



USAID
ВІД АМЕРИКАНСЬКОГО НАРОДУ

RESPOND



fhi360
THE SCIENCE OF IMPROVING LIVES



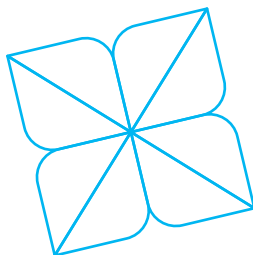
EVALUATION OF INTEGRATED PROMISING INTERVENTIONS FOR PEOPLE LIVING WITH HIV



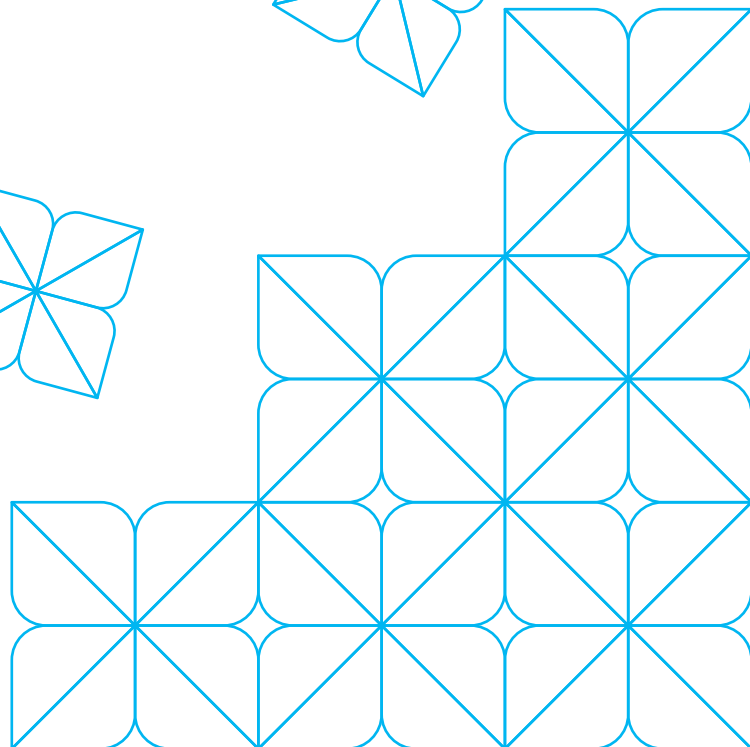
“PATIENT’S SCHOOL” AND “STUDIO OF OPPORTUNITIES”



SUMMARY OF THE ANALYTICAL REPORT



KYIV – 2017



BACKGROUND

Ukraine has one of the highest rates of HIV prevalence of in the European region. The third “90” of the UNAIDS “90-90-90” goals to reduce the impact of HIV is to ensure a high level of adherence to antiretroviral therapy (ART) in order to reduce transmission. Implementation of behavioral interventions addressing adherence to ART can help to achieve this goal.

Lately, global experience implementing “integrated interventions”¹ is being documented. The theory is that when several interventions, focused on welfare in different aspects of life (health, education, financial well-being etc) are combined, there is greater impact on a given issue. For example, simultaneous improvement of education, child health and financial prosperity of a family has better effect on the child’s education than individual educational projects. Realizing all this, the RESPOND project, with financial support of the US Agency for International Development (USAID) integrated interventions on adherence to ART (titled “Patient School”) and increasing the economic independence of a person (titled “Studio of Opportunities”). The purpose of the integrated intervention was improving treatment of HIV infection through strengthening the financial situation of the most vulnerable clients: women with young children. Clients of NGOs implementing the integrated intervention could influence simultaneously two important areas of their life: health and economic independence that reinforced each other in the process of participating in the interventions.

The aim of this study was to evaluate the integrity, the possibility of implementation and effectiveness of two interventions on adherence to ART – “Patient School” and integrated intervention (“Patient School” and “Studio of opportunities”) – the purpose of which was to increase the adherence to ART through improving economic independence.

