidence and experience related to the costs and efficiency of integrating HIV/AIDS services with other health services suggested that the costs of integrating HIV/AIDS services with other services would improve efficiency, but the authors of the review argue that good quality evidence on the costs and efficiency of integration were scarce.[24]

4.1 Objective of the study

The main objectives of the study are to (i) evaluate the effects of the introduction of the integrated model of provision of basic HIV services at the primary health care level, (ii) analyze the associated costs of providing such services, and (iii) estimate the cost-effectiveness of the model compared to the current HIV services delivery model. The study results will be used to inform decisions on the further scale up of the integration of HIV services into PHC facilities in Ukraine.

Specifically, the study explores the following questions:

1. What is the incremental effectiveness of the PHC model?
2. What is the incremental cost of the PHC model?
3. What is the incremental cost-effectiveness of the PHC model?

In order to answer the above questions, We employ a before-after study design, using non-pilot rayons and municipalities in Chernigiv Oblast with HTC provided through the network of Trust Cabinets as comparison areas. **The primary measure of effectiveness is the number of HIV cases detected (with confirmatory rapid test)**. Thus, we analyze the difference in HIV case detection among intervention and comparison rayons/municipalities both before and after the implementation of the pilot. These data are taken from the monitoring and evaluation processes described previously in this report.

We further collected, reviewed, and analyzed data on the costs associated with the integration of HIV services into PHC as well as the costs of the existing program. In this case, we used only data from the pilot rayons/municipalities but include data from the year before and the year after the start of implementation. Cost data were collected from routine government expenditure reports. In addition, a brief survey was administered to health facility staff in order to assess the amount of time they spend providing HIV services (as compared with other services).

Using the resulting costs and effectiveness metrics, we then calculated the cost-effectiveness of providing HIV services at PHC facilities.

Additional effects studied included the following: the proportion of tested positive among all tested, the total number of tests conducted, and number of tests conducted for the previously define at-risk populations and their sexual partners. These outcome measures were defined before the start of

[24] Sweeney S, Dayo Obure C, Maier CB et al. Costs and efficiency of integrating HIV/AIDS services with other health services: a systematic review of evidence and experience. Sex Transm Infect 2012;88:85e99. doi:10.1136/sextrans-2011-050199 http://www.integrainitiative.org/blog/wp-content/uploads/2012/01/Costs-and-efficiency-of-integrating-HIV-and-AIDS-services.pdf

implementation.

The number of population who received HTC at the PHC level is included as a measure of effectiveness because, during consultations with partners and desk review,[25,26] the feasibility of the model was questioned because high levels of stigma and discrimination among medical workers, along with the potential that clients might fear having their PHC practitioner know their HIV status, could result in people not seeking HTC services at the PHC level. This could be especially pertinent in rural regions, where these issues are most common. Comparing the number of people who received HTC in pilot and non-pilot territories was used to test the assumption.

In the absence of the Trust Cabinets, HTC would be still available to all pregnant women (through ANC and PMTCT programs), blood donors, and patients admitted to in-patient departments. Therefore, the assumption was made that the additional effect of the operation of the Trust Cabinets was in provision of HTC to vulnerable populations and other populations seeking HTC for various reasons (e.g. work permits, voluntarily learning about their HIV status, or referred by other services and organizations). For this reason, all tests provided by the Trust Cabinets (and at PHC facilities in pilot areas) were seen as additional to the current HTC services available at other departments of health facilities, but we did not include these other HIV tests in these analyses.

The costs associated with the integration of HIV services into PHC facilities were assessed as the costs of the model implementation, including costs for the training of PHC physicians and nurses, logistics costs, costs of supplies, and the costs for supervision and coordination of implementation. However, these costs excluded the model development costs, which would not occur in the case of expansion of the program into other areas. The costs of running the current program were also assessed, both before and after the integration of HIV services into PHCs was implemented.

Cost-effectiveness was be measured using incremental cost-effectiveness ratio (ICER). ICER is the ratio of the change in costs to incremental benefits of the PHC/HIV model intervention.

In order to allow for the comparison of the current program, and the program where HIV services were integrated into PHC, the cost-effectiveness ratio was calculated:

1) Average cost-effectiveness ratio the 'current program' (i.e., cost per HIV case detected in the current program through the network of Trust Cabinets), and
2) ICER for adding 'HIV/PHC integrated program' to the 'current program' (i.e., the additional cost per additional HIV case detected in the HIV/PHC integrated program compared to the current program).

[25] Stigmatization and discrimination of HIV-positive people by providers of general medical services in Ukraine. The USAID | Health Policy Initiative (HPI), 2007. http://pdf.usaid.gov/pdf_docs/PNADM170.pdf
[26] Judice, N., O. Zaglada, and R. Mbuya-Brown. (2011). HIV Policy Assessment: Ukraine. Washington, DC: Futures Group, Health Policy Project. http://www.healthpolicyproject.com/pubs/7_Ukraine_Policy_Assessment_FINAL_7_18_11_acc.pdf

4.2 Design and Methodology

The study is a quasi-experimental comparison study. As mentioned above, it includes data from before and after the start of implementation, as well as from both pilot areas and comparison areas; this results an analysis that includes assessing whether the *change in* the number of HIV cases detected in pilot areas from the year before the start implementation to the year after the start of implementation is difference than the *change in* the number of HIV cases detected in non-pilot areas in the same time periods. The perspective for the CEA is the health care administration of Chernigiv Oblast; the costs included reflect the economic costs that would be incurred to implement the integration program, including the costs of staff time at health facilities associated with the implementation of the program. The analytic horizon is one year after inclusion of all PHC sites in four intervention rayons/municipalities[27].

The unit of analysis for the evaluation is the rayon or municipality (both are sub-regional administrative divisions) of Chernigiv Oblast. This is the lowest level of disaggregation possible because HIV service at the rayon level is provided by Trust Cabinet or Infections Department, both located in the rayon/municipal hospital or polyclinics.

The independent variable of interest is an indicator variable of whether the HIV service is provided by the PHCs in a particular area at a particular time (=1 if yes, otherwise =0). We estimate the effects of the intervention in regression analysis controlling for the population of different rayons/municipalities.

4.2.1 Selection of sites

There are 25 different rayons and municipalities in Chernigiv Oblast. The capital city Chernigiv was excluded from the analysis because the Oblast AIDS Center as well as other tertiary health care facilities operate in Chernigiv city and receive patients from other rayons without a referral. At the same time, many patients prefer to seek care at the oblast level facilities, also anonymously, avoiding the local health care network. Thus, data collected from the Chernigiv city may include data from clients from all the other rayons, and bias the comparison with areas that do not attract a large number of patients from outside their immediate catchment areas.

Only those rayons that had completed reorganization of their PHC units and defined catchment population for each PHC district at least 2 months before the date of selection were eligible for the study as pilot territories.[28] Four rayons/municipalities were chosen as intervention sites, as described above.

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[27] The initial plan was to measure the implementation phase for at least one year after all PHC sites had started implementing the model. It was expected that all sites would be fully operational by January 2014. In practice, however, half of PHCs started provision of HTC in February, and the other half in March, which limits the implementation phase to 10-11 months.

[28] The process of reforming the existing system of health care provision was ongoing at the time when the study was launched. The target of the government of Ukraine was to complete the first stage of the reform, including a clear financial and budgetary division between the primary and secondary care and the establishment of PHC centers at each administrative unit of regions in Ukraine. This aforementioned process was fully completed in the regions of Dnipropetrovsk, Donetsk, Vinnytsya, and Kyiv City. The reorganization of the primary health care system in Chernigiv Oblast was in process in 2013-2014, and it is still not completed in terms of clear financial and budgetary division between the primary and secondary care.

To assess the effectiveness of the intervention, the remaining 20 rayons in the Chernigiv Oblast comprise the comparison group. The effects in the comparison group are assessed based on the data collected from the Trust Cabinets (there is one in each rayon). Only publically available, non-personally identifiable data are collected from this comparison group.

