

# Prevention of Mother-to-Child Transmission (PMTCT) of HIV in Iran: Situation Analysis of the Pilot Phase

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## Research article

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## **Abstract**

Background The reproductive health and Prevention of Mother-to-Child Transmission of HIV (PMTCT) programs in Iran were integrated as a pilot project in September 2014. This study aims to provide a comprehensive evaluation and situation analysis of the PMTCT programme in Iran.

Methods Pilot phase of PMTCT was launched in early September 2014 in selected centers including 170 health centers and 40 hospitals affiliated to medical universities of 16 provinces of Iran. In each medical university, a researcher-made checklist was administered to all newly-diagnosed HIV-positive pregnant women by the AIDS expert. Data was analyzed using SPSS 19 software.

Results Overall, 69.4% of eligible pregnant women were enrolled in the pilot phase. From 134 reactive cases, 76 (56.7%) were confirmed as HIV positive. In 10 (13.2%) of HIV positive pregnant women, consumption of ARV was irregular. Also, 82.5% had CD4 count more than 350 after treatment with an average of 55.5% increase in the number of CD4 in comparison to the baseline, and 84.8% had viral load suppression (<200 copies/ml). Counseling and testing was done for the husbands of 75% of the women, and resulted in the identification of 15 (39.5%) new HIV cases among husbands. Of tested individuals, 23 (60.5%) males already knew their HIV status and were registered HIV patients. HIV was diagnosed in one (1.5%) newborn.

Conclusion Implementation of rapid HIV testing and PMTCT in Iran is strength in the national HIV control program. To eliminate MTCT, it is necessary to understand and overcome barriers and challenges the program faced in the pilot phase.

## **Background**

The most significant route of HIV infection in children under the age of 15 is through vertical transmission during pregnancy, delivery and breastfeeding. Despite improvements in prevention of mother to child transmission of HIV (PMTCT), in 2016 there were 160.000 new infections in children globally, most of which in low middle income countries. The percentage of virus transmission in the prenatal period in developed countries is about 15–25% and in developing countries, 25–45% in absence of prevention interventions [1]. The results of implementing worldwide preventive and control programmes such as PMTCT, indicate the effectiveness of these programmes in reducing HIV transmission from mother to child and the transmission rate can be lower than 2% nowadays [2]. Given the importance of the issue and the effectiveness of preventive and control measures in reduction of the risk of vertical transmission of infection, different countries have put these measures on their agenda.

Iran is pioneer country in the evidence-based implementation of HIV control program in the Middle East region. Today, the increase in the prevalence of infection in Iranian women in recent years [3] has raised the likelihood of an increase in mother-to-child transmission and highlights the need to reinforce preventive measures in this regard. According to estimation by Ministry of Health )MOH( projection in Iran, the number of newborn babies born to HIV-infected women will increase by 2020 and will reach

about 470 newborns. Therefore, in Iran, HIV infection in women and children is one of the main priorities of the HIV control programme, and the need for planning for this vulnerable stratum is vital [4].

In Iran, due to the inherent relationship between HIV/AIDS, sexual health and reproductive health, and considering the structure of the primary health care system of the country, the HIV control programme, sexually transmitted infections and reproductive health programme can be integrated. The integration of reproductive health programme and PMTCT programme in Iran was conducted as a pilot programme in 2014 at 16 universities by doing HIV rapid test in pregnant women. Given the fact that several years have passed since the launch of the pilot phase, Iran's MOH has decided to move towards the elimination of mother-to-child transmission of HIV (EMTCT). Understanding programs' current status and its achievements is a necessary step in this regard. Therefore, we aimed to provide a comprehensive evaluation and situation analysis of the PMTCT programme in Iran.