Locations

Both interventions were implemented by regional offices of the “All-Ukrainian Network of People Living with HIV”, including:

- Dnipropetrovsk office of All-Ukrainian Network of People Living with HIV (city of Dnipro);
- Charitable Foundation “Svitlo Nadii” (cities of Poltava and Kremenchuk);
- Cherkasy office of All-Ukrainian Network of People Living with HIV (city of Cherkasy);
- Chernigiv office of All-Ukrainian Network of People Living with HIV (city of Chernigiv).

“Patient School” was implemented in all these cities, whereas the integrated intervention was only implemented in regional centers.

Intervention “Patient School”

The aim of the intervention is to improve PLWHIV adherence to ART and medical services, including timely intake of drugs and regular check-ups. The intervention is based on trans-theoretical model of behavior change, motivational interviewing, the health concept model and the theory of planned behavior.

The intervention consists of seven individual sessions (introduction, five main sessions, and a). The main sessions last about 45 minutes each with a two to three week intervals between sessions and the total duration of the course is three months. The concluding session is conducted three months after the last “main” session. Additionally, there is a supportive period which includes telephone contact with clients and monitoring of their progress after the main sessions, thus the total duration of the intervention is six months.

Intervention “Studio of opportunities”

The aim of the intervention is to improve the quality of life of HIV-positive women with children from zero to six years old by integrating programs targeted at health and economic issues. Participants get into the program after completing the intervention “Patient School.”

¹ See <http://www.pactworld.org/our-integrated-approach> and <https://www.fhi360.org/integrated-development>

“Studio of opportunities” consists of four components: (1) meeting with a multidisciplinary team at the beginning of the intervention to determine the level of financial assets; (2) at least six individual meetings with a case manager to provide individual social support; (3) 12 weekly group sessions, based on the “90 days” methodology; (4) a final meeting with the multidisciplinary team to set a plan for further development. Also within the framework of the intervention, a participant can receive a grant for studies or establishment of one’s own business (with the approval of the multidisciplinary team).

The total duration of integrated intervention, “Patient School” and “Studio of Opportunities” is six months.

METHODS

Research design

In order to assess the “Patient School” project a randomized controlled research was conducted on 5 sites (Dnipro, Poltava, Kremenchuk, Chernihiv, Cherkasy); total sample - 402 respondents. In order to evaluate integrated intervention a non-randomized cluster controlled research was conducted on 8 sites (Dnipro, Poltava, Chernihiv, Cherkasy, Sumy, Zaporizhia, Mykolaiv, Kharkiv); total sample - 399 respondents. Participants took part in 5 polls, which were held every 3 months.

Research Time periods

The research was conducted from April 2015 to September 2016.

Criteria for inclusion

The criteria for inclusion in the control and intervention groups of the “Patient School” study were: age of 18 years or more; registered at the dispensary at the AIDS Center; and first time on ART or poor adherence to ART. Low adherence to ART was determined by one of three criteria: (1) more than three instances of skipping doses during the last 30 days; (2) failure to attend planned meetings and receive ART drugs during the period of 7 to 30 days after the date of a planned visit; (3) a lowering CD4 and raising of VL (or VL remains at the same level) is observed.

People who were engaged into the integrated intervention and control group of integrated intervention had additionally to meet the following criteria: to be a women; to have at least one child under six years old or be pregnant and planning to give birth; to be unemployed or to have a temporary work; to be in difficult circumstances (please see below); and be willing to change. A woman was defined as the one in difficult circumstances, if she meets at least one of the following criteria: is indigent; is unemployed for more than six months (before child care leave); was subjected to violence in the family (also economic); had negative relationship in the family; and is at risk of having her children removed from her custody.

Standard set of services for people living with HIV in Ukraine

The standard package of services for people living with HIV is defined and provided by the Global Fund project (direction 09M) “Social support for HIV-positive people” and is available at the regional branch of the Network.

This package includes the following components:

- 1) Consultation with a the social worker (assessment of needs; support for adherence to ART and medical services; information counseling on STIs, healthy lifestyle, and information about available resources; provision of information about the location and conditions of testing / diagnostics etc.; consultation with further referrals for additional services to other NGOs, hospitals, rehabilitation institutions, charities, etc.; periodic assessment of adherence to ART and TB screening).
- 2) telephone reminders for appointments
- 3) Clients’ support in obtaining public benefits and payments, registration / renewal of documents, registration (renewal) of disability and more.
- 4) social worker in person support (delivery of ART medicines, facilitating the process of diagnosis, assistance in maintaining the medical treatment such as self-service or housekeeping)
- 5) client transportation
- 6) Delivery of tuberculosis drugs and
- 7) Provision of food packages.