4.3 Limitations

The present study has a number of limitations, including:

1. **Sampling**: the sample included only four regions participating in the piloting of the model, and the total sample of 24 regions in Chernigiv Oblast limits the statistical power of the study.[29]
2. **Duration of implementation**: the original intention was to have at least one year of the implementation phase. This intention was not met because the completion of trainings and distribution of supplies was finished only in February 2014, which limited the participation of PHC units in the implementation phase to 10-11 month.
3. **Slow speed-up of testing by PHC units in first months of implementation**: the model also suffered from the novelty of the proposed intervention in the oblast, and, despite the coordination efforts, participating PHC units naturally took some time before they became fully prepared and ready to provide HTC service to population. This 'slow start' is reflected in the lower number of people tested in February and March 2014.
4. **Influencing the expected number of HTC per PHC unit**: the project implementation team potentially biased the results of the implementation model in terms of the number of people tested by PHC units because the expected number of HTC per one PHC unit per month was communicated to the participants.
5. **Expiry of tests and induced provision of HTC**: approximately half of the PHC units received HIV tests with the expiry term in end November-early December 2014, and to avoid waste of tests due to non-utilization of tests, some PHC units increased the provision of HTC to the catchment population in October-November 2014, which may also affect the detection rate of HIV positive people among people tested.
6. **Data quality**: the project made a concerted effort to ensure that the data received from PHC units on the results are accurate and meet quality standards. The data were collected on a monthly basis, and verification of data was conducted mathematically and through supervision missions to PHC sites. However, the project also relied on the data from Trust Center and health facilities, and the quality of data from these sources we not verified. Also, MoH form #3, used to report the performance of Trust Cabinets accounts for only counseling, not for the actual number of people who received HIV testing and the number of detected HIV cases, thus making it impossible to properly evaluate the results of Trust Cabinet performance using these data (an additional data collection was needed for the study).
7. **Overall situation in the country**: Ukraine in 2014 experienced a political and financial crisis, due to the armed conflict in the east of the country and overall political instability after the government of former President Yanukovich was dismissed by the Revolution of Dignity. This resulted in limited availability of finances at health facilities, and overall affected the expenditures

[29] This is referred to as a high probability of a 'Type II' error, namely that the pilot model had an effect (in reality) but the statistical uncertainty is such that we cannot conclude that the pilot model did have an effect.

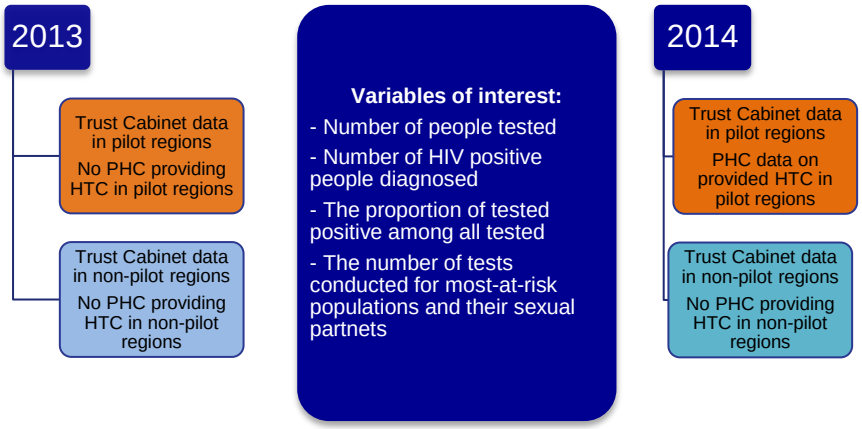
of facilities where Trust Cabinets operate, the number of people tested for HIV, the availability of the CD4 and other diagnostics tests, etc.

Points 1 through 3 above should bias the study in the direction of not finding an effect (if, for example, start-up could be implemented faster, then we would expect that the program would have found more HIV cases). Point number 5 above should bias the study in the direct of finding an effect of the program, since PHC personnel increased testing more than they would have if tests had not been nearing their expiry date. The mentioned limitations were mitigated to the extent possible, as described in the other sections of the report. Also, some of the limitations are related to the real-life situation, and therefore their influence cannot be controlled, but should be considered when interpreting the results (e.g., many programs encounter unexpected difficulties during implementation; and thus, the results reported here reflect 'real life' implementation).

4.4 Effectiveness

The effectiveness of the model was evaluated comparing outcomes for pilot and non-pilot territories using data for 2014, and comparing to baseline data for 2013.

Figure 7: Outcomes for pilot and non-pilot sites, 2013 and 2014



We first compare the outcomes for the pilot and comparison within the same year, using Student's t-test. Bootstrapping was used to help limit possible bias in using t-tests due to our small sample size and the possibility that the data are not normally distributed.[30] Bootstrapping is a process of repeatedly sampling with replacement from existing data. The descriptive statistics for the main outcome and control variables are presented in Table 8 separately for the years 2013 and 2014.

[30] We used 500 iterations for each t-test, and report the bias-corrected and accelerated results.

Table 8. Description of the results before and after the model was implemented

Variable	2013				2014			
	Pilot areas	Non-Pilot areas	Difference	p-value	Pilot areas	Non-Pilot areas	Difference	p-value
All Cases (Trust Cabinets and PHC units)								
Total number of people tested for HIV	503 ± 422	570 ± 481	-67	0.80	1745 ± 901	503 ± 357	1241	<0.001 ***
Total number of HIV positive cases found	13 ± 9	4 ± 5	8.4	0.009 ***	27 ± 13	4 ± 4	22.4	<0.001 ***
Proportion of people tested found positive	3% ± 2.1%	1% ± 1.6%	2%	0.04 **	2% ± 0.4%	1% ± 1.3%	0.5%	0.48
Number of Most at Risk people tested	155 ± 147	206 ± 260	-51	0.71	1034 ± 235	156 ± 205	878	<0.001 ***
Population	56000 ± 16000	30000 ± 11000						
Trust Cabinets only								
Total number of people tested for HIV	503 ± 422	570 ± 481	-67	0.80	138 ± 112	503 ± 357	-366	0.06*
Number of people from key population tested	155 ± 147	206 ± 260	-51	0.71	69 ± 71	156 ± 205	-88	0.41

*Significance notation: * = p<0.1 (suggestive but not conclusive results); ** = p<0.05 (statistically significant difference in means at a 0.05 error level); *** = p<0.01(statistically significant difference in means at a 0.01 error level).*

Interpretation of the results presented in the Table 8:

Total number of people tested for HIV: the average number of people, who received an HIV test at the Trust Cabinets in 2013, was 503 (SD=422) in pilot regions versus 570 (SD=481) in non-pilot regions, and the analysis of means showed no statistically significant difference between the two areas. The number of people who received HIV test after the model was implemented in 2014 is statistically significantly higher in the pilot regions compared to the non-pilot regions (p<0.001), and overall 1745 (SD=901) people received HTC per rayon/municipality, on average, in the pilot regions. At the same time, the average number of people tested in pilot regions at the Trust Cabinets decreased more than 3.5 times to 138 (SD=112) people tested per region (on average).

Total number of HIV positive cases found: the average number of HIV cases detected per region among people tested for HIV was different for pilot regions compared to non-pilot regions in both 2013 and 2014. In 2014, however, after the model was implemented, the average number of positive cases detected in pilot regions increased from 13 (SD=9) cases in 2013 to 27 (SD=13) cases in 2014, while in non-pilot regions the average number of cases detected remained unchanged.

Proportion of people tested found positive: the proportion of people with positive result out of the total number of people who received HTC was higher in pilot regions, both in 2013 and 2014. The difference was statistically significant in 2013 (p=0.04), but not in 2014. The average proportion of tested positive was 3% (SD=2.1%) in pilot regions compared to 1% (SD=1.6%) in non-pilot regions in 2013. In 2014, this was 2% (SD=0.4%) and 1% (SD=1.3%), respectively.

Number of people from key populations tested: the average number of people tested from at risk populations[31] did not significantly differ between the pilot and non-pilot regions on 2013. In 2014, the

[31] See description of key population groups in the introduction to the report.

pilot regions tested on average 1034 (SD=235) people at risk of HIV infection, compared with 156 (SD=205) on average in comparison areas (p<0.001).

4.4.1 Analysis of the comparative change from 2013 to 2014 between pilot and non-pilot areas

To evaluate the results of the model implementation, we analyze whether the change between 2013 and 2014 was comparable between pilot and non-pilot areas for each of the outcome indicators (number of tested, number of HIV cases detected, the proportion of HIV positive results among tested, and the number of most-at-risk people tested).

To address the issue of small numbers in rank orders, the Poisson regression was applied. The goodness-of-fit test was used to check whether Poisson regression is applicable for testing each parameter. If Poisson was shown to be inappropriate, a negative binominal regression was used. As the population of rayons/municipalities largely influenced the number of people tested, it was included as the exposure in order to maximize the usefulness of these models. See table 9 for the results of the analysis.