## Methods

### Setting

In 2013, in line with the policies of the National Strategic Plan for AIDS, the HIV/AIDS and reproductive health programs were inter-linked with the aim to reduce the Mother-to-Child Transmission of HIV, and the initiative was given high priority by the Office for AIDS and Sexually Transmitted Diseases Control of the MOH and supporting of UNICEF. Accordingly, the guidelines for general principles and national policies on linking HIV/AIDS control and reproductive health programs for pilot centers were prepared with the participation of MOH offices for AIDS control and maternal health, which made it possible to carry out the planned activities of the program at field level. The guidelines were subsequently provided to all health care staff working in health and treatment centers and HIV service providers, AIDS experts and family health experts. The same guidelines were presented and taught in a three-day workshop for managers of family health and disease control units, as well as maternal health experts and AIDS experts in 16 pilot universities, and it was agreed that each university coordinates the pilot implementation of the program in 10 health centers and several nearby hospitals. The training subjects included methods of conducting and testing by rapid test, referral processes for reactive patients, treating women infected with HIV, conducting infant prophylaxis, and providing lactation counselling.

The program was launched in early September 2014, after making necessary requirements including coordination with the Treatment Department of Iran's MOH, training the field personnel, and supplying the HIV rapid test kits. The total selected centers for pilot implementation included 170 health centers and 40 selected hospitals in 16 medical universities. The 16 universities were selected based on the criteria set forth by the offices for maternal health and AIDS control, with the aim to ensure inclusion of different geographical areas with respect to HIV incidence (high/ moderate/ low incidence), the extent of development of cities, urban areas and rural areas, as well as cultural and ethnic diversities.

### Conducting the study

Ethic approval was taken from Ethics Committee of Kurdistan University of Medical Sciences (IR.MUK.REC.1397.5006). A checklist was developed by an expert team according to the study aims. Then the checklists were filled out through interview by the university AIDS expert for all newly diagnosed HIV-positive pregnant in the pilot phase (76 patients) and evaluation of the patient files. Twenty percent of these checklists were evaluated again by research team for approving the validity of data.

## Data analysis

Quantitative data was entered into Excel software where program indices were calculated. Data was described by median and interquartile range (IQR) as well as means, standard deviation, frequency and percentages. Data was analyzed using SPSS 19 software.

## Results

During the pilot phase of the program, a total number of 25,808 pregnant women were tested for HIV using rapid test kits, of which 134 cases were reported as reactive, and 76 (56.7%) cases were confirmed as HIV positive. Of eligible pregnant women, 69.4% underwent rapid HIV testing at their first medical visit.

Level of education of the study group was mostly middle and high school. Twelve (15.8%) women lived in suburban areas. Totally, 24 (31.6%) pregnancies were unplanned. About 46% of pregnant women were primigravida (Table 1). Median (IQR) age of mothers and their husbands was 31 (28.2, 35.7) and 35 (32,41) years, respectively. Median gestational age at the time of HIV testing and at birth was 13 (8, 18) and 38 (38, 38) weeks, respectively. Median age and birth weight of newborns was 16 (6, 26) months and 3,100 (2,900, 3,300) grams, respectively. Median time interval between reactivation (positive rapid test) and confirmation of HIV was 0 (0-3) days, and median interval between confirmation of HIV and start of ART was 7 days (0-25).

Post-treatment CD4 counts were more than 350 in 85% of mothers, with 55.5% increase in CD4 counts respective to the baseline. Also, 84.8% of mothers had viral load suppression (<200 copies/ml). Median of increase percentage in CD4 after ART and decrease percentage in viral load after ART were 38.9 (10.2-81.8) and -99 (-99.7 – 0) percents, respectively. Viral load and CD4 count testing was not performed for 54 (71.1%) and 10 (13.2%) women before HIV treatment was started. Ten (13.2%) pregnant women did not regularly consume their ARV drugs. Two mothers (2.7%) were under irregular lifelong ART after pregnancy (Table 2).

Husbands' counseling and testing was performed for 75% of the husbands/partners, of which, 6.6% rejected the counseling, and 25% did not accept the testing. Fifteen tested husbands (39.5%) were newly identified as HIV case while 23 (60.5%) were already registered as HIV cases (Table 2).