Participants of both interventions and control groups could receive services listed above during the research period.

Data analysis

In order to take into account baseline differences between groups and those that have arisen due to uneven loss of participants, multivariate analysis of differences was conducted in each of the sections, accounting for age, location, education, income, intake of alcohol, injecting and non-injecting drugs, lifetime experience of HIV and ART use (naive/averse), gender (for "Patient School" participants), and the number of children and age of the youngest child (for women engaged into integrated intervention). Three models were built: 1) comparison of the effects on the participants of the intervention and control groups of "Patient School"; 2) comparison of the effect on the participants of the intervention and control groups of integrated intervention; 3) comparison of the effects of the participants of intervention group "Patient School" and integrated intervention. Modeling was performed using the generalized linear model. The results are shown as adjusted odds ratio and 95% confidence intervals.

Ethical principles

The study protocol and tools were approved by the Committee on Medical Ethics of State Institution "Gromashevsky Institute of Epidemiology and Infectious Diseases of NAMS of Ukraine".

RESULTS

Levels of recruitment and retention

Levels of retention in the research were high (more than 85% in all sections), namely 91%, 89%, 89% and 84% in the 3-, 6-, 9- and 12-month cutoffs, respectively. The final sample size was 801 participants during the recruitment, and 667 participants who were recruited before December 2015 were included in the nine month survey, and 431 participants recruited by September 2015 were engaged for the for 12-months-interview. The number of participants in 3-, 6-, 9- and 12-month cutoff were 725, 712, 593 and 364 persons respectively.


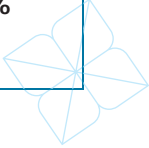
Integrity and accuracy of implementation

The levels of successful implementation of interventions were sufficient: 77.3% of the "Patient School" participants and 85.7% of integrated intervention participants successfully completed the program.

Table 1

Indicators of good faith and accuracy implementing interventions.

Indicator	Calculation methodology	Percentage	Target value
Indicators for the «Patient School»			
<i>Integrity of the intervention implementation *</i>			
Average duration of the sessions		46 mins¹	45 mins
The share of intervals between the sessions, relevant to the standards of intervention	number of 2-3 weeks intervals between the sessions 1-5	1309/1895=69,1%	70%
	total number of intervals between conducted sessions		
<i>Accuracy of the intervention implementation **</i>			
Share of participants, who successfully completed the program	Number of participants who completed the program	307/397=77,3%	75%
	Number of participants who were involved in the intervention		

Indicator	Calculation methodology	Percentage	Target value
Indicators for the "Studio of opportunities"			
<i>Integrity of the intervention implementation*</i>			
The share of intervals between the sessions, relevant to the standards of intervention	number of 1 week intervals between the sessions 1-12 for one participant	1766/2202=80,2%	80% 
	total number of intervals between conducted sessions		
<i>Accuracy of the intervention implementation**</i>			
Share of participants who successfully completed the program	Number of participants who completed the program	162/189=85,7%	75%
	Number of participants who were involved in the intervention		
Share of participants who did not attend all sessions, but successfully completed the program	Number of participants, who attended less than twelve sessions	23/162=14,2%	15% 
	Number of participants who completed the program		

* Counted for all conducted sessions ** counted for study participants

Effectiveness of interventions

The effectiveness of intervention "Patient School"

"Patient School" was effective in terms of increasing the quality of life. Members of the intervention group of "Patient School" had a higher quality of life in terms of HIV in all spheres compared to control group participants.

"Patient School" improved the adherence to ART, but this increase was not statistically significant. After taking into account all factors, the participants in the intervention group of "Patient School" had two times higher chances of being adhere to ART compared with participants in the control group in all cutoffs after the recruitment. With the available data, these results can not be applied to all people living with HIV, due to limitations of the design of the study... Nevertheless, in all four indicators that measured subjective adherence to ART, the same trends between indicators and cuts can be observed, which indicates the sequence of results.