Table 9. Difference in differences estimate comparing pilot to nonpilot rayons

Variable	IRR (95% CI)	z-score	p-value
Total number of people tested for HIV	3.52 (2.09 to 5.94)	4.71	<0.001***
Total number of HIV positive cases found	2.01 (1.12 to 3.61)	2.33	0.02**
Proportion of people tested found positive	0.44 (0.23 to 0.84)	-2.48	0.01**
Number of people from key populations tested	8.004 (3.62 to 17.69)	5.14	<0.001***

The results of the regressions are presented as incidence rate ratios (IRR),[32] and can be interpreted as the proportionate increase (or decrease) in results associated with the pilot. Therefore, we may interpret the results of implementing the model as following:

- There was a 3.52 times increase in the number of HTC per capita in pilot regions compared to non-pilots after the implementation of the program;
- There is about 2 times increase in the number of HIV positive cases detected (per capita) in pilot regions;
- The proportion of people found positive among those tested in pilot areas was just under half that of the comparison areas;
- There is an 8 times increase in the number of people who received HTC from the most-at-risk groups in pilot regions (per capita) as compared to the comparison areas.

All four of these results are statistically significant at p<0.05.

[32] The IRR is the ratio of incidence rates, with the comparison area as the denominator. For example, if the comparison areas had 15 HIV tests per 1,000 people per month (on average), and the pilot area had 30 HIV tests per 1,000 people per month (on average), the IRR would be calculated as 30/15 = 2.

4.4.2 Analysis of regional characteristics within pilot regions

We also looked at the variance among key variables of interest within participating PHC units, and ran regressions with available characteristics of different PHC units as predictors of the selected outcomes: total number of people tested for HIV; total number of HIV positive cases found; proportion of people tested found positive; and number of people from key populations tested.

For each participating PHC unit[33] we included the following characteristics as predictors in the regression model:

- Region where PHC unit is located (Bobrovytsky or Chernigivsky rayon, Nizhyn or Pryluky city);
- Supplier of tests (CHAI or Alliance);
- Residence (rural or urban);
- Location (based at the policlinics or at separate location);
- Distance to the nearest Trust Cabinet in km;
- Distance to the AIDS center in km;
- The catchment population of the facility for the ages 15-49 years;
- Years of professional experience of the PHC physician;
- Years of professional experience of the PHC nurse.

In general, for the variables of interest we found that the characteristics of PHC units could help to explain 14-30% of variation in results of the implementation of the model (see Table 10).

Table 10. Regressions of factors among PHC Units

Variable of interest	% of explained variation	Significant predictors of the outcome*
Total number of people tested for HIV	26%	PHCs located at policlinics tested more people
Total number of HIV positive cases found	19%	No
Proportion of people tested found positive	14%	No
Number of Most at Risk people tested	30%	PHCs located at policlinics, and those received tests from the Alliance, tested more people from most-at-risk groups

* *Significance at p<0.05*

[33] PHC unit is a team of PHC physician and nurse(s) providing HTC to their catchment population. There could be more than one PHC unit at PHC ambulatory.

4.5 Costs

All costs associated with the work of the Trust Cabinets are included, although we allocated some of the costs to other services if appropriate (e.g., for antiretroviral therapy), and a baseline ICER was calculated specifically for HTC services available through the network of such facilities. (We consider that Trust Cabinets are incremental to HIV testing through ANC, PMTCT, blood donation, and in-patient wards).

It was not expected that the implementation of the model would require an increase in human resources at any level of care, but redistribution of functions was expected as recommended in the Appendix E. Increased infrastructural costs are similarly not envisaged, but all costs that occurred were analyzed, and counted if considered relevant to the implementation of the model.

4.5.1 Cost assessment

The assessment of costs was based on accounting costs, considering financial expenditures and costs incurred or agreed to be paid (i.e., accrued) within a financial year (January 1st-December 31st).

For the assessment of the costs associated with the current model, the costs of the Trust Cabinets (current HTC providers for general populations) in the intervention sites were analyzed retrospectively for one financial year before the implementation of the pilot. The baseline calculation was used to control the potential changes in costs related to the difficult political situation and the financial crisis in 2014. After one year of implementation, the financial costs of the same Trust Cabinets were re-assessed and included as a part of the total costs for the HIV service provision in the intervention rayons and municipalities.

As Trust Cabinets are structural units within polyclinics, the step down approach was used to allocate capital and recurrent costs of the polyclinics to the specific activities of the Trust Cabinets. For the assessment of the costs of the PHCs participating in the study, the ingredient-based costing was applied, where each HIV-service related component of activity was considered, including capital and recurrent costs.

Time estimates were used to weight HTC related costs in the total costs of PHCs. The estimates for different components of HIV service provided were collected through a questionnaire administered to all PHC units participating in the study in the end of the implementation of the pilot. The components of the HIV services provided at the level of PHC used for time estimates included:

- HIV pre-test counseling
- HIV testing procedure if one rapid test is applied (including paperwork)
- HIV testing procedure if two rapid tests are applied (including paperwork)
- HIV post-test counseling if the result is negative
- HIV post-test counseling if the result is positive
- Referral of the PLHIV and follow-up with the Trust Cabinets or AIDS Center.

The time estimates were calculated based on responses from all 65 PHC units. The mean and median averages were both assessed to get the best approximation of the time needed for each procedure related to HTC service (see results in the Table 11).

Table 11. Time estimates for PHC units related to the provision of htc service

Variable	Mean time estimate (min-max), minutes	Median time estimate (min-max), minutes	Used for costing	Physician engagement	Nurse engagement

Regular visit of any patient, excluding those coming for HTC	14.8 (13.2–17.3)	12.5 (10.0–15.0)	15	15	15
Duration of pre-test counseling	15.3 (14.2–17.8)	12.5 (15.0–15.0)	15	15	0
Duration of HIV test type I procedure, (blood test)	14.7 (12.9–18.1)	17.5 (15.0–20.0)	15	0	15
Duration of post-test counseling if the result is HIV-negative	9.8 (13.3–15.1)	7.5 (15.0–15.0)	10	10	0
Duration of HIV test type II procedure, (blood test)	14.6 (14.3–17.8)	17.5 (15.0–20.0)	15	0	15
Duration of post-test counseling if the result is HIV-positive	18.3 (16.1–20.8)	17.5 (15.0–20.0)	18	18	0
Time needed to record the results and the HTC procedure in all forms and journals for HIV-negative result	13.3 (14.4–17.0)	12.5 (15.0–17.5)	13	3	10
Time needed to record the results and the HTC procedure in all forms and journals for HIV-positive result	19.1 (17.3–21.6)	22.5 (20.0–25.0)	20	5	15
Communication with the AIDS Center or Trust Cabinet (per month)	12.8 (12.1–20.5)	12.5 (15.0–22.5)	12.5	12.5	0
Time needed to refer HIV-positive patient to Trust Cabinet (motivation, arrangements and follow-up)	48.1 (29.3–74.1)	37.5 (15.0–60.0)	45	45	0
Time needed to fill-out the reporting forms (per month)	47.7 (31.8–63.6)	45.0 (30.0–60.0)	45	20	25
Average time per HTC with negative result, min				**31.6**	**27.8**
Average time per HTC with positive result, min				**86.6**	**47.8**

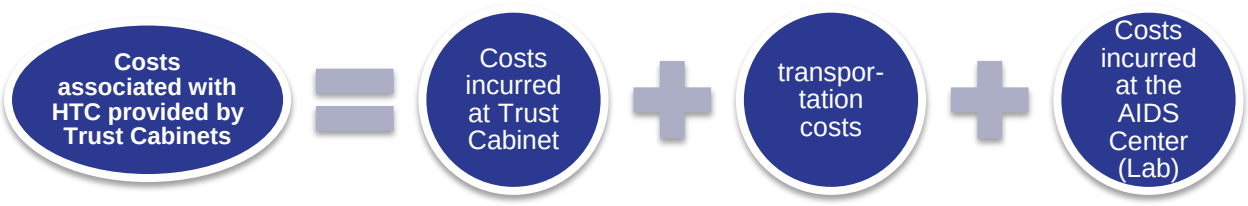
All estimates were used to calculate the estimated total time for the provision of the HTC service, including the necessary engagement of the PHC nurse and physician for different procedures. Time estimated for the month period (communication with the AIDS Center of Trust Cabinets, and time for reporting) were divided by the average number of 9 HTC tests conducted per month by a PHC unit. As a result of these calculations, the total time needed to provide one HTC service for a negative test is about 32 minutes for a PHC physician, and 28 minutes for a PHC nurse. If the result of the test is HIV positive, the duration of HTC increases to 87 minutes of physician time, and 48 minutes of nurse time. This almost 3 times increase in the physician time is mainly explained by the longer lasting post-test counseling, and the time to ensure referral of an HIV-positive patient to effectively link them to HIV care. The 2 times increase of a nurse time is mainly explained by the need to conduct the type II confirmation test, and more time requested to fill out all mandatory forms and journals.

