academicJournals

Vol. 7(6), pp. 61-67, July 2015
DOI: 10.5897/JAHR2014.0342
Article Number: C81B3BE54105
ISSN 2141-2359

http://www.academicjournals.org/JAHR

Journal of AIDS and HIV Research

Full Length Research Paper

Analysis of the national early infant diagnosis dataset, Zimbabwe: 2007 to 2010

Madziro Nyagura Tendai[1], Mugurungi Owen[2], Chirenda Joconiah[1], Mungati More[1], Bangure Donewell[1]*, Gombe T Notion[1] and Tshimanga Mufuta[1]

[1]Department of Community Medicine, University of Zimbabwe.
[2]AIDS and TB Unit, Ministry of Health and Child Welfare, Zimbabwe.

Received 30 April, 2015; Accepted 29 June, 2015

Zimbabwe introduced the early infant diagnosis (EID) for human immunodeficiency virus (HIV) exposed infants in 2007. Data captured through this initiative has never been analysed in detail. A detailed EID data analysis was carried out to evaluate the effectiveness of the prevention of mother to child transmission (PMTCT) of HIV in reducing HIV transmission. A retrospective record review of the national EID dataset for the period of January, 2007 to August, 2011 was conducted. Secondary data analysis was done to calculate EID population coverage and HIV positivity amongst samples tested, to compare effectiveness of PMTCT regimens among tested children, and to determine the correlation between mode of delivery and infant outcomes. EID population coverage increased from 1% in January, 2007 to 38% by August, 2011, far below universal access target of 80%. Of the samples tested, HIV positivity showed an apparent decline from 38% in 2007 to 11% in 2011. HIV positivity in infants born vaginally was comparable to those delivered by caesarean section for the years 2010 (p-trend 0.427) and 2011 (p-trend 0.99). Both maternal and infant antiretroviral (ARV) prophylactic regimens were found to reduce HIV positivity significantly (p-trend < 0.001). The national EID database is an important and readily available tool for monitoring and evaluating the PMTCT program and paediatric HIV trends. The Ministry of Health through its PMTCT programme should regularly use this data to inform prioritization of PMTCT interventions. Increased access to both maternal and infant ARV prophylactic drug regimens is critical, if the target of eliminating paediatric HIV by 2015 is to be met in Zimbabwe.

Key words: Early infant diagnosis, PMTCT, ARV prophylaxis, Zimbabwe.

INTRODUCTION

Transmission of HIV in Zimbabwe is primarily heterosexual and vertical. Mother to child transmission (MTCT) of HIV (vertical) occurs when an HIV infected woman passes on the virus to her child during pregnancy (30 to 50%), in labour and delivery (50 to 70%) or through breastfeeding (15 to 25%) (Paediatric HIV Training Manual, 2010). Without any intervention, 15 to 45% of infants born to mothers living with HIV will become infected

*Corresponding author. E-mail: bangured@yahoo.com.

(PMTCT Zimbabwe Training Manual, 2008). The Prevention of Mother to child transmission of HIV (PMTCT) program was introduced in Zimbabwe in 1999, with an overall goal of reducing HIV infection among children as well as reducing HIV related morbidity and mortality. The PMTCT program has evolved through the years, to incorporate and adopt new strategies based on new technologies.

In 2008, the World Health Organization (WHO) recommended the change of antiretroviral therapy (ARV) regimens for PMTCT from single dose Nevirapine (sdNVP) being used since 2001 to the More Efficacious Regimen (MER). The MER employed a combination of ARV drugs during antenatal (from 14 weeks), labour and post natal period and has been found to be more effective than sdNVP in reducing MTCT (Zimbabwe PMTCT Annual Report, 2009). Meanwhile, antiretroviral therapy (ART) was available for pregnant women who suited the prevailing adult criteria for ART. This criterion was either during the review period clinical (WHO stages ≥ 3) or immunological (CD4 ≤ 200 copies/ ml). ART services were however still largely centralized at some district hospitals and above. Because of rapid disease progression in infants, early recognition of infected infants is critical. Definitive diagnosis of HIV-infection at any age requires diagnostic testing that confirms the presence of the virus.

Two types of tests are in use: serological tests which detect antibodies to HIV proteins in blood and other body fluids and virologic tests which detect actual viral particles (Sherman et al., 2005). In 2007, Zimbabwe introduced virological testing which detects a component of the HIV deoxyribonucleic acid (DNA) through the use of a polymerase chain reaction (DNA-PCR) from 6 weeks of age in HIV-exposed infants. The test is conducted at the National Microbiology Reference Laboratory (NMRL) in Harare.