Also, the size of the effect (the difference between the adherence of intervention and control groups) was greater in 3- and 6-month cutoffs, and less in the 9- and 12-month cutoffs, indicating the importance of long-term results measuring.

Effectiveness of integrated interventions

Women enrolled in the intervention group of Integrated intervention had up to six times higher statistically significant chance of adhering to ART, compared to the women in the control group of integrated intervention in all cutoffs after the recruitment.

However, the total self-efficiency was statistically higher in the control group of women, and the quality of life did not differ between the intervention and control groups. As mentioned above, based on defined characteristics, the women in the control group were more successful than the women from intervention group at the time of involvement in the study (as the participants were recruited at different sites, the distribution was not coincidental). Thus, women from the control group of Integrated intervention had higher levels of independence, a better relationship with family, less time living with HIV and no experience of injecting drugs. Self-efficiency is the only parameter that remained statistically significantly higher for women from the control group at the time of the recruitment into the study, even after taking into account all other factors. Therefore, even when

self-efficacy in intervention group changed, it remained relatively lower than in the control group.

Another factor to consider is that the tools that were used to measure quality of life and self-efficacy were not validated for Ukraine, thus they might be not sensitive enough to measure changes occurring during the study.

In multivariate analysis, statistically significant differences between the effects in intervention groups

of "Patient School" and integrated intervention were not found. This may be due to the location of all studied groups at the same site, different target groups of intervention and non-validated instruments for measuring quality of life and self-efficacy in Ukraine.

During the focus group discussions, participants of "Patient School" and "Studio of opportunities", noted that the intervention positively impacted their lives in many ways.