4.5.2 Baseline calculations

Because there was no data or studies accessing the costs (or cost-effectiveness) of HTC in Ukraine, the Project conducted its own calculations for the territories participating in piloting of the model. Baseline data was collected to understand the costs of the work of Trust Cabinets in pilot regions of Chernigiv Oblast.

To allocate costs incurred by the operation of Trust Cabinets, ingredients-based costing was applied. The total cost of the HTC provided was calculated based on costs of the operation of the Trust Cabinets within the municipal or rayon policlinics, costs of transportation of blood samples and test results, and costs incurred at the AIDS Oblast Center laboratory.

Figure 8: Elements of costs associated with HTC provided by Trust Cabinets

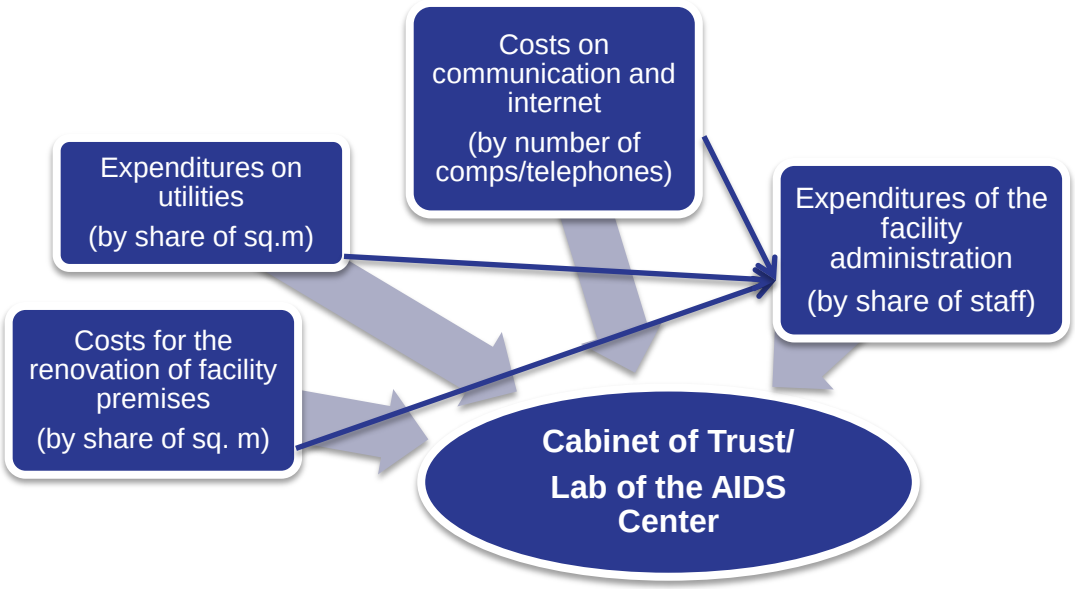


As there was no system in place in health care facilities of the pilot regions to calculate costs incurred at the level of different departments within policlinics, the total actual costs of the facility were consecutively allocated using a simplified step-down cost accounting method (general costs for the operation of the facility are consecutively allocated to the facility administration and Trust Cabinet). To extract and allocate costs, the data collection tools designed for the purpose of this study were applied for the Trust Cabinets and laboratory of the Oblast AIDS Center.

The logic of the step-down allocation of costs are as follows:

1) Clients of the Trust Cabinet do not require hotel services, including the use of kitchen, laundry and other axillary services, and therefore costs of these services were not included.
2) Clients of the Trust Cabinet do not use ambulance and emergency services, therefore expenses for these services were also excluded.
3) The service of the Trust Cabinet is available without preliminary appointments/ use of registration service of policlinics; expenses of the registration were not included.
4) Costs for the renovation of facility premises (in general) were allocated according to the square meters of the Trust Cabinet and facility administration compared to the whole facility.
5) Expenditures on utilities (electricity, water, heating, other) were allocated according to the square meters of the Trust Cabinet and facility administration (compared to the whole facility).
6) Costs on communication and internet were allocated according to the number of phones/computers at the Trust Cabinet and administration (compared to the whole facility).
7) Expenditures of the facility administration (policlinics managers, accounting department, statistics, etc.) were calculated as a sum of salaries, reallocated costs for utilities and renovation, communication, redistributed to the Trust Cabinet using the coefficients based on the share of staff at Trust Cabinets to the total number of staff working in the policlinics.
8) Costs of serving regular patients with known HIV status were calculated based on average costs per one ambulatory visit to the policlinics and excluded from the total costs of the Trust Cabinets for HTC.

Figure 9: Allocation of costs scheme



Transportation costs for the delivery of blood samples from the Trust Cabinet to the AIDS Center laboratory were calculated as a share of mileage and frequency of transport communication with Oblast facilities in total mileage of the polyclinics. The distance to the Oblast AIDS Center explains the difference in the transportation costs, as well as the frequency of sending blood samples to the Oblast AIDS Center.

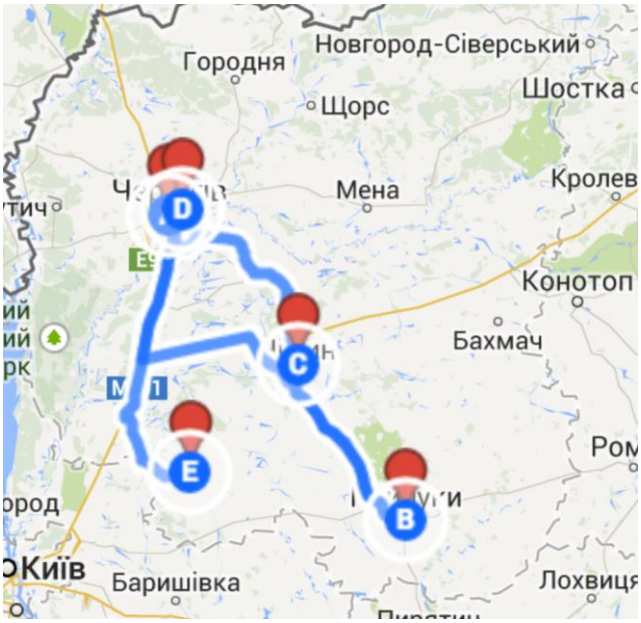
For further reference, see Figure 10. The distances from the Trust Cabinets located in pilot regions to the AIDS Center are:

- Bobrovytsky Trust Cabinet (E) to the AIDS Center (A): 105 km
- Chernigivsky Trust Cabinet (D) to the AIDS Center (A): 6 km
- Nizhyn Trust Cabinet (C) to the AIDS Center: 90 km
- Pryluky Trust Cabinet (B) to the AIDS Center: 175 km

The expenses and performance data of health facilities and Trust Cabinets in pilot regions is provided in the Appendix C to this report.

As there was a considerable difference for the costs of HTC service among Trust Cabinets per one HIV positive case detected, and there is a wide variance of transportation costs per 1

Figure 10: Location of the AIDS Center and Trust Cabinets in pilot regions



blood sample transported (including received results) to the Oblast AIDS Center. Across all four pilot regions, weighted average costs were recalculated (Table 12), based on the number of patients at each Trust Cabinet.

Table 12. Weighted costs of Trust Cabinet's HTC services and transportation costs

Trust Cabinet Ratios	Weighted costs for all pilots	Range	Weighted costs for all pilots	Range
	2013, UAH		2014, UAH	
Costs per one HTC episode	**79.4**	[42.0 – 180.6]	**231.4**	[140.6-569.2]
Costs per one positive detected	**4099.0**	[3208.8 – 6031.2]	**2997.7**	[2290.1-5102.9]
Costs per one sample transported to the AIDS Center	**11.1**	[1.14 – 46.40]	**12.4**	[2.31-47.7]

To calculate costs for the AIDS Center Laboratory, which is a centralized unit responsible for screening and verification HIV tests for the entire oblast, a similar strategy of costs allocation of the Laboratory service at the Oblast AIDS Center was applied (see Appendix D for costs associated with Laboratory services). As the Laboratory at the AIDS Center is conducting various types of lab examinations, our task was to attribute costs specifically to screening and verification ELISA/WB tests, and this was estimated using the proportion of lab staff's workload associated with screening and verification ELISA and Western Blot (WB).

The results of the calculation of costs associated with the performance of the AIDS Center laboratory are provided in Table 13. As the number of screening tests was 1.1 more than the number of samples tested, and the number of verification examinations of blood was repeated on average 4 times, the corresponding coefficients were applied to calculate the adjusted cost per screening and verification tests.