The median time interval between live birth and start of infant prophylaxis was 1 (IQR= 0, 2) hours. Four infants (5.4%) were born through natural vaginal delivery (NVD). Two infants did not receive prophylaxis. All infants were fed with formulated milk and completed their prophylaxis. About 86.6% of infants were

tested for HIV in 6-8 weeks. Of 27 infants who were ≥18 months old, 20 were tested for HIV during 18-months. During September 2014 and Jun 2017, one (1.5%) infant was diagnosed with HIV. The HIV-positive infant received vaccination and ART according to the PMTCT protocol (Table 3).

Husband HIV status of HIV positive pregnant women showed in Figure 1. Of 258088 rapid tests performed for mothers, 134 (0.1%) turned reactive, of which 76 (56.7%) were confirmed. Seven HIV-positive (9.2%) women were pregnant and two (2.6%) had abortion. Ten (13.2%) pregnant women did not receive regular ARV treatment. Two mothers (2.7%) were under irregular lifelong ART after pregnancy (Fig 2).

Percentage of HIV negative and positive HIV tests, as well as HIV-exposed infants under follow-up were 84.2%, 1.3% and 10.5%, respectively. Seven (9.2%) women were still pregnant and 2 (2.6%) had abortion. Ten (13.2%) pregnant women did not receive ARV treatment regularly. Two mothers (2.7%) were under irregular lifelong ART after pregnancy (Fig 3).

## Discussion

In the past, the incidence of HIV in Iran was higher among addicted women or those married to injecting drug users who were mainly from low-income socioeconomic groups, but the disease pattern is changing in the country. Based on the results, the educational level of mothers with HIV is now higher than the educational level of previously diagnosed cases, which indicates an increase in the prevalence of HIV among people with a higher educational level. The majority of new cases are often due to unprotected sexual contacts, indicating the importance of the integration of the PMTCT program into the health program in the country. The pilot phase of the PMTCT program in Iran is one of the strengths in the integration of this program into PHC.

In the pilot phase, HIV infection was confirmed only in 56.7% of the cases with a positive result in the HIV rapid test. The fourth generation of ELISA test was used in the pilot phase pf the program in Iran. The sensitivity and specificity of this test is over 99% [5]. However, it seems that this test was not used in a standardized manner in the pilot phase. Nevertheless, the problems have been solved during the implementation of this phase. In order to reduce false positives, it is very important to keep compliance with the protocol when performing these tests in the program. In line with a similar study in Uganda [6], 69.4% of eligible people in the pilot phase underwent HIV rapid test, which could be due to lack of training for the personnel, lack of tools for the rapid test at a specific point of time (because of sanctions imposed by the USA), and custom-made practices by the personnel in some cases. It is of great importance to ensure the sustainability of people's access to rapid test at the integration stage, and it is necessary to conduct the rapid test for all pregnant women in order to achieve the goals of EMTCT.

In 75% of cases, the test was performed before the 18th week of gestation. Rapid diagnosis of and counseling for HIV in the first trimester of pregnancy is one of the key points in preventing the transmission of disease from mother to child, because during that time the treatments can be more effective [7]. In the pilot phase, some of the studied pregnant women were in the last weeks of gestation

and some of them were diagnosed at the end of pregnancy; this problem will be resolved at the integration phase. According to different studies, from 1.2–40% [6, 8, 9] of pregnant women are tested and diagnosed in the first trimester of pregnancy. Since a very high percentage of pregnancies in small towns and rural areas are recorded at the early stages in health centers, it is expected that, after the initiation of the integration phase, a high percentage of pregnant women will be tested in the first trimester of pregnancy.

In 75% of cases, the time interval between reactive testing and definitive diagnosis was less than three days and the median time interval between the definitive test and the start of treatment was seven days. These time intervals do not cause a program failure in the first trimester of pregnancy, but when the test is performed in the third trimester, these short time intervals can be problematic. Therefore, strong efforts should be made to conduct the rapid test in the first trimester of pregnancy for all pregnant women. In this study, CD4 test and blood Viral Load (VL) test were performed only for a low percentage of cases. This will impede the monitoring of the treatment, and before integrating the program it is necessary to adopt the required measures for conducting these tests and increase the level of access to the mentioned tests. The implementation of USA sanctions against Iran is one of the main reasons for the shortage of a Viral Load testing device in Iran, which should be considered when running the program. In various studies in different countries, it has been reported that between 30% and 100% of women diagnosed with HIV had undergone CD4 testing [10, 11]. After the treatment, the mean level of CD4 was significantly higher than before, and the level of VL was also increased. In Ethiopia [12], the mean CD4 at the time of the initiation of ART was about 302, which reached 404 after the treatment, and in Uganda [6], the median CD4 was 368.