Samples for the DNA-PCR are collected from the infants in the form of a dry blood spot (DBS) which is then sent to the National Microbiology Reference Laboratory (NMRL) via district or provincial laboratories (Figure 1). The sample is accompanied by an HIV DNA PCR Laboratory request form. The request form captures identification variables (request number, province, district, health facility, mother's name, infant's name, sex and date of birth). It also captures the date the sample was taken; mode of the infant's delivery, infant's PMTCT prophylaxis, mother's PMTCT prophylaxis, infant's feeding practice, reasons for the DNA PCR test, entry point for the test and finally the result of the test. All this information is captured into an electronic database at the NMRL. Since the inception of EID in 2007, there was no formal mechanism to periodically analyse and manage the data for program monitoring and evaluation. The data captured through the EID initiative only had fragmented (on request) rather than a detailed analysis, yet it is an important source of information that should influence PMTCT programming. Detailed EID data analysis was carried out with the aim of informing and evaluating the PMTCT and paediatric HIV programme using variables that already existed within the dataset and producing information which had not previously been readily available. Zimbabwe is geographically divided into ten provinces of which eight of them are rural and two (Harare and Bulawayo) are urban.

METHODOLOGY

A retrospective record review of all the available electronic national EID dataset records for period January 2007 to August 2011 was conducted. The EID dataset comprised of a cumulative 48,915 records of which (38%) were completed and included in the analysis. The data collection tool that was initially used for EID in 2007 was changed in 2009. This change led to the introduction of new variables which included the type of ARV prophylaxis that the infant and the mother received. This introduction made it possible for comparison of HIV positivity according to different PMTCT regimens to be made for the years 2010 and 2011. The national HIV estimates were used to calculate the expected number of HIV infected women who were expected to deliver in a particular province/region.

Data was extracted from the national EID electronic database at the NMRL and the data set was checked for duplications and completeness of all entries before being analyzed. Incomplete records were excluded from the data analysis. The data was then analyzed using Microsoft Excel to generate graphs and tables and STATA10 for statistical tests. Secondary data analysis was done to calculate EID population coverage and HIV positivity amongst samples tested, to compare effectiveness of PMTCT regimens among tested children, and to determine the correlation between mode of delivery and infant outcomes. Permission to carry out the study was sought from the director AIDS and TB, Chief Laboratory Scientist at the NMRL, as well as the Health Studies Office in the Ministry of Health and Child Welfare.

RESULTS

Of the years with entries from a complete year, 2010 was chosen for further analysis due to the higher proportions of data completeness for most of the variables, infant ARV prophylactic regimen (49%) and maternal ARV prophylactic regimen (57%). The EID dataset comprised of a cumulative 48,915 entries since 2007. There was a significant increase in the total yearly EID requests received by the NMRL from 712 in 2007 to 25,445 in 2011 (January to August). The number of sites offering EID rose from 48 in 2009 to 379 in 2010.

EID coverage

When expressed as a percentage of the expected number of babies born to HIV positive women, the EID