Table 13. Costs associated with HIV screening and verification

Lab Ratios	2013, UAH
Costs per screening ELISA test	11.3
Costs per verification ELISA/WB test	36.9
Costs per screening ELISA test adjusted for repeated tests	12.4
Costs per verification ELISA/WB test adjusted for repeated tests	145.1
Costs per 1 HIV + detected (from all samples)	1198.3
Costs per 1 HIV + detected (Trust Cabinet samples)	**1407.7**

The total costs related to the provision of HTC service by the Trust Cabinets in the four pilot regions, and the calculation of total costs per one positive case detected are presented in the Table 14 below for the year 2013.

Table 14. Total costs of HTC provided by Trust Cabinets before and after the model was implemented

Ratios	Ingredients	Weighted costs for 4 regions, UAH **(2013)**
per one HTC episode	Trust Cabinet costs + transportation + screening ELISA	**102.96**
per one HTC episode if found HIV+	Trust Cabinet costs + transportation + screening ELISA + verification ELISA/WB	**248.01**

per one positive detected	Total Trust Cabinet costs associated with HTC + all transportation costs + lab costs associated with testing of all samples sent, recalculated per number of HIV+ detected by Trust Cabinets	**5506.69**

4.5.3 Cost in 2014

The cost-effectiveness analysis of the model implied the need to calculate the additional costs related to the implementation of the model at the PHC level. These costs include the expenditures at the PHC facilities related to the HIV counseling and testing, the expenditures related to training of PHC physicians and nurses, and the costs of the supplies. The costs incurred at the Trust Cabinets level in 2013 are adjusted using 2014 financial data (as described below). The detailed description of steps and results of calculations are provided in the below sections.

4.5.3.1 Costs incurred at the PHC level

For the calculation of facility expenditures related to seeing patients to provide HIV testing and counseling service, the total facility costs (PHC Center) were allocated to two types of activities conducted by PHCs: seeing patients at the PHC facilities on an ambulatory basis, and seeing patients at their homes. For each PHC Center, the allocation of time for each type of activity, and for bookkeeping was requested for both physicians and nurses. The management and administration costs were allocated to these two types of activities equally. The expenses on utilities were allocated to patients' visits on an ambulatory basis, and the transportation costs to seeing patients at their homes. The number of patient visits, and the number of patients visited at home, was used to calculate the average duration of seeing the patients for each type of visit, and thus the average costs associated with such visits. In addition, for the further calculations, the costs per 1-minute time of the physician and 1-minute time of the nurse with all overhead costs included were calculated. The results are presented in Table 15.

Table 15. Facility-level costs of PHC

Indicator	Bobrovytsky rayon	Chernigivsky rayon	Pryluky	Nizhyn	Weighted average for pilot regions
Time to see 1 patient visiting ambulatories, min (physicians)	10.71	13.81	7.54	8.71	10.05
Time per 1 patient visiting ambulatories, min (nurses)	16.76	47.56	13.96	16.70	23.40
Time per 1 patient visit at home, min (physicians)	60.49	25.30	23.41	36.84	34.59
Time per 1 patient visit at home, min (nurses)	94.69	87.16	43.36	70.61	80.50
Time for bookkeeping by physician per 1 patient, min	4.09	3.01	2.60	2.74	3.06
Time for bookkeeping by nurse per 1 patient, min	7.38	8.63	5.98	7.82	8.23
Total cost of 1 min physician time to see patients on an ambulatory basis	**0.97**	**1.00**	**0.58**	**0.49**	**0.87**
Total cost of 1 min nurse time to see patients on an ambulatory basis	**0.77**	**0.38**	**0.27**	**0.28**	**0.44**
Total costs per 1 visit of the patient on an ambulatory basis	**32.86**	**38.26**	**11.20**	**12.42**	**25.31**
Total costs per 1 visit at the patient's home	140.94	64.88	28.25	41.14	71.76

As the calculation presented in Table 15 suggests, the average duration of the patient's visits to ambulatories lasts 10.5 minutes on average across the four pilot regions. However, the survey among PHC personnel showed that provider estimated the average physician time for a regular patient visit to be 15 minutes. We assume that the other time estimates (for HTC specific services) are also subject to time overestimation, and, therefore, adjustments were applied to bring the time estimates in line with the statistical average of the duration of the patient's visit. For the nurses, we found that a duration of time for a patient's visit was higher than reported, and thus adjust the time spend to be 23.4 minutes on average (compared to 15 minutes based on the survey), and thus we adjust the time estimates upward. These adjustments are shown in Table 16.

Table 16. Adjusted time estimates and HTC-related costs at PHC units

HTC-related procedures at PHC	Physician engagement, min	Nurse engagement, min	Cost of physician time, UAH	Cost of nurse time, UAH	HTC-related costs for a negative result, UAH	HTC-related costs for a positive result, UAH
Duration of pre-test counseling	10.1	0	8.71	0.00	8.71	8.71
Duration of HIV test type I procedure, (blood test)	0	23.4	0.00	10.33	10.33	10.33
Duration of post-test counseling if the result is HIV-negative	6.7	0	5.80	0.00	5.80	5.80
Duration of HIV test type II procedure, (blood test)	0	23.4	0.00	10.33	10.33	
Duration of post-test counseling if the result is HIV-positive	12.1	0	10.45	0.00	10.45	
Time needed to record the results and the HTC procedure in all forms and journals for HIV-negative result	3	10	2.60	4.41	7.01	7.01
Time needed to record the results and the HTC procedure in all forms and journals for HIV-positive result	5	15	4.33	6.62	10.95	
Communication with the AIDS Center or Trust Cabinet (per month)	12.5	0	10.82	0.00	10.82	1.20
Time needed to refer HIV-positive patient to Trust Cabinet (motivation, arrangements and follow-up)	45	0	38.96	0.00	38.96	
Time needed to fill-out the reporting forms (per month)	20	25	17.32	11.04	28.35	3.15
Total time per HTC (negative result), minutes	**23.37**	**36.18**		**Total cost estimate for HTC session**	**36.20**	**99.88**
Total time per HTC (positive result), minutes	**75.73**	**64.58**				

The proper disposal of waste was also mentioned by PHC practitioners as one of the HTC-related procedures. However, the assumption was made that the waste materials are all utilized in a regular way, and the time for this is already included into staff's timing for servings one patient, and these costs were not counted separately.

Another component of HTC-related costs at the PHC level is related to the training of PHC staff to be able to provide HTC service. The calculation of the training-related costs per one HTC session is provided in Table 17 for the physician training, and in Table 18 for the training of a nurse. We excluded from these calculations the project-related costs for the organization of the training, and per diem and transportation reimbursement for project specific staff, because if the training would be provided as the regular qualification improvement course, these costs would not be incurred. However, we included

both the participation fee costs and the salary paid by the employer, because these represent the real-life costs associated with the training.

Table 17. Costs per HTC service associated with PHC physician training

Physician training components	Costs, UAH
Fee for participation	975
Materials used for the training (2 HIV tests) and hand-outs	56.5
Salary paid for the period of participation in the training	1775.72
Total per 1 physician	2807.22
Total costs depreciated for 5 years	561.44
Per one HTC session	**5.20**

Table 18. Costs per HTC Service associated with PHC nurse training

Nurse training components	Costs, UAH
Speakers fees	137.14
Materials used for the training (2 HIV tests) and hand-outs	56.5
Salary paid	213.52
Total per 1 nurse	407.17
Total costs depreciated for 5 years	81.43
Per 1 test	**0.75**

The totals costs associated with the training were depreciated for 5 years, because it is expected that the PHC physician and nurse may require training refreshment after 5 years of providing HTC; the total training costs were subsequently divided by the average number of tests conducted by one PHC unit participating in the study. The total training costs associated with an HTC session is UAH 5.95.

The final component of HTC-related expenditures is costs associated with the utilization of supplies and HIV test kits for HTC service. For the purpose of the commercial interests, we will not provide the detailed calculation of the costing of supplies, but the elements and the logic of allocation are presented in Table 19 below.

Table 19. Costs of suppliers allocation per HTC session

Materials	Rule for calculation
Test type I	Both, HTC positive and negative result
Test type II	Only for HTC positive result
Gloves	One pair per HTC positive and negative result
Masks	One per HTC positive and negative result
Disinfectants	Total amount allocated to the number of tests conducted
Capacities for disinfection	Total amount depreciated for 3 years and allocated to the number of tests conducted
Forms and journals (recording and reporting)	Total amount depreciated for 3 years and allocated to the number of tests conducted
Total cost for HTC, negative result (UAH)	**11.42**
Total for HTC, positive result (UAH)	**22.62**

As HIV test kits were received from two different partners (CHAI and International HIV/AIDS Alliance), the average price for HIV test type II and II were taken into calculation. The total cost of materials used to perform 1 HTC if the result is negative is UAH 11.42, and if the result of the test is positive, the cost is UAH 22.62.