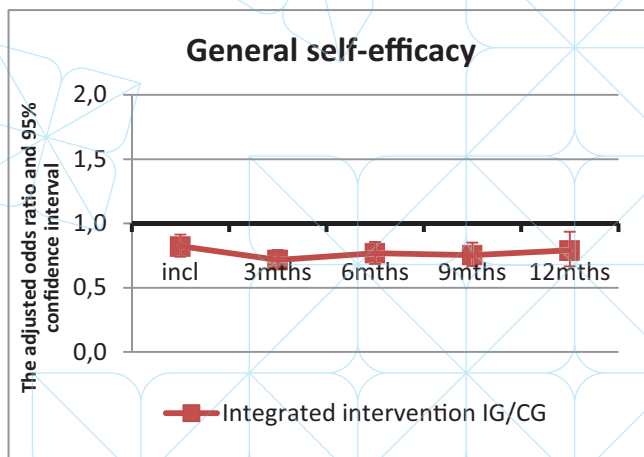
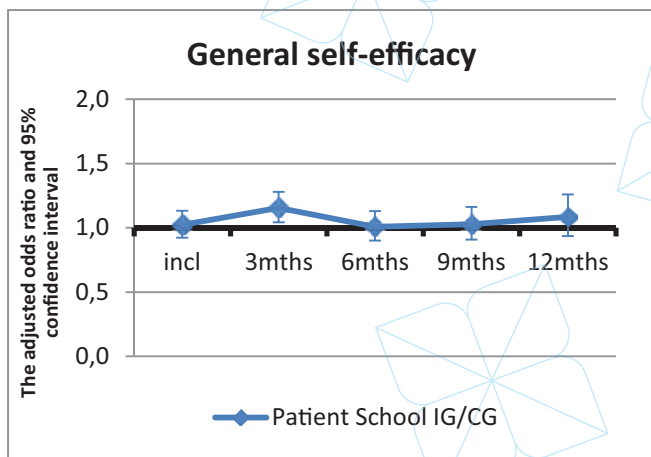
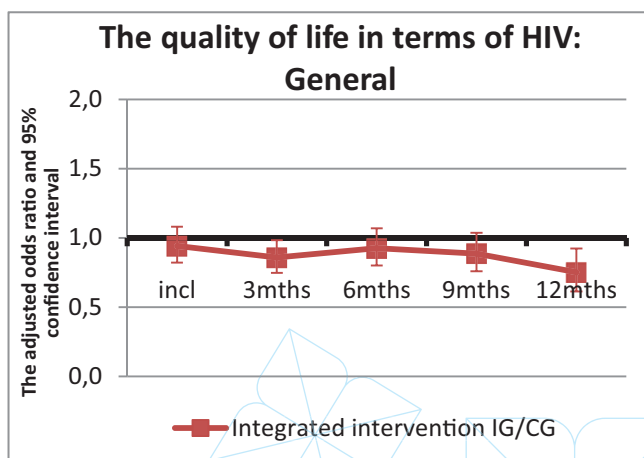
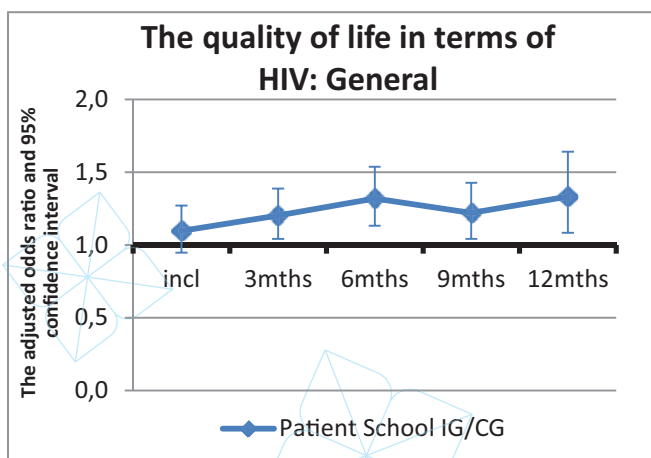
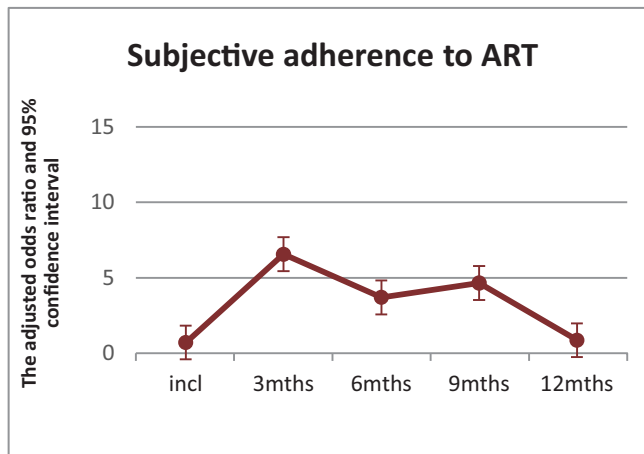
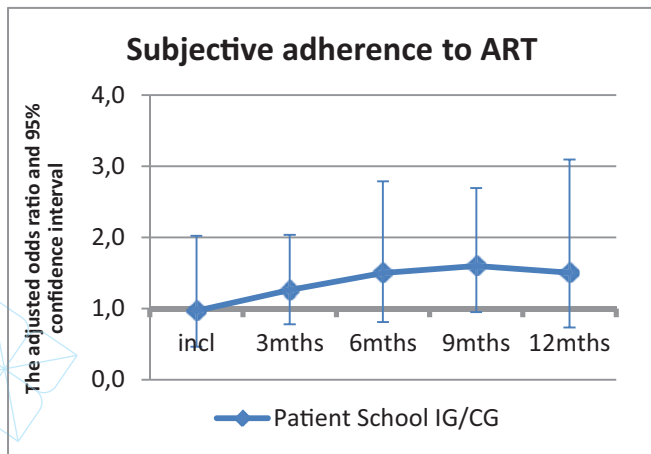


Fig. 1. The odds ratio of intervention group participants' chances to have higher values of basic secondary measuring results, compared with the control group; adjusted for the main socio-demographic and medical characteristics.

Research limitations

The total sample size was limited by the number of ART drugs in the region and is sufficient to evaluate the change in adherence to ART, but may not be sufficient to measure the influence of other factors in the multivariate analysis. Thus, not a big difference between the intervention and control groups could be statistically insignificant, but only due to the fact of small sample size.

Mixing of participants from the intervention and control groups for “Patient School” took place, most likely due to the presence of both groups of participants at the same site. This reduced the real effect of the intervention and therefore the possibility to see this effect in the statistical analysis was also reduced.

Data on the primary outcome parameter, viral load, was very limited due to lack of test systems in the regions throughout the study. Any conclusions based on the number of participants for which the information about VL is available at the beginning and completion of the study, would be impossible and incorrect.