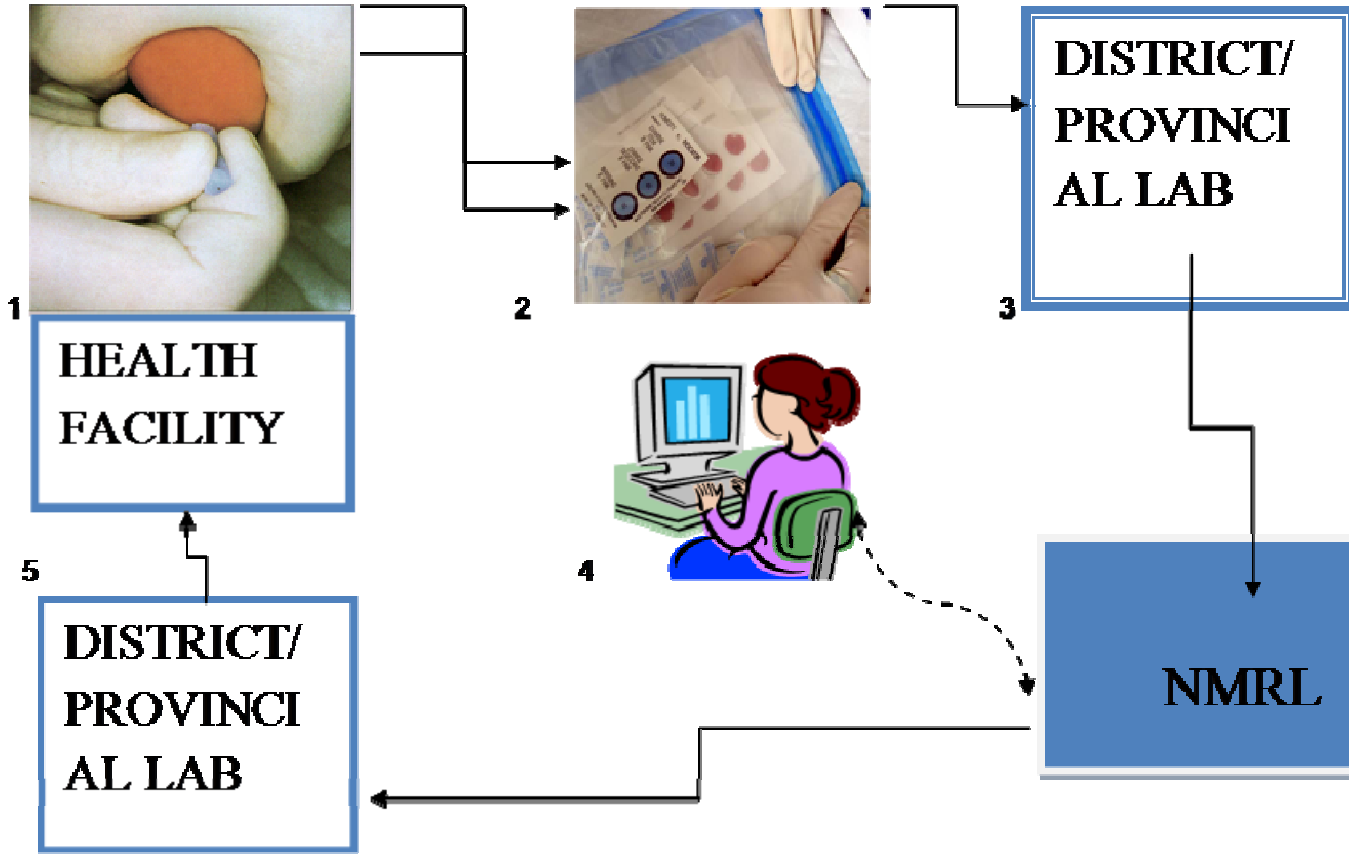

Figure 1. Description of the EID process through DBS samples.

coverage as calculated by the number of infants having had a DNA PCR test in each year, increased from 1% in 2007 to 38% by August 2011 (Figure 2). The increase peaked from 2010 (13%) to 2011 (38%). The increase in coverage of DNA PCR from 2007 to 2011 was statistically significant. EID coverage was generally low across the eight rural provinces. Bulawayo and Harare provinces have been doing much better than the rest of the country with coverages of 124 and 94%, respectively in 2010. In the rural provinces, Matebeleland South and Mashonaland West had the lowest EID coverages of 16 and 21%, respectively, while Midlands province had the highest coverage of 57% in 2010.

Indications for DNA PCR

An analysis of EID entry points was also done and it showed that the highest proportion (42%) of infants had been through the PMTCT follow-up program. Another significantly high proportion (34%) of infants had been tested from the routine well baby/immunization clinics. Routine EPI outreach was contributing the smallest proportion (2%) of samples tested. When we also analysed the reasons for requesting a DNA PCR test, most (72%) of the infants had a PCR test done because it was a first routine post natal test in an HIV-exposed baby. 14% of tests were post-weaning tests whilst symptomatic infants contributed the least (8%) number of PCR requests.