Table 20. Costs of suppliers allocation per HTC session

Cost category	HTC (negative)	HTC (positive)	Difference for HTC positive	Full HTC costs
Facility-associated costs	36.20	99.88	63.68	236153.08
Training costs	5.95	5.95	0.00	38263.14
Materials	11.42	22.62	11.20	74028.11
Total	**61.45**	**136.33**	**74.88**	**348444.33**
PHCs performance				
Number of people tested	6428			
Number of HIV cases	54			
PHC costs per 1 HIV case detected	**6,452.67**	(Full HTC-related costs divided by the total number of positive cases detected)		
Transportation of the blood sample for verification test	12.40			
Lab expenses for the verification test	194.37			
Total cost per 1 HIV case detected	**6,659.44**			

4.5.3.2 Adjustment of the 2013 costs at the Trust Cabinet and AIDS laboratory

As the performance of the Trust Cabinets was influenced by the implementation of the model, and the number of people tested at the Trust Cabinets decreased substantially in 2014 compared to 2013, the baseline 2013 costs per one positive result detected at the level of the Trust Cabinet were used for the calculation of the cost-effectiveness model. However, some adjustments to the prices of 2013 were made to reflect the potential influence of the inflation on certain expenditures of the facilities where Trust Cabinets were operating.[34]

The same types of adjustments were applied to the performance of the AIDS Center Laboratory, as some prices for the materials went up in 2014. The adjusted ratios are presented in the table 21.

Table 21. Adjusted baseline costs

Ratios	Ingredients	Baseline costs, UAH	Adjusted baseline costs, UAH
per one HTC episode	Trust Cabinet costs + transportation + screening ELISA	**102.96**	**113.00**
per one HTC episode if found HIV+	Trust Cabinet costs + transportation + screening ELISA + verification ELISA/WB	**248.01**	**290.78**

[34] Ideally, all costs would be subject to inflation, but as in 2014 salaries and some other expenders decreased due to financial shortcuts, then only items subject to inflation were adjusted.

per one positive detected	Total Trust Cabinet costs associated with HTC + all transportation costs + lab costs associated with testing of all samples sent, recalculated per number of HIV+ detected by Trust Cabinets	**5506.69**	**6693.94**

4.5.3.3 Costs at the Trust Cabinet and AIDS laboratory in 2014

Activity in the Trusts Cabinets declined in the pilot areas in 2014 as compared to 2013, resulting in a different costing structure. The same analysis as done at the baseline was repeated at the end of 2014. The results indicate that the cost per one HIV case detected in 2014 was 4455.91 UAH. The cost per one HIV case detected decreased as compared to 2013 due to the combination of two facts: the Trust Cabinets overall tested fewer people in 2014 than in 2013, but the number of HIV positive cases found remained almost the same. Thus, lower testing costs resulted in the same number of cases found, and cost per case detected declined.

4.6 Cost-effectiveness analysis

For the calculation of the incremental cost-effectiveness ratio (the ratio of the change in costs to incremental benefits), the change of total costs due to the implementation of the model was compared to the total number of new HIV cases detected after the model was implemented. See Table 22 for the details of ICER calculation.

Table 22. ICER of the model (in UAH)

Year	Total positive detected	Total HTC expenditure of Trust Cabinets	Total HTC expenditure of PHCs	Total cost	Cost per Positive detected	ICER
Method of calculation	Sum of cases detected at Trust Cabinets and PHC facilities (no cases detected at PHC in 2013)	Total number of HIV cases detected at Trust Cabinets in the oblast multiplied by average costs per positive case detected	Total number of HIV cases detected at PHCs in the pilot regions multiplied by average costs per positive case detected	Sum of expenditures at Trust Cabinets and PHCs	Total cost divided by number of positive cases detected	(Total costs in 2014 minus total costs in 2013)/(total positive detected in 2014 minus total positive detected in 2013)
2013	50	334,697	0	334,697	6,693.94	-
2014	107	236,163	359,610	595,773	5,567.97	**4,580.28**

The resulting ICER of UAH 4,580.28 per one additional HIV positive result detected means that the costs for detection of each additional HIV case with participation of PHCs in HTC provision is lower than the cost per case detected in the pilot regions before the implementation of the model, and therefore we may conclude that in general the new model is cost-efficient in terms of detecting HIV cases. However, although the model is more cost-efficient, affordability issues remain because the PHC

integration program costs about 260,000 UAH more than the Trust Cabinet only model. This is because, with the implementation of the new model, the decrease in the costs per detected HIV case at Trust Cabinets decreased, but the required additional investments on the PHC side more than offset this decrease.

4.6.1 Sensitivity and Uncertainty Analysis

We conducted sensitivity and uncertainty analyses to assess the changes in the results if ranges around costs and effectiveness are applied. To define plausible ranges, we use the minimum and maximum costs observed across the four pilot areas for costs at the Trust Cabinets and for the costs at the PHC level. For the number of positive cases detected, we use the 95% CI range of the results of regression (IRR) (as given in Table 9). The resulting ranges are shown in Table 23.

Table 23. Uncertainty Ranges for model components

Category	Average (best estimate)	Lower bound	Higher bound
Cost per HIV positive case detected by Trust Cabinets in 2013, UAH	6,693.94	4,886.33	7,931.87
Cost per HIV positive case detected by Trust Cabinets in 2014, UAH	4,455.73	3,748.27	6,561.11
Cost per HIV positive case detected by PHCs, UAH	6,659.44	4,890.77	8,787.43
Incidence rate ratio for the positive cases found	2.01	1.12	3.61
HIV cases yield of the model	107	59	191

The sensitivity analysis was conducted for two variables (Trust Cabinet costs in 2014 and the number of cases detected). For the sensitivity analyses the minimum/maximum/best estimates are used to show different ICERs (see Table 24) based on the values used.

Table 24. Sensitivity ranges for ICER at different scenarios of HIV cases detected

Sensitivity analysis	Estimated ICER		
	Lowest cost	Best (average) estimate of costs	Highest costs
Low number of additional people positive detected	Cost saving	Cost saving	7,307
Best estimate of additional people positive detected	2,247	4,580	8,554
Highest number of additional people positive detected	3,846	5,866	8,740

With the highest possible costs, the model with PHC engagement may be a little more expensive per case detected than the previous model of providing HTC only through Trust Cabinets (i.e., 6,694 UAH). If there were a low number of cases detected, the PHC model would detect more cases at lower costs than the previous model with Trust Cabinets, and have a lower total cost. This, however, is due to the lower costs at Trust Cabinets in 2014 than in 2013 (as with PHC participating in HTC provision, Trust Cabinets were doing more targeted testing).

The maximum and minimum values for the ICER were calculated using the Monte-Carlo simulation with all uncertainty parameters randomly distributed within 100 iterations.

Table 25. Uncertainty ranges for ICER based on plausible ranges of input variables

Uncertainty analysis	Best estimate	Low at 95% CI	High at 95% CI
ICER	4,580	(4,708)*	8,170

*Represents lower total costs and a higher number of cases detected; i.e., the program is cost-saving.

The uncertainty analysis shows similar results to the sensitivity analyses (with the range extending form possibly cost saving to possibly slightly more expensive than the previous model with HTC provided through Trust Cabinets).

The difference between the two analyses is that in the uncertainty analysis, the variables are independent (e.g., if costs are high at PHC, they could be low, medium, or high at the Trust Cabinets), whereas in the sensitivity analysis they are correlated (if cost are high at PHC, we assume costs are also high at Trust Cabinet and the opposite as well). The uncertainty analysis suggests that the higher cost scenarios from the sensitivity analyses are unlikely.

We also assessed the specific ingredients of the cost per HIV positive case detected at the PHC level. One area of potentially increasing the efficiency of the model is the time spent by PHC practitioners for recording and reporting HIV cases. Even with change of time consumption of nurse time from 10 to 5 minutes spent to record results of the HTC result, the ICER would decrease by UAH 249.20.

Additionally, if the time at the PHC facility to provide HTC would equal to the average time of a patient's visit to the PHC ambulatory (13 minutes of physician time and 32 minutes of nurse time, including bookkeeping), and will last twice as longer if the result of the test would be positive, the ICER would decrease to UAH 3315.48 per HIV positive case detected.

