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IMPACT OF CHANGED NACO GUIDELINES ON HIV VERTICAL TRANSMISSION AT TERTIARY REFERRAL INSTITUTE IN MUMBAI

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ABSTRACT

OBJECTIVE : To assess the impact of changed guidelines of National AIDS Control Program on vertical transmission at our centre.

DESIGN: Retrospective analysis of outcomes of standard treatment as per revised national guidelines

SETTING: H B T Medical College and Dr. R N. Cooper Hospital Mumbai.

METHODS: All antenatal (ANC) cases over 4 years (2015 to 2018), sero-positive women delivering at our institute, and newborns screened for HIV by DBS (dried blood spot) testing as per NACO Guidelines were reviewed.

RESULTS : Out of 18,342 ANC cases registered over 4 years, totally 16,664 were screened using opt-out policy (91%). Overall 25 cases (0.15%) were detected to be HIV –positive, with a decreasing trend over the 4 years. However 0.6% (100) of antenatal women were seropositive as many (75) had been referred to us for delivery due to sero-positive status. Of the 75 livebirths, 65 (86.7%) neonates underwent DBS testing and all tested negative. In the last 4 years there has been ZERO positivity - 100% prevention of vertical transmission of HIV in those tracked.

CONCLUSION: The rate of vertical transmission can be reduced to zero by antenatal screening, highly active anti retroviral therapy (ARV) during antenatal and intra-natal period and treating newborns with ARV as per revised NACO Guidelines.

KEYWORDS

HIV, vertical transmission.

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INTRODUCTION:

Although heterosexual transmission is responsible for 88.2% of HIV Infections in India, 5% were attributed to parent to child transmission (NACO Report 2011-12). HIV infection in young children is mostly due to mother to child transmission and prevention of MTCT will greatly reduce the infection in young generations. Nevirapine (NVP) therapy given as single dose to mother just before delivery and to newborn within 72 hours of birth was being done at our centre as per national guidelines till 2013. WHO recommends ART in all HIV positive women in pregnancy which was accepted by our National AIDS Control Organization (NACO) in 2013 and implemented from 2014.[1,2]

Identifying women living with HIV, initiating them on lifelong antiretroviral treatment (ART), and retaining them in care are among the important challenges facing this generation of health care managers and public health researchers. The development of antiretroviral treatment (ART) that effectively suppresses HIV viral load has fundamentally transformed the tragedy that HIV/AIDS has represented for mothers and children living in high prevalence settings. [3]

In 2013, the WHO released new guidelines which recommend to provide life - long ART (triple antiretroviral drug regimen) for all pregnant women living with HIV, irrespective of the CD4 cell count; this new option (B+) will result in substantial reduction in transmission of mother to child transmission and would help in maximizing coverage for those needing treatment for their own health and survival. It would also avoid stopping and starting drugs with repeat pregnancies, providing early protection against MTCT in future pregnancies, reducing transmission to sero-discordant male partners and avoiding drug resistance.[4]

OBJECTIVE :

To assess the impact of changed guidelines of National AIDS Control Program on vertical transmission in the past 4 years at a tertiary referral centre in Mumbai.

DESIGN:

Retrospective analysis of 4 years data of outcomes of standard treatment given to pregnant women (as per revised NACO national guidelines) who were diagnosed as HIV-positive in our antenatal clinic, or referred to us for further care being diagnosed elsewhere to be seropositive. All received free testing and triple-drug anti-retroviral therapy (ART) as per revised guidelines. Newborns of sero-positive women were given syrup Nevirapine for minimum 6 weeks, or more as per standard protocol. Dried blood spot (DBS) testing of newborns was done at regional molecular biology lab free of cost, following NACO guidelines.

SETTING:

Hinduhridaysamrat Balasaheb Thackeray Medical College and Dr. R N. Cooper Hospital which is a tertiary referral centre located in the suburbs of Mumbai city, which became a medical college in 2015.

SUBJECTS:

All antenatal (ANC) cases over 4 years (2015 to 2018), sero-positive women delivering at our institute, and newborns screened for HIV by DBS (dried blood spot) testing as per NACO Guidelines were reviewed.

METHODS:

We are a stand-alone centre for counselling, testing and provision of anti-retroviral therapy, supported by MDACS (Mumbai District AIDS Control Society). Being part of the public health care system, all services are subsidized or provided free of cost. All pregnant women who presented at our institute for antenatal registration, were offered HIV screening by opt-out policy. Those who did not refuse underwent testing after taking informed consent.