HIV prevalence

There was been a decline in HIV positivity rates among samples tested, from 35% in 2007 to 11% by August 2011. Data for HIV positivity was further analysed for the years 2009 to 2011 because the others years had incomplete data. When disaggregated by province, the HIV positivity rates showed a general decline between 2009 and 2011. The range of HIV positivity rates between provinces narrowed from 13 to 37% in 2009, to 10 to 15% in 2011. In 2009, the highest positivity was 37% in Manicaland province, whilst the lowest was 13% in

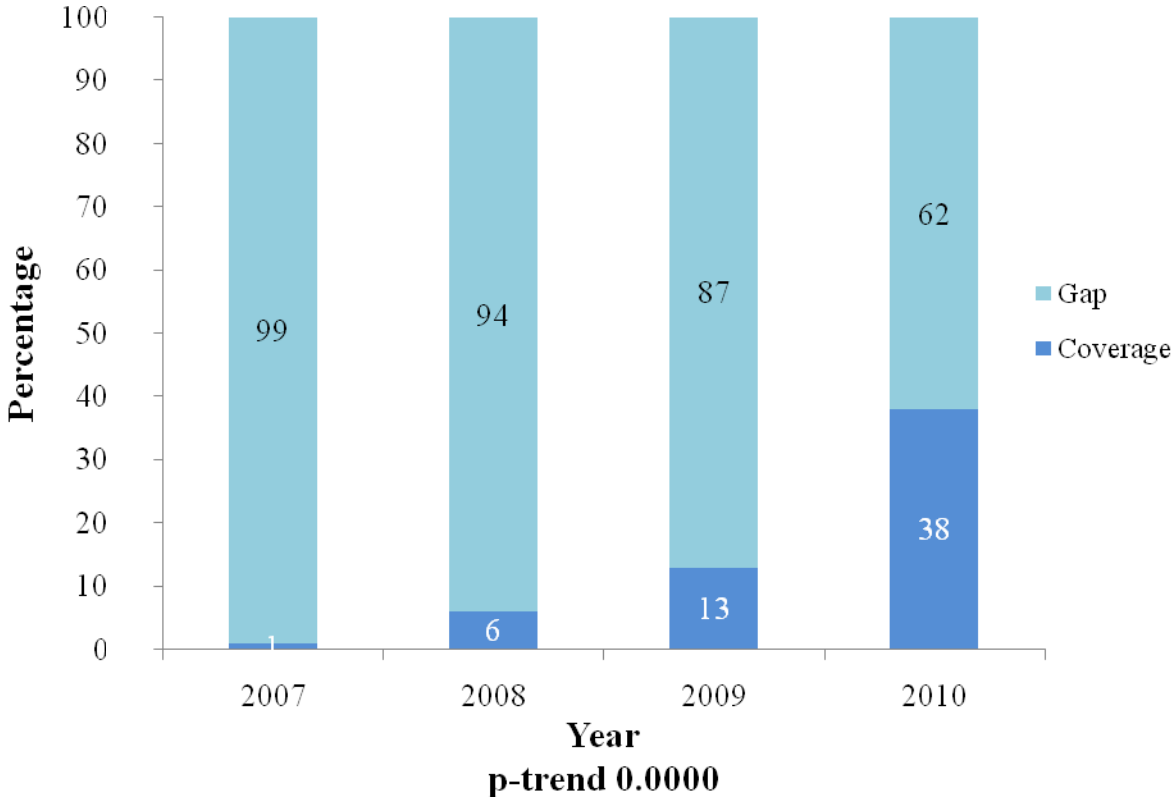

Figure 2. National EID population coverage by year, Zimbabwe: 2007 to 2010.

Midlands province. Mashonaland West province had the highest positivity rates of 18 and 15% for the both 2010 and 2011, respectively.

A total of 22,622 entries had mode of delivery documented. Of all infants, 93% were born vaginally whilst 7% were delivered through caesarean section. In 2011, 11% of infants born by caesarean section and 11% of infants born vaginally tested HIV positive by DNA PCR whilst in 2010, 14% of infants born vaginally tested HIV positive against 10% in those born by caesarean section. There was no significant difference between these proportions at 5% level of significance both in 2010 and 2011.

Infant ARV prophylaxis

Infants who received some form of ARV prophylaxis were significantly less likely to be HIV positive when compared to infants who did not receive ARVs (10% against 23%) at six weeks post natal period in 2010 (p-trend < 0.001). Of the 18,199 entries with the infant ARV prophylaxis indicated, most (72%) of the infants received SDNVP + AZT for 7 days, 20% received SDNVP only and 8% received the extended NVP for 6 weeks. Infants who received a single dose of NVP only had the highest HIV positivity at 16% followed by 12% among those that received the extended NVP for 6 weeks, whilst the least positivity was for those infants who received SDNVP + AZT for 7 days.