The ICER is also dependent on the number of HIV cases found. If the detection rate of HIV cases among all tested at the PHC level increased from the observed 0.84% to 1%, the ICER would decrease to UAH 3433.63, which is almost two times lower than the cost per HIV positive case detected before the model was implemented.

5. DISCUSSION

Information on the effectiveness and cost-effectiveness of HIV testing and counseling strategies is scarce globally and absent for Ukraine[35]. The results of the HTC service implementation at the PHC level in addition to the HTC service available through the network of Trust Cabinets working in general polyclinics showed a significant 3.5 times increase of the number of people who received HIV testing. The increase was especially observed in the number of population from key population groups who received HTC service, which increased more than 8 times. The number of HIV cases found almost doubled, but the detection rate (among those tested) decreased.

The cost-effectiveness of the model in Chernigiv region of Ukraine, which belongs to the group of regions with medium-level HIV prevalence, shows that the ICER is lower than the average cost per case detected before the model was implemented. Thus, from an efficiency point of view it is desirable to further engage PHC units into provision of HTC services to population. At the same time, affordability issues remain, because, although the model is more efficient than the provision of HTC services through Trust Cabinets only and the scale-up of the model would increase efficiency of the Trust Cabinets, it likely will require additional investments.

[35] A PubMed search with key words "cost" AND "effectiveness" AND "HIV" AND "Ukraine" produced a result of only six studies (as of March 2015). Of these six studies, four are relevant to the topic, but only two contain CEA analyses conducted specifically for Ukraine. Both of the CEA studies focused on harm reduction programs. The studies of cost-effectiveness of HIV testing strategies are mostly focused on African countries and the US, and only one recent CEA study is published about HTC provided by PHC units in India.

6. NEXT STEPS

The model of HTC services provided by PHC in four regions of Chernigiv oblast was supported by local stakeholders, and with the provided supplies (HIV test kits, gloves, disinfectants) from the International HIV/AIDS Alliance, as well as with technical assistance from the oblast AIDS Center and other international partners, it will be possible to continue its implementation throughout 2015. It is desirable to monitor the results of the second year implementation of the model.

7. CONCLUSIONS AND RECOMMENDATIONS

The evaluation of the cost-effectiveness of HTC service integration at the PHC level provides useful information for decision making and planning future implementation research on HIV interventions. In general, the implemented model of HTC provided at the PHC level increased the number of people tested and the proportion of people tested from key populations (by recommendation from the health care provider), in contrast to the baseline situation when the majority of people who applied for testing were self-applying for this service. The implementation of the model also allowed doubled the number of HIV cases detected in the pilot regions before the model was implemented. The incremental cost-effectiveness ratio of the model shows that the cost per additional HIV cases detected were lower than the baseline costs, when the HTC service was mainly provided by Trust Cabinets.

The recommendations based on the results of the implementation of the model address the model set-up, its implementation, recording and reporting procedures, organization of the referrals, financial aspects, and recommendations for the future studies.

The following recommendations are based on the results of the study implementation, they were discussed and agreed with counterparts in Chernigiv during the final steering meeting of the HFG Project, and therefore would be useful to consider for the further implementation of the proposed model:

- **More attention to screening:** PHC practitioners are seeing many patients, and naturally when the HTC service is provided free-of-charge, many patients would be interested to know their HIV status even if they are low-risk. It is desirable that PHC provide opt-out HIV counseling to all their patients, but make decisions to offer HIV testing for patients that are most likely have risks of contracting HIV. Focusing on testing people with risky behaviors or clinical indications may ensure higher yield of HIV cases detected and thus increase the cost-effectiveness of the approach.
- **Case management for linkage of patients to HIV care:** one of the most time-consuming procedures when the result of HIV test is positive is to refer and make sure that the HIV-positive patient is linked to care. However, it would be desirable to increase the proportion of people who were successfully linked to HIV care. Where possible, the efforts of PHC practitioners should be combined with the case management projects for PLHIV, implemented by HIV service NGOs.
- **Review the possibility of using HIV rapid tests at Trust Cabinets:** in the model the traditional ELISA testing was offered at Trust Cabinets for people who applied for HTC. Given that the transport expenditures are high for remote regions, and that the HIV rapid tests do not lead to losses of patients while they are waiting for the result of the test, it is desirable to consider the possibility to use HIV rapid tests for HIV diagnostics at Trust Cabinets.
- **Taking blood samples for verification and CD4 test at once for registration of PLHIV for HIV care:** for the cases when a patient is referred from the PHC unit after two HIV rapid tests were showing positive results, it is recommended to send the blood sample for both the verification ELISA/WB test and the CD4 test in order to make timely decisions on ART initiation. This is also cost-saving, because the transportation costs would be reduced.

- **Simplify recording and reporting**: a considerable amount of time associated with delivering HTC by PHC personnel is devoted to records and reporting HIV testing and counseling sessions. The current recording and reporting requirements maybe reasonable for Trust Cabinets procedures, where the most amount of time is dedicated to seeing patients coming for HTC; however, for PHC routine care, where the volumes of patients served are much higher, the recording and reporting procedures around HTC have to be simplified to the minimum possible. This simplification may also save costs at the PHC site.
- **Coding of reasons for HIV testing:** the coding of key population groups needs to be made clear for the staff implementing the model to avoid incorrect coding and have more accurate information of the groups of people who received testing.
- **Develop standard supervision procedures:** the project has developed procedures for regular supervision of the HTC service provided at the PHC level; however, these procedures were project specific and required certain investment of time from the Clinical Advisor to the project.
- **Review the terms of reference (ToRs) for the AIDS Center, Trust Cabinets, and PHC to enable and support the provision of the new model.** The current ToRs do not include the needed coordination and implementation functions. The suggested amendments to the ToRs are provided in the Appendix E.
- **Availability of tests at PHC facilities:** while the project implemented a model with each PHC physician and nurse were trained and equipped for the provision of HTC, and also maintained their own records on HTC-related procedures. From the project prospective, it is recommended to make sure that HIV tests and books for recording of HTC-related procedures are available at PHC facilities, and staff are properly trained and have access to the materials and books to be able to provide HTC when necessary.
- **Expiry date for HIV test and other materials:** to avoid waste of tests, and unnecessary utilization of tests it is important to supply facilities with the stock of tests with expiry date at least 3 months after the end period of the expected utilization.
- **Incentives for PHCs:** the incentives for PHCs providing the HTC to their catchment population is to be considered as a part of a broader motivation for health promotion and health risks cessation. However, it is recommended that the capitation payment will be used for PHCs with risk-adjusted coefficients, so that PHCs will get additional payment if it provides care to patients with chronic conditions, including HIV, which will enable appropriate attention and case management of patients with HIV.
- **Further assessment of the model:** The project was limited in time, and could not assess effects in a longer-term period. It is recommended to repeat the evaluation after the next year of implementation in the Chernigiv region. Also, it is desirable to assess the effectiveness of the model in regions of Ukraine with high HIV burden. The potential HIV prevention effects of the model of HTC service provided by PHCs is not assessed due to limitations of the implementation phase; however, such results could be expected in a long-term perspective, and it would be valuable to assess them.

APPENDIX A: AN INFORMATIONAL POSTER ABOUT AVAILABILITY OF HIV TESTING AT PHCS

Тут можна пройти
БЕЗКОШТОВНЕ ТЕСТУВАННЯ на ВІЛ

та **отримати результат протягом 15 хвилин!**

Пройти тестування особливо рекомендується тим, хто мав незахищені статеві контакти або досвід вживання наркотиків.

Тестування проводиться конфіденційно.

Вчасне виявлення ВІЛ рятує життя!