As piloting of the interventions and the research began at a time when there was a lack of ART drugs and therapy was prescribed to a limited number of new patients, most people who were engaged into the intervention belonged to a category of non-adherent patients. Therefore, the data mainly concern those who had a negative experience of taking ART. Although the intervention was planned primarily for new PLWHA who only start their therapy.

4. Due to the lack of reagents in the regions during the study period, it was difficult to measure the objective adherence to ART (via change of VL).

5. After taking into the consideration the influence of other factors, it was determined that the intervention group members had higher levels of subjective ART adherence compared to the members of the control group. In the “Patient School” these differences were not significant as there was mixing of groups at one site, and therefore, the ratio of the size of the effect of sample size.

6. The participants of “Patient School” intervention group had statistically significantly higher quality of life in all cutoffs compared with participants of “Patient School” control group. Participants of Integrated intervention control group had statistically significantly higher levels of general self-efficacy, even at the stage of recruitment, after taking into account all other factors.

This is due to the fact that the IG and CG of integrated intervention were recruited at different sites in coincidental way, and the participants of CG turned out to have less risk factors than the members of the IG at the very beginning (HIV positive for a shorter period of time; did not use injecting drugs; had very good relationship with family members, etc.).

7. Study participants started to attend infectionist on a regular basis and undergo TB screening. Compliance with recommended frequency of tests for viral load and CD4 was impossible to assess due to the lack of reagents for these tests in the regions.

8. The added value of the Integrated intervention, unlike the “Patient School”, could not be quantified due to a number of reasons: mixing the groups due to their presence on the same site; different target audience of each intervention; and lack of validation for the Ukraine instruments for measurement of quality of life and self-efficacy. The results of qualitative interviews demonstrate a significant value of the component “Studio of opportunities” for people living with HIV.

9. One of the limitations of this study is that the intervention involved mainly people who were not adherent to ART, not new patients given the lack of ART availability in the region. Therefore, intervention effects found in this study may be underestimated.