Given that in Iran the PMTCT program is implemented as Option B+, it is expected that all mothers with HIV use ART for a lifetime. ART during pregnancy was not fully used in 13% of cases, which is a risk to the program. However, there was a proper reduction in the percentage of viral load in patients and the lifetime treatment was properly started after the delivery. One of the reasons for the lack of full and regular adherence to the medication is the patients' fear of disclosing their illness to the family, which is a serious problem that must be addressed properly. Of all eligible women with HIV, 30.6% in Uganda [6], 77% in Côte d'Ivoire [13], and almost 100% in China [7] received ART from the early time of diagnosis. HIV infection in spouse, high level of education, availability of services in health centers, the presence of knowledgeable staff during childbirth, and maternal training have been reported to be effective in the acceptance of ARV by mothers [14].

Counseling was performed only for 75% of the spouses of the studied patients; the low rate of counseling is also due to the same cultural problem and stigma. Furthermore, 25% of the spouses refused undergoing HIV testing, and 50% of them had previously been diagnosed with HIV, indicating that care services were poorly provided for the patients. Thus, it is necessary to fundamentally review and modify processes at the Voluntary Counselling and Testing (VCT) centers. Moreover, it can be concluded that the quality of counseling for HIV-positive men had been probably low and did not reduce the risk of transmission of HIV to their spouses. On the other hand, 39.5% of men who had been counseled and

tested were diagnosed as new cases of HIV, indicating that the PMTCT program could also be very effective in detecting men with the disease. In Uganda [6], 91% of husbands were informed of their spouse's disease, which is higher than the rate observed in our study.

Since it is impossible to conduct viral load testing for all patients in Iran, it has been recommended to perform cesarean section for delivery; however, 5.4% of cases in this study had a normal delivery, which is a defect in the program. Of course, all of these cases were diagnosed during delivery; the late diagnosis of the disease, after the natural childbirth, might be attributed to the lack of awareness, inappropriate adherence to the standards in the processes, or the late request for the services by pregnant women, which increase the risks in the program. Prophylaxis was not considered in 3% of all newborns, but all of them had received powdered milk; moreover, the vaccination in 5.4% of them had some defects. These shortcomings in the program are also a risk factor for the transmission of HIV from mother to infant, which could disrupt EMTCT. According to the findings of other studies [6, 10], 96% of cases in African countries had a natural delivery while the majority of patients in China [7] had delivered via a cesarean section. Of all, 97.8% cases in Rwanda [10] and 87% in Ethiopia [12] were exclusively breastfed. However, taking into consideration the economic status of every country, it is advised to practice or do not practice breastfeeding; In Iran, it is not recommended to practice breastfeeding by mothers with HIV.

In Uganda [6], 14.2% of newborns did not receive prophylactic drugs at birth, and the rate of HIV transmission to the child was reported to be about 15%. Over a period of five years in Uganda [15], 18% of children born to HIV-infected mothers died. Of all children born to HIV-infected mothers, 6% in Ethiopia [12] and one out of 67 children in China [7] were infected with HIV. The prevalence of HIV infection among 6-week old children at risk of HIV exposure in South Africa [9], ranged from 0.3–2.4% in different regions. In a pilot study in the country, only one newborn was infected with HIV and no children died before the end of the pilot study, indicating that the treatment for pregnant women and prophylaxis for infants were effectively provided.