Про проходження тесту запитайте свого сімейного лікаря

Якщо маєте питання щодо ВІЛ, телефонуйте на Національну лінію телефону довіри з проблем ВІЛ/СНІД за номером багатоканального телефону **0-800-500-451**, дзвінки є безкоштовними на всій території України зі стаціонарних телефонів

Контакти КЗ "Обласноий центр з профілактики та боротьби зі СНІДом":
вул. Щорса, 3, м. Чернігів, тел. (0462) 640-120, (0462) 660-926

Надання послуг з консультування та тестування на ВІЛ на рівні первинної медико-санітарної допомоги здійснюється в межах проекту "Фінансування і управління в сфері охорони здоров'я", що фінансується USAID

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APPENDIX B: CHECKLIST FOR SUPERVISION VISITS TO PHC SITES

Date of the visit	
Visit conducted by	
Name or # of PHC site	
Name of PHC physician	
Mobile # of physician	

1. Storage and availability of materials

Indicator	*Comments ("+" if everything is in order, additional comments)*
Keeping to the storage regimen	
Actual stocks correspond to journal notes	
Staff understands the storage requirements	
Additional remarks	*Mention types of tests used:*

2. Counceling

Indicator	*Comments ("+" if everything is in order, type in additional comments)*
Staff understands where and how to provide counseling	
Staff understands the confidentiality principles of counceling	
Staff shows understanding of post-test counseling if the result is negative	
Staff shows understanding of post-test counseling if the result is positive	

Additional remarks	

3. Testing

Indicator	*Comments ("+" if everything is in order, additional comments)*
Availability of proper space for HIV testing	
Staff understands the procedure of testing with HIV type 1 test	*- when and to where buffer is to be added* *-the volume of blood to be put to the stripe/cassetee* *-waiting time for the result*
Staff understands the procedure of testing with HIV type 2 test	
Additional remarks	

3. Record keeping

Indicator	*Comments ("+" if everything is in order, additional comments)*
Availability, completeness and accuracy of recording forms	
Availability, completeness and accuracy of reporting forms	
Records are kept in a security place	
Additional remarks	

4. Communication materials

Indicator	*Comments ("+" if everything is in order, additional comments)*
Poster/ad about the availability of rapid HIV test is present and visible	
Staff and patients are aware of the HTC service at the site	
Additional remarks	

5. Referrals

Indicator	*Comments ("+" if everything is in order, additional comments)*
Staff has contact details of the Trust Cabinet	

colleagues	
Staff has contact details of the AIDS Center	
Staff has contact details of the PLWH network	
Staff knows which documents are issued for the referral	
Staff knows how and which data should be exchanged with the Trust Cabinet for PLWH detected	
Additional remarks	

Additional explanations and practical excercises conducted (list all):

Recommendations to PHC unit:

APPENDIX C. EXPENSES AND PERFORMANCE DATA OF HEALTH FACILITIES AND TRUST CABINETS IN PILOT REGIONS

Parameters	Bobrovytsky rayon	Chernigivsky rayon	Nizhyn	Pryluky	Bobrovytsky rayon	Chernigivsky rayon	Nizhyn	Pryluky
	(2013 data in UAH)				(2014 data in UAH)			
Total spent budget of the facility	16147939	29583600	32904544	38300286	16404693	25464400	31031552	31442640
Total policlinics budget	3523979	8875080	8308316	7660057	2924750	7639320	7757888	4491877
Total salary expenditures	9835825	24903600	20068134	30717050	9953824	19921800	16517597	24954876
Total salary of physicians	2795226	4288600	5063847	6115713	2683229	4333078	4167498	6847111
Total salary of nurses	3394198	5745900	8439624	10856221	3376440	5824029	7492279	11025300
Total renovation/refurbishment	11739	98300	198785	2721325	1413	349000	671429	14147
Total utilities	1826315	4454500	2785400	4218534	1643674	3544729	2449096	3022300
Total communication	24113	21600	34820	60000	23371	23526	31314	57800
Total transportation expenditures	161849	416400	216812	182071	182080	427400	216827	395410
Resources of the health facility								
Total staff	421.25	508	883.75	759.25	436.75	445	643.25	751
Total physicians	67.5	87	154	123	70.5	89	137.75	110
Total nurses	152	223	412.5	329.5	156	244	365.75	341
Total premises, sq. m	8851	23360	16153.2	19154	8851	23360	15325.9	19154
Total phones	24	28	76	128	24	28	63	128
Total outpatient visits	97672	222737	557600	246566	109500	168444	424247	262400
Allocated costs								
Total admin expenditures	*516087*	*916648*	*394304*	*901487*	*601026*	*836550*	*444869*	*695802*
Total Trust Cabinet expenditures	*18281*	*51265*	*38717*	*83732*	*23060*	*59359*	*39276*	*71694*
Total Trust Cabinet without costs associated to visits of regular patients	*17450*	*49110*	*34733*	*73290*	*20771*	*40757*	*24476*	*41048*
Trust Cabinet activity								
Total tests conducted	*434*	*1129*	*239*	*384*	73	141	43	292
Total visits of HIV patients	*32*	*96*	*53*	*108*	40	110	26	218
Total positive detected	*6*	*16*	*7*	*21*	8	11	5	24
Trust Cabinet Ratios								
Costs per HTC	**40.2**	**43.5**	**145.3**	**190.9**	**284.5**	**289.1**	**569.2**	**140.6**

Costs per one positive detected	**3908.7**	**3149.5**	**5866.0**	**4338.4**	**2791.5**	**3734.8**	**5102.9**	**2290.1**
Transport ratios								
Costs per 1 sample transported to the AIDS Center	**13.83**	**1.14**	**26.48**	**46.40**	**21.38**	**2.31**	**24.14**	**47.65**

APPENDIX D. COSTS OF CONDUCTING ELISA TESTS BY THE AIDS CENTER LABORATORY

Parameters	2013 data in UAH	2014 data in UAH
Total spent budget of the facility	4141223.53	5151855.14
Total salary expenditures	2151698.69	2701598.38
Total salary of physicians	798500	862306.89
Total salary of nurses	635900	942269.35
Total renovation/refurbishment	336060	0
Total utilities	151823.12	249286.21
Total communication	13500	15100.17
Resources of the AIDS Center		
Total staff	75.75	75.25
Total physicians	14.75	20.25
Total nurses	27.5	31.5
Total premises, sq. m	927.16	1459.35
Total phones	46	48
Total admin expenditures	390803	514629
Laboratory		
Total reallocated admin expenditures for lab	96708.8	142152.0
Reallocated admin expenses for screening ELISA	46633	73729
Reallocated admin expenses for verification ELISA/WB	18770	25586
Total fixed lab expenditures for screening ELISA	370222	483002
Total fixed lab expenditures for verification ELISA/WB	149019	168850
Suppliers		
suppliers for screening ELISA, cost per one set	6.58	7.12
suppliers for verification tests, costs per one set	17.06	19.59
suppliers for maintenance per one test	0.23	58825
gloves and micro tubes per 1 test	0.29	0.24
Lab activity		
Total tests conducted	253724	249446
Total first screening ELISA	88764	67978
Total repeated screening	9124	7855
Total verification ELISA/WB	7711	7646
Total number of samples for verification	1962	1660
Total number of HIV positive detected	1101	1110
Coefficient of repeated screening tests	1.10	1.12
Coefficient of repeated verification tests	3.93	4.61
Total number of screening samples for Trust Cabinets	13407	10619
Total positive cases detected for Trust Cabinets	132	140

APPENDIX E. RECOMMENDED REVISIONS OF THE TORS

To effectively conduct HTC, PHC physician and nurse (an in accordance with already defined job responsibilities) should do the following:

- assess risks for catchment population, define the need for HTC rapid test kits and other necessary materials;
- provide HIV counselling to population as needed and as appropriate, educate about HIV-related risks;
- initiate HIV testing for patients with risky behaviors or with clinical signs that may indicate HIV infection;
- conduct HTC if a patient requests HIV test;
- perform HIV testing using current guidelines and also ensuring confidentiality;
- store HIV test kits and other materials as recommended by the current guidelines and manufacturer's recommendations;
- dispose of used materials according to infection control standards;
- record data and report on conducted HTC according to current requirements;
- coordinate with Trust Cabinets, AIDS Centers, and other medical and non-medical services to ensure timely linkage to care for PLHIV;
- coordinate with Trust Cabinets, AIDS Centers, and other medical and non-medical services to ensure HIV patient remains on prescribed treatment or HIV medical care.

To effectively provide HTC at the PHC level, the responsibilities of the Trust Cabinets should include the following:

- assist in assessing HIV risks for catchment population
- planning of HTC activity with PHCs;
- planning of HIV test kit allocation among PHC sites;
- collect data from PHC facilities on numbers of people tested for HIV, and number of positive results;
- registration and linkage to care for PLHIV referred from PHCs with an HIV positive test result confirmed with two positive rapid test kit results (with positive confirmatory test drawn at AIDS Center)
- coordination with PHCs to ensure HIV patient compliance with treatment plan;
- supervision and mentoring of PHCs providing HTC.

To effectively provide HTC at the PHC level, the responsibilities of the AIDS Center should include the following:

- critically assess the need to provide HTC at PHCs;
- coordinate with PHC Center management on HIV prevention and treatment strategic planning issues;
- organize HTC training for PHC staff;
- organize supply of HTC materials for PHCs;
- perform troubleshooting in difficult situations related to HTC delivered at PHC level;
- Assist PHC and Trust Center in confirmation of new HIV cases, and assist in linkage to care for PLHIV;
- organize external quality control of PHC delivered HIV testing and counselling.