These differences were found to be statistically different using the Chi square test (p-trend < 0.001) (Figure 3). The proportion of HIV positive infants born to mothers who received ARV prophylaxis was 13% compared to 27% in infants born to HIV positive mothers who did not receive ARV prophylaxis in 2010. This difference was statistically significant (p-trend < 0.001). Further analysis showed that infants born to mothers who received ART, MER 14 and MER 28 were significantly less likely to be HIV positive and had lower HIV positivity rates of 0, 8 and 8%, respectively compared to 17% positivity in infants born to mothers who received single dose Nevirapine only (Figure 4).

DISCUSSION

Despite limitations in the nature of study design in that we

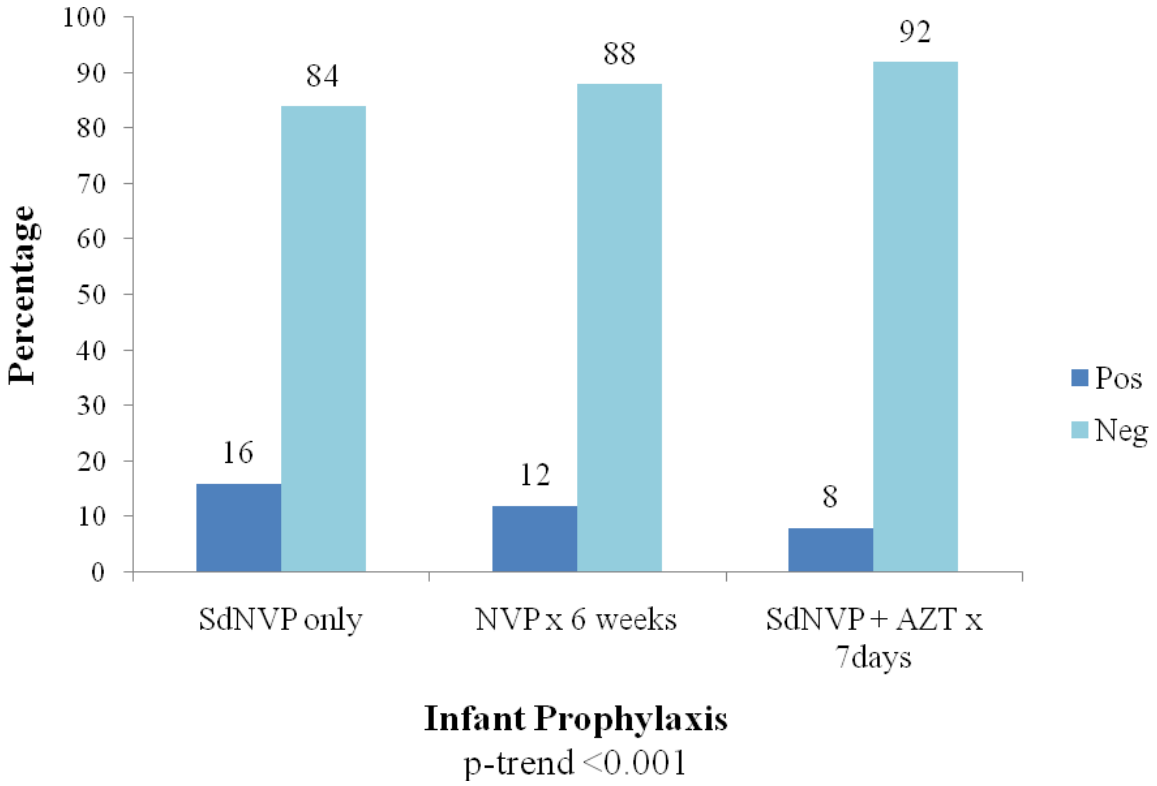

Figure 3. Infant ARV prophylaxis compared to HIV outcome, Zimbabwe: 2010. Pos: positive; Neg: negative.

were relying on already collected data and could not come up with definitive reasons as to why there were certain trends and anomalies in our findings, our study revealed a number of important findings. In our findings, we noted that a significant proportion of entries were incomplete. Gaps in data completeness were mainly because DNA PCR request forms were not properly filled in at the health centre level. If there had been regular data analysis, these gaps could have been addressed earlier on to correct this important aspect of data quality.

According to our study findings, the national EID population coverage has been increasing since 2007. This can be attributed to the roll out of EID in the PMTCT programme through health worker training as well as partner support for expansion and provision of the necessary logistical and technical support. However, the national EID coverage remains below the target of at least 80%. Loss to follow-up of HIV-exposed babies may be contributing to the low EID coverage in Zimbabwe. Experience from South Africa reveals that without a systematic and structured plan that incorporates testing at 6 weeks, up to 85% of HIV-exposed infants are lost to follow-up from clinics providing services for PMTCT by one year of age (Unite for children, 2009).