## Conclusion

In general, the implementation of rapid HIV testing in pregnant women and PMTCT in Iran is a strength in the national HIV control program. Conducting such a pilot, before its integration into the national program, can prevent major problems and increase the knowledge about the defects and the processes of the program. To achieve the EMTCT stage, it is necessary to carefully examine and resolve the problems observed in the pilot phase.

## Abbreviations

PMTCT: Prevention of Mother-to-Child Transmission; MOH: Ministry of Health; EMTCT: elimination of mother-to-child transmission of HIV; NVD: natural vaginal delivery

## Declarations

## **Ethics approval and consent to participate**

A written informed consent was obtained from all participants. The approval for this study was obtained from the Ethics Committee of Kurdistan University of Medical Science (IR.MUK.REC.1397.5006).

## **Consent for publication**

Not Applicable

## **Availability of data and materials**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## **Competing interests**

The authors declare that they have no competing interests.

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## **Authors' contributions**

SA, MT, PK and BZ analyzed and interpreted the data. EG, PK, MG and ZM were involved in designing of the research. MS, MT and EG gathered the data from the field. All authors were major contributor in writing the manuscript, read and approved the final manuscript.

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## Tables

Table 1: Profile of pregnant women with HIV identified in the pilot study

| Variable             |              | Frequency | %    |
|----------------------|--------------|-----------|------|
| Mothers' educations  | Illiterate   | 6         | 7.9  |
|                      | Primary      | 19        | 25.0 |
|                      | Secondary    | 21        | 27.6 |
|                      | High School  | 21        | 27.6 |
|                      | College      | 9         | 11.8 |
| Husbands' educations | Illiterate   | 7         | 9.2  |
|                      | Primary      | 16        | 21.1 |
|                      | Secondary    | 25        | 32.9 |
|                      | High School  | 25        | 32.9 |
|                      | College      | 3         | 3.9  |
| Residency areas      | Urban        | 60        | 78.9 |
|                      | Suburb       | 12        | 15.8 |
|                      | Rural        | 4         | 5.3  |
| Gravid               | Primigravida | 35        | 46   |
|                      | 2.00         | 21        | 27.6 |
|                      | 3.00         | 11        | 14.5 |
|                      | 4.00         | 5         | 6.6  |
|                      | 5.00         | 4         | 5.3  |
| Type of pregnancy    | Planned      | 48        | 63.2 |
|                      | Unplanned    | 24        | 31.6 |

Table 2: Therapeutic profile and other processes in pregnant women with HIV identified in the pilot study

| Variable                            |                                     | Frequency | %    |
|-------------------------------------|-------------------------------------|-----------|------|
| CD4 count testing before treatment  | Yes                                 | 66        | 86.8 |
|                                     | No                                  | 10        | 13.2 |
| CD4 count level before treatment    | <350                                | 18        | 23.7 |
|                                     | >350                                | 48        | 63.2 |
| Viral load testing before treatment | Yes                                 | 22        | 28.9 |
|                                     | No                                  | 54        | 71.1 |
| Viral load level before treatment   | <200 copies/ml                      | 5         | 22.7 |
|                                     | >200 copies/ml                      | 17        | 77.3 |
| ART during the pregnancy            | Complete                            | 66        | 86.8 |
|                                     | Irregular consumption               | 10        | 13.2 |
| CD4 count testing after treatment   | Yes                                 | 57        | 75   |
|                                     | No                                  | 19        | 25   |
| CD4 count level after treatment     | <350                                | 10        | 17.5 |
|                                     | >350                                | 47        | 82.5 |
| Viral load testing after treatment  | Yes                                 | 33        | 43.4 |
|                                     | No                                  | 43        | 56.6 |
| Viral load level after treatment    | <200 copies/ml                      | 28        | 84.8 |
|                                     | >200 copies/ml                      | 5         | 15.2 |
| Lifelong ART after delivery         | Lifelong                            | 67        | 89.3 |
|                                     | Irregular consumption               | 2         | 2.7  |
|                                     | Death                               | 0         | 0    |
|                                     | Pregnant at the moment of the study | 7         | 9.2  |
| Consultancy with husband            | Yes                                 | 57        | 75.0 |
|                                     | Rejected counselling                | 5         | 6.6  |
|                                     | Under follow up                     | 14        | 18.4 |
| HIV testing for husband             | No                                  | 19*       | 25   |
|                                     | HIV Negative                        | 19        | 25   |
|                                     | HIV positive                        | 38        | 50   |
| HIV situation in husband            | New case                            | 15        | 39.5 |
|                                     | Previously registered               | 23        | 60.5 |