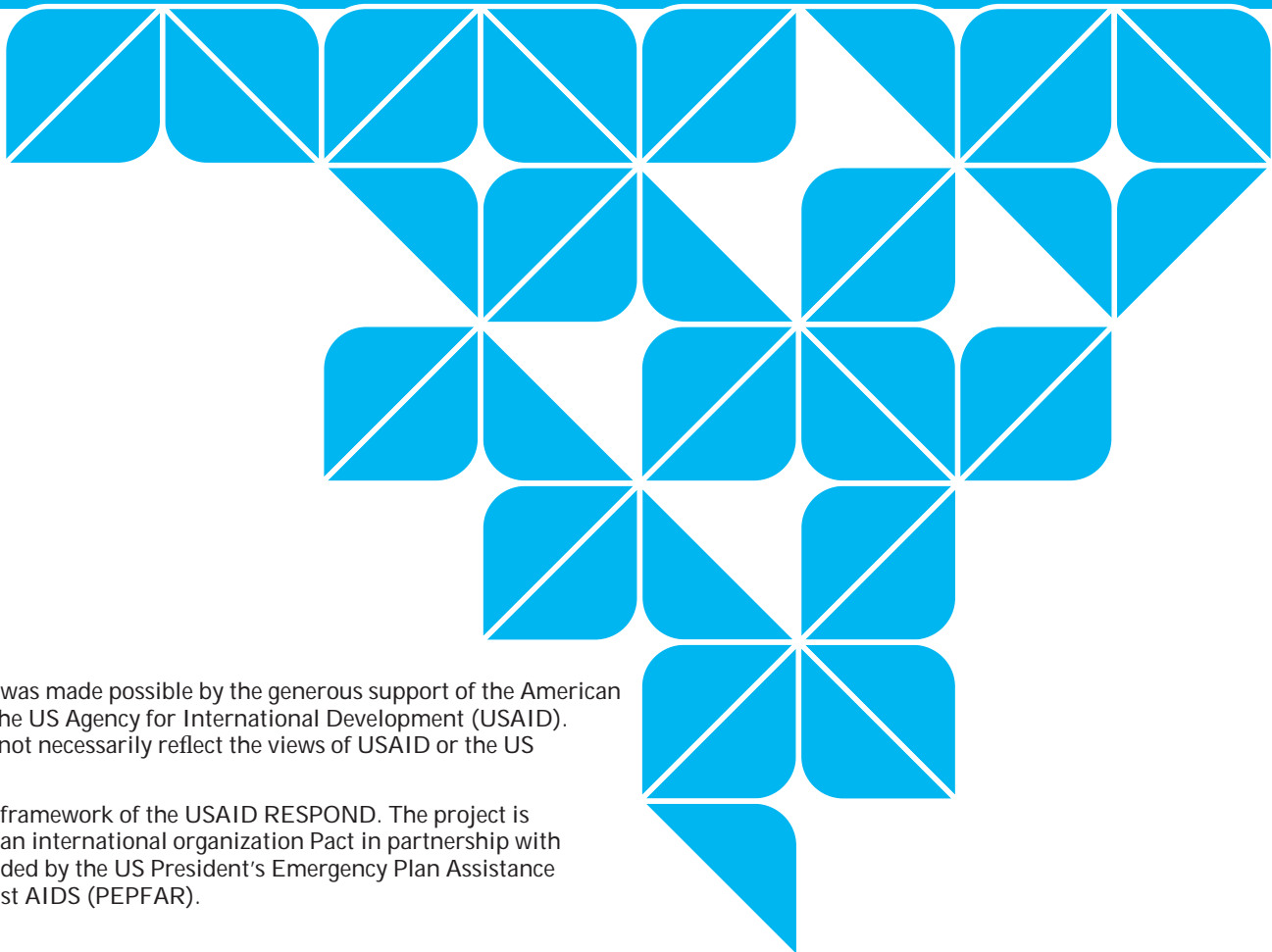
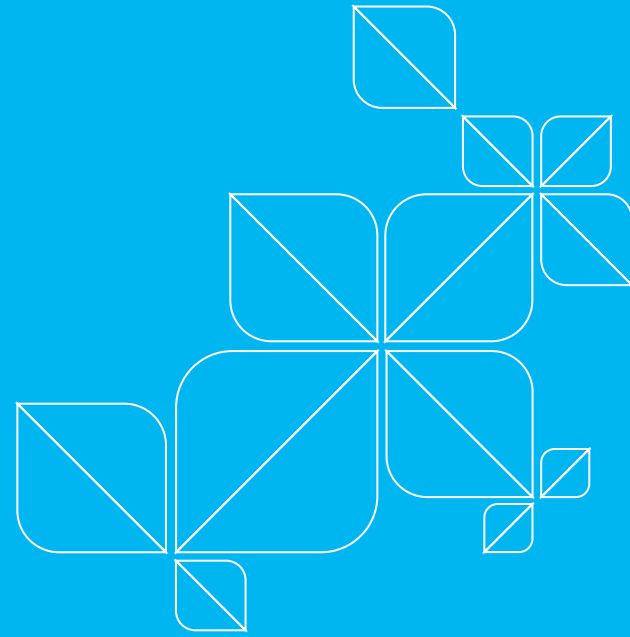
10. A significant advantage of the study, compared with the others, is the measurement of the effects of interventions in the long-term (six months after the project). The behavior of the participants differed immediately after the project and over time.

CONCLUSIONS

1. Levels of maintenance in the study were high (more than 85% in all sections).

2. Both interventions were implemented with sufficient integrity and accuracy. Indicators of compliance with standards of intervention implementation ranged from 70% to above for all components.

3. According to the participants of the “Patient School” intervention group, the main value of services received is information about HIV and ART; participants of control group highlighted information and financial assistance from NGOs; participants of intervention group of integrated intervention stated information and the possibility of self-development as highly valued; and participants of the control group of Integrated intervention noted psychological help and communication as valued. Pillbox wasn't popular.



This publication was made possible by the generous support of the American people through the US Agency for International Development (USAID). The contents do not necessarily reflect the views of USAID or the US Government.

Published in the framework of the USAID RESPOND. The project is implemented by an international organization Pact in partnership with FHI 360 and funded by the US President's Emergency Plan Assistance in the fight against AIDS (PEPFAR).