Variable provincial EID coverages have been experienced with urban provinces (Bulawayo and Harare) being higher than the eight rural provinces. This may be attributed to the fact that the EID program was piloted in these provinces before expansion to rural provinces. Similar findings were found in Uganda where health centers that comprised 47% of the EID collection sites, collected only 11% of the total tests, and in Namibia 15% of EID sites collected > 93% of all samples. The study concluded that, while expanded geographical coverage across the countries reviewed brought services closer to the patient, it did not always translate into significantly greater sample collection at lower-level facilities or more even geographical distribution of sample collection (Tripathi et al., 2010). Many possible explanations exist for the general decline in the HIV positivity rate in this study. These include the fact that the PMTCT program changed its prophylactic regimens from the single dose nevirapine (SDNVP) to the more efficacious regimens, or it is simply because more asymptomatic infants are now being tested. Similar findings have been reported in South Africa where the PCR positivity rates in infants tested at < 2 months dropped from 6.2% in 2009 to 4.6 in 2010 possibly due to the start of dual therapy in 2008

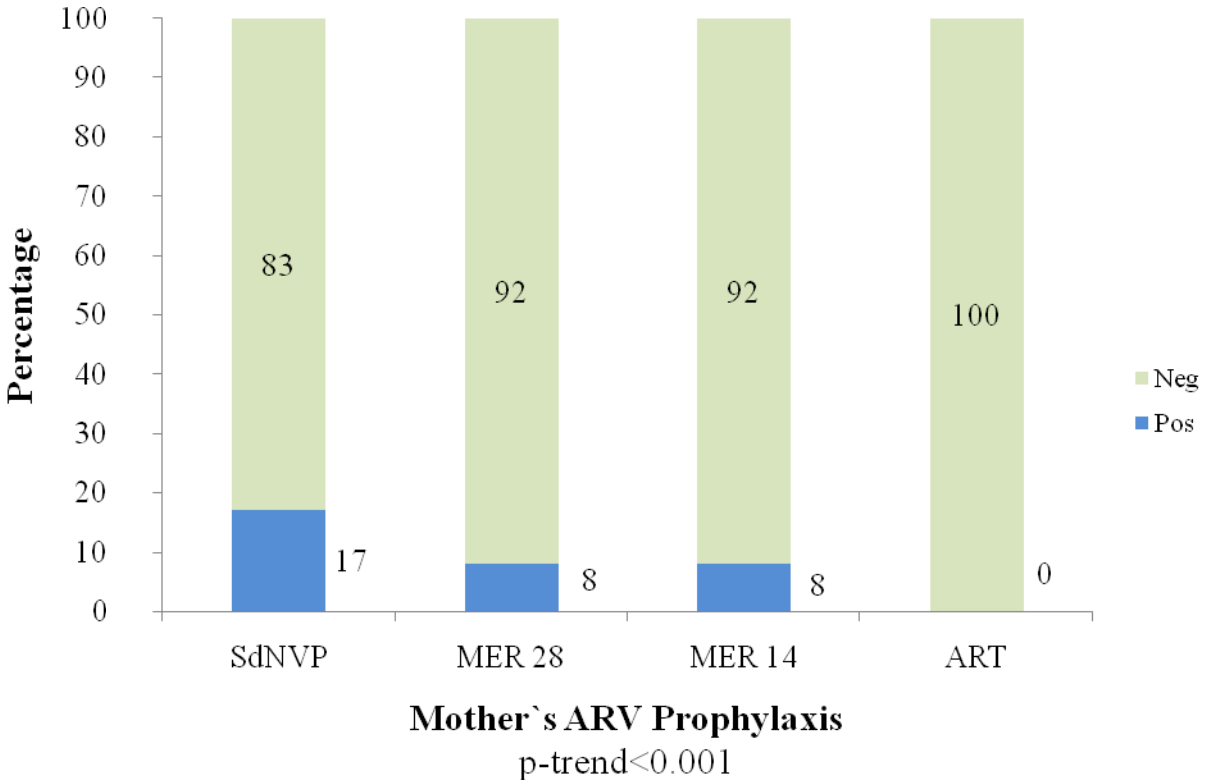

Figure 4. Infant HIV outcome based on maternal ARV prophylaxis, Zimbabwe: 2010. Pos: positive; Neg: negative.

leading to reductions in PCR positivity rates (South Africa National PMTCT Accelerated Plan, 2010).