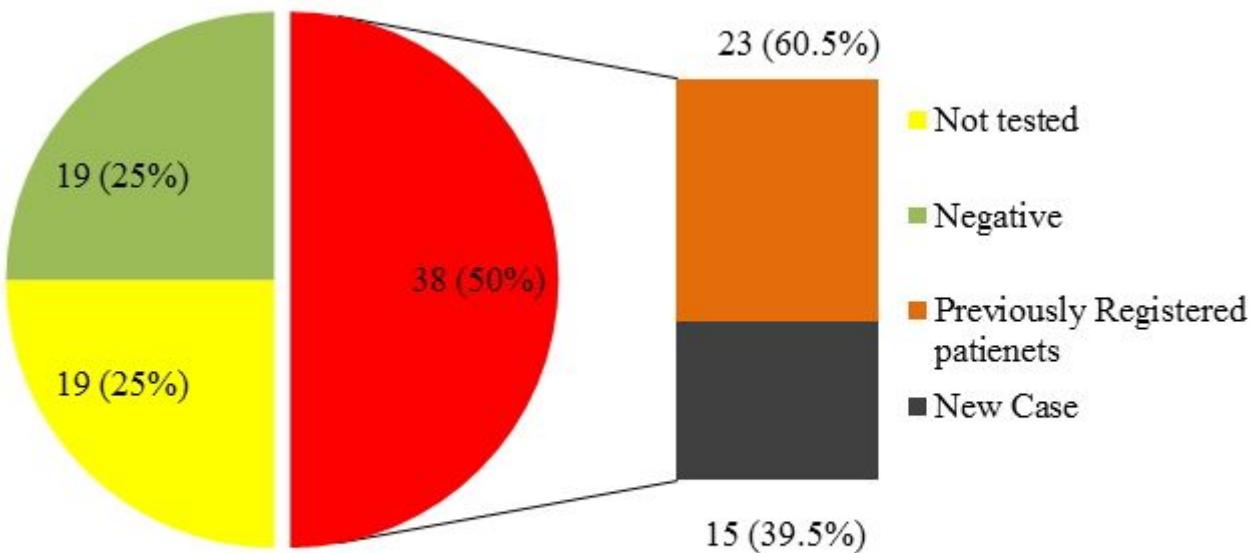
\*14 of them were under follow up for consultancy and 5 of them did not accept testing.

Table 3: Specifications related to infants born to pregnant women with HIV identified in the pilot study

| Variable                             |                                     | Frequency | %    |
|--------------------------------------|-------------------------------------|-----------|------|
| Type of delivery                     | Cesarean section                    | 63        | 85.1 |
|                                      | NVD                                 | 4         | 5.4  |
|                                      | Pregnant at the moment of the study | 7         | 9.5  |
| Outcome of pregnancy                 | Abortion                            | 2         | 2.6  |
|                                      | Live birth                          | 67        | 88.2 |
|                                      | Pregnant at the moment of the study | 7         | 9.2  |
| Newborn prophylaxis                  | Yes                                 | 66        | 95.5 |
|                                      | No                                  | 2         | 3    |
|                                      | Unknown                             | 1         | 1.5  |
| Feeding with formulated milk         | Yes                                 | 67        | 100  |
|                                      | No                                  | 0         | 0    |
| PCR in week 6-8                      | Yes                                 | 58        | 86.6 |
|                                      | No                                  | 9         | 13.4 |
| HIV testing in month 18 (27 infants) | Yes                                 | 20        | 74.1 |
|                                      | No                                  | 7         | 24.9 |
| Prophylaxis situation in infants     | Completed                           | 67        | 100  |
|                                      | Incomplete                          | 0         | 0    |
| HIV positive infant                  | Yes                                 | 1         | 1.5  |
|                                      | No                                  | 66        | 98.5 |
| Infant growth status                 | Normal range                        | 60        | 78.9 |
|                                      | Abnormal range                      | 3         | 3.9  |
|                                      | Unknown                             | 4         | 5.3  |
| Infant vaccination status            | Per protocol                        | 59        | 77.6 |
|                                      | With some error                     | 4         | 5.3  |
|                                      | Unknown                             | 4         | 5.3  |