In our centre since January 2014 all HIV positive pregnant women are offered lifelong triple drug ART as per NACO guidelines 2013. These drugs are Tenofovir 300mg once daily, Lamivudine 600 mg once daily, Efavirenz 600mg once daily given as a fixed-dose combined pill as the preferred regime.

All seropositive women delivered in our institute and women referred from outside because of sero-positive status were also included in this study. All newborns were screened for HIV by DBS as per NACO guidelines.

Statistical Analysis :The data has been analysed using Microsoft office Excel 2007. The categorical variables are summarized as frequencies and percentage .The data is graphically presented as bar diagrams.

STANDARD TREATMENT OFFERED IS SUMMARIZED BELOW:

Antiretroviral therapy options are as follows:

- *Known positive and on ART*: If the pregnant woman is already a known positive and on ART, and clinically and immunologically stable with suppressed viral load if available, continue the same drugs
- *Known positive and not on ART*: Counsel and link with ART services and initiate on ART irrespective of clinical stage and CD4 count
- *Newly identified*: Link to ART services and initiate ART irrespective of clinical stage and CD4 count. Partner is also offered testing.

DELIVERY PRACTICES:

We reserve cesarean section for obstetric indications, follow safe delivery practices with minimal interventions, and have facility for on-site emergency testing for women presenting to labour room with unknown HIV status.

POST DELIVERY

- Infants born to HIV-infected mothers receive NVP prophylaxis immediately after birth.
- It is recommended that infants should be given exclusive breastfeeds for the first six months preferably. Exclusive replacement feeding may be done only if the mother has died or has a terminal illness or decides not to breastfeed despite adequate counselling.
- If the mother has not made a decision about feeding yet, she is counselled to give exclusive breastfeeds for the first 6 months which is the preferred option, followed by complementary feeds after 6 months. No abrupt weaning to be done after 6 months
- We counsel and support parent to give infant NVP prophylaxis using the syringe/dropper provided.
- All infants (irrespective of maternal ART in mother) receive a minimum of 6 weeks of infant NVP prophylaxis daily until the first visit for immunization at 6 weeks of age.
- Infants who are diagnosed DNA/ PCR negative by DBS testing can continue breastfeeding and be re-evaluated as per protocol.
- If exclusive replacement feeding is being done, then infant NVP prophylaxis may be stopped at 6 weeks of age.

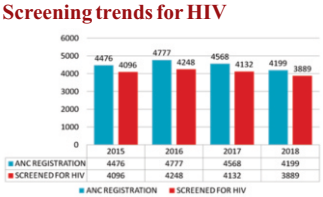
RESULTS :

Out of 18,342 ANC cases registered over 4 years, totally 16,664 were screened using opt-out policy (91%). (Table 1 and Graph 1)

Table 1: ANC Screening trends for HIV

SR. NO	ANC REGISTRATION YEAR	TOTAL ANC REGISTRATION	TOTAL ANC SCREENING FOR HIV	% SCREENED
1	2015	4,476	4,096	91.5 %
2	2016	4,777	4,248	88.9 %
3	2017	4,568	4,132	90.45 %
4	2018	4521	4188	92.6%

Graph 1 : ANC Screening trends for HIV



Overall 25 cases (0.15%) were detected to be HIV –positive, with a decreasing trend over the 4 years.

Table 2: HIV POSITIVE- NEW & REFERRED

ANC DETECTED HIV POSITIVE				
SR.NO	YEAR	Newly detected positive ANC Cooper	Known positive referred to us	TOTAL
1	2015	8	19	27
2	2016	3	30	33
3	2017	11	16	27
4	2018	3	10	13

However of total ANC, 0.6% (100) were seropositive as many cases (75) had been referred to us for delivery due to sero-positive status. (Table 2)

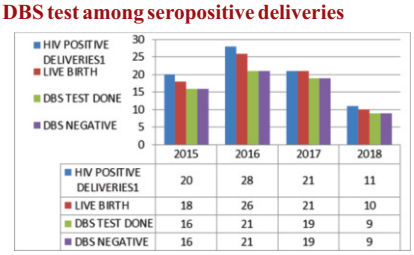
The labor outcomes are shown in Table 3. Some of the women did not deliver with us despite being treated with ART, and there were 5 stillbirths totally in the study period.