Our study also compared HIV outcomes in infants according to their PMTCT regimens in 2010. Infants who received SDNVP only had the highest transmission rates compared to infants who received either extended NVP or NVP and AZT for 7 days. This is consistent with the findings of the HIVNET study and different studies, some of which have influenced the shift in WHO recommendations for PMTCT regimens (Guay et al., 1999; Valerianea, 2005).

Maternal PMTCT regimens were also compared in our study and as expected, women who took SDNVP only had the highest transmission rate compared to women who took MER 28, MER 14 or ART in 2010. A Zambian study in 2005 concluded that, more efficacious ARV regimens may prevent a greater number of infant HIV infections assuming that regimen complexity does not severely compromise population coverage (Megazzini et al., 2005). Comparison between mode of delivery and HIV outcome showed that no significant difference in positivity rate was found between infants delivered either by caesarean section or vaginally. Similar findings were noted in a study in England where transmission rates were similar for mothers on highly active ARV therapy with planned caesarean section, and mothers on highly active antiretroviral therapy (HAART) with planned vaginal delivery. One assumption is that transmission rates may be attributed to lowered viral loads because the women were on HAART (Townsend et al., 2008). The low HAART coverage among pregnant women and low rates caesarian section (4.8%) rates may have resulted in HIV outcomes may have resulted in HIV positivity among infants delivered vaginally being similar to that among infants delivered by caesarian section (Gibbons, 2010; Anderson, 2005).

Our study found that most infants were being tested through the PMTCT follow-up in maternal and child health units. The routine immunization clinics were a significant entry point. All the other entry points made minimal contribution to the pool of PCR tests. Several countries, including Cameroon, Malawi, Rwanda, Swaziland, United Republic of Tanzania and Zimbabwe have revised child health cards to include HIV-related information, making tracking of exposed children easier and increasing the likelihood that infants known to be exposed to HIV are referred for virological testing and put on treatment (Unite for children, 2009). Due to the

evaluation being based on desk review of the national EID dataset, assessment of some variables such as infant feeding method was not feasible due incompleteness of data. Another limitation of this dataset was that similar comparisons could not be made for some variables due to the change in the data collecting tool in the different years.

The fact that combination ARVs were prescribed to women with more advanced disease could have confounded the relationship between HIV positivity and maternal ARV prophylaxis regimen and similarly, women who were sick may be more likely to receive HIV testing and PMTCT thus again confounding this relationship. Regular data analysis on an annual basis is also recommended in order to document important trends in PMTCT and Paediatric HIV transmission more so as the country is working towards eliminating paediatric HIV transmission by 2015.

CONCLUSION

The national EID coverage has been increasing during the period under review with urban provinces having better than rural provinces. Prevalence of HIV declined in infants who received and whose mothers received ARV prophylaxis. The prevalence of HIV was comparable between infants delivered vaginally and those delivered by caesarian section. The major entry point for EID was PMTCT program follow-up.

RECOMMENDATIONS

We therefore recommend to the national PMTCT training officers and monitoring and evaluation officer that the importance of correctly completing PCR request forms should be emphasized at all EID sites in trainings, during support and supervision. The PMTCT training officers in liaison with the Director of the NMRL should follow-up to facilitate training of data capture clerks at NMRL in relevant PMTCT/EID topics. Further research is also needed to establish other determinants of HIV transmission as well as why Mashonaland West has the highest positivity rate. We recommend to the National PMTCT coordinator to step up efforts to increase ART coverage in pregnant women. Due to limitations in our dataset, the combined effect of maternal and infant prophylactic regimens on HIV positivity could not be assessed and we recommend further research in this regard. It is important to note that, there is need for further research that takes into account potential confounders and/or effect modifiers for the comparisons made in this study, for example, mother's CD4 count/viral load, maternal co-morbidities, viral genotype, intra-partum hemorrhage and prematurity amongst others.

ACKNOWLEDGEMENTS

This study received support from the following people and organisations: National Microbiology Reference Laboratory at Harare Central Hospital, Harare, Zimbabwe; Health Studies Office and AIDS and TB Unit, MoHCC; Department of Community Medicine.

Conflicts of interest

Authors have none to declare.

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