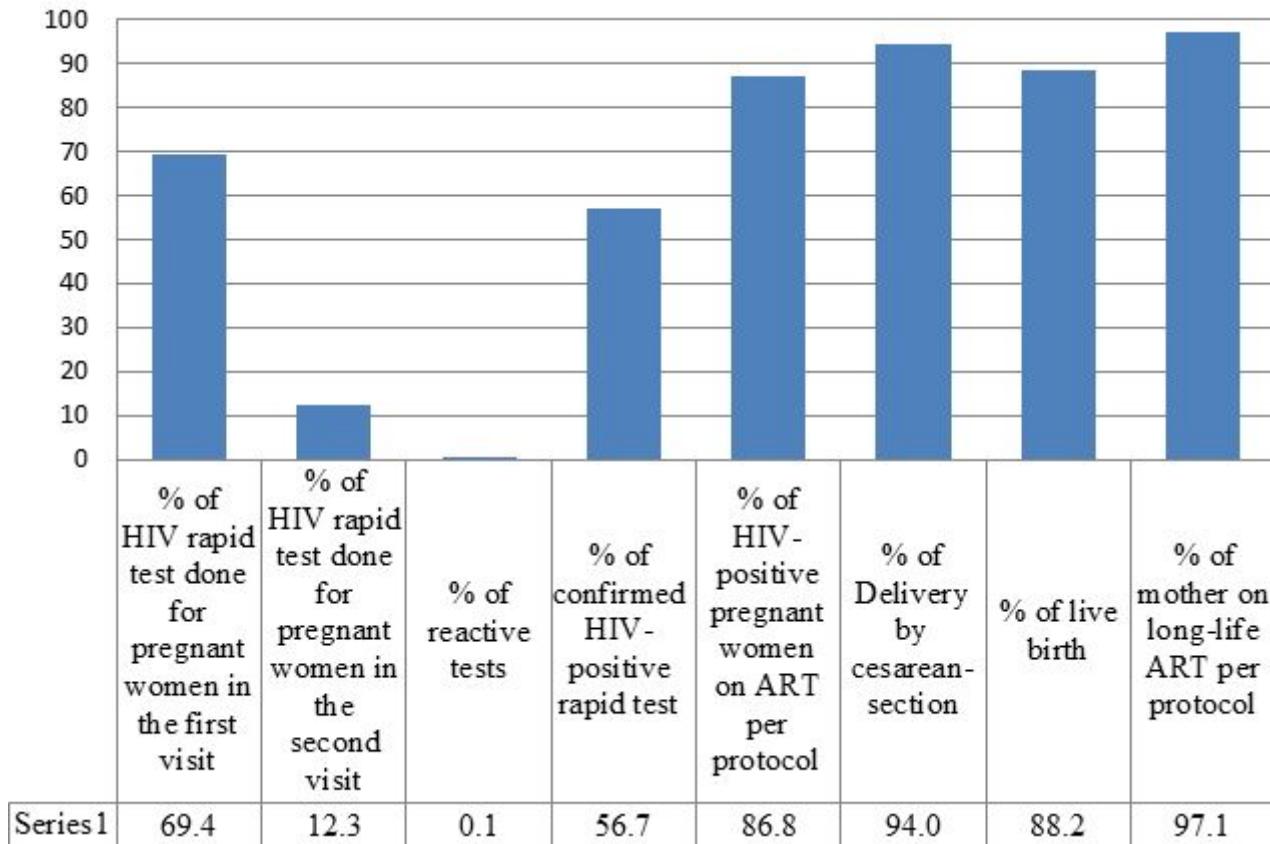
NVD: Natural vaginal  
delivery

## Figures



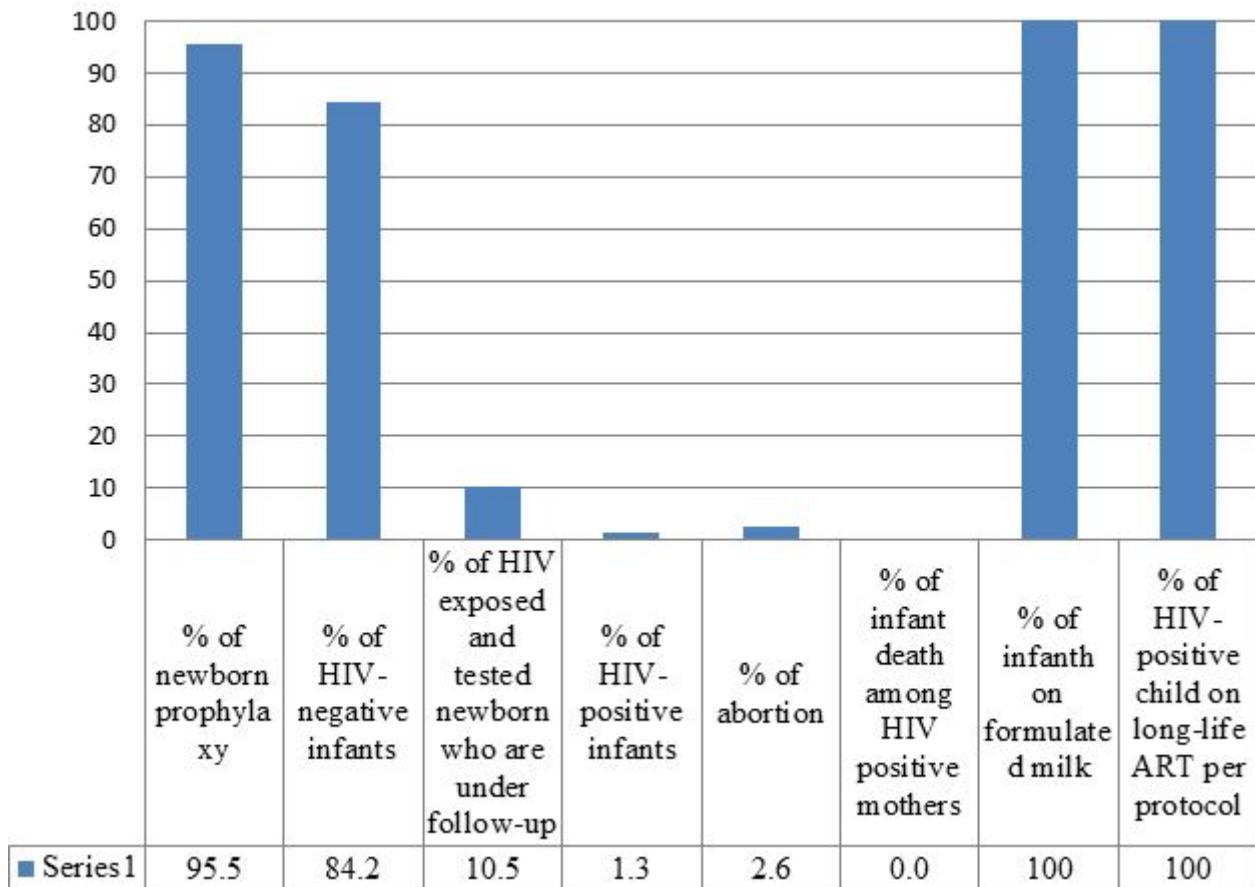
**Figure 1**

Husband HIV status of HIV positive pregnant women.



**Figure 2**

Cascade for pregnant women in the pilot study.



**Figure 3**

Cascade for infants in the pilot study.

## Supplementary Files

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