Table 3: BIRTH OUTCOME - HIV POSITIVE WOMEN

SR.NO	YEAR	ANC DETECTED TO BE HIV POSITIVE	HIV POSITIVE DELIVERY	LIVE BIRTHS	STILL BIRTHS	DBS DONE
1	2015	27	20	18	2	16
2	2016	33	28	26	2	21
3	2017	27	21	21	0	19
4	2018	13	11	10	1	9

Of the 75 live births, 65 (86.7%) neonates underwent DBS testing and all tested negative. (Graph 2)

Graph 2: DBS test among seropositive deliveries



In the last 4 years there has been ZERO positivity - 100% prevention of vertical transmission of HIV in those tracked.

DISCUSSION:

According to WHO, UNICEF, Clinton Health Access Initiative and National AIDS Control Organization all ANC cases should be screened for sero- positive status.[1,5,6,7]

At our center all ANC cases are undergoing Counseling and then HIV screening by opt-out policy. Table 1 and graph 1 show that number of ANC Counseling and percentage of ANC screening is increasing and we are able to cover more than 90% of the target population.

Newer NACO and WHO Guidelines 2013 have been implemented from 2014 in our institute after which, the incidence of seropositive mother and newborn HIV positive cases are declining although we are now a referral center offering ART also. Table 2 shows that three-quarters of the sero-positive women were referred from elsewhere. Only 0.15% were our ANC-screen positive but 0.6% of total ANC were seropositive women.

According to the UNAIDS report on Global AIDS 2013, the number of newly infected children has been declining since 2003 due to increasing access to prevention of parent to child transmission (PPTCT) services.[5,6]

In 2014, the year before our institute became a medical college and stand-alone ART centre, we had 2 newborns who were DBS positive. In the subsequent 4 years of our study (2015-18) of the 75 live births, 65 newborns (86.7%) were screened for HIV by DBS (dried blood spot) testing according to NACO guidelines[8, 9] None of them were

HIV-positive i.e. zero vertical transmission in those tracked.

INDIAN STRATEGY, VISION AND TARGETS TOWARDS ENDING HIV[10]

In June 2016, the Minister of Health and Family Welfare reiterated the country's commitment at the United Nations' High-Level Meeting on AIDS towards the goal of 'ending the AIDS epidemic as a public health threat by 2030', inclusive of the Joint United Nations Programme on HIV/AIDS (UNAIDS) Fast Track targets for 2020 as well as in line with the Sustainable Development Goals (SDGs) for 2030.This National Strategic Plan (NSP) will herald the country to the midpoint of the 2030 goals. The goals remain those of the 'Three Zeros' - i.e. zero new infections, zero AIDS-related deaths and zero discrimination which form the basis of this strategic plan.

By 2020, the focus of the national programme will be on achieving the following fast track targets:

1. 75% reduction in new HIV infections,
2. 90-90-90 goal:
   - 90% of those who are HIV positive in the country know their status,
   - 90% of those who know their status are on treatment and
   - 90% of those who are on treatment experience effective viral load suppression,
3. Elimination of mother-to-child transmission of HIV and Syphilis, and
4. Elimination of stigma and discrimination

CONCLUSION:

Our study conforms to the fast track targets of our national program, shows that Triple-drug regime is highly effective and our screening program works!

The rate of vertical transmission can be reduced to zero by antenatal screening, highly active anti retroviral therapy (ARV) during antenatal and intra-natal period and treating newborns with ARV as per revised NACO Guidelines.

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DISCLOSURE OF INTERESTS :

all authors hereby declare that there is no conflict of interest or financial disclosures involved.

CONTRIBUTION TO AUTHORSHIP:

R.J. conceptualized and wrote-up the study, being lead investigator in-charge of running the PPTCT Program in the institute and is also a trainer and facilitator of the program with MDACS. P.Y. assists her in this program, and collated the data with the help of the counsellor and S.T, who also supervises the laboratory work and DBS processing.

COMPLIANCE WITH ETHICAL STANDARDS:

the study was approved by Institutional ethics committee for waiver of consent, being a retrospective analysis of standard treatment.

Informed consent was obtained from all individual participants being screened and their confidentiality was maintained.

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