

National PPTCT (Prevention of Parent to Child Transmission) of HIV Drug Protocol—Urgent Need for a Change

The National AIDS Control Organization (NACO) recommends use of single dose Nevirapine (NVP) 200 mg to the mother at onset of labour and a single dose to the baby (2 mg/kg) within 48 hours of birth. This intervention is expected to reduce transmission by nearly 50%(1). The simplicity of the protocol and the sizable reduction in transmission that it achieves has worked in its favor so far. However, presently available data reveals that transmission can be further reduced by the addition of Zidovudine (AZT). Additionally, NVP resistance has been documented in 25-75% cases even with single dose therapy and this could have serious implications for future treatment options. For both these reasons the present protocol needs urgent revision.

Longer preventive protocols using Zidovudine (AZT) alone for the mother (14-16 weeks gestation to term and peripartum) and to the baby for upto 6 weeks after are known to reduce transmission by as much as 68%(2). In this study oral AZT was used antenatally and intravenous AZT was used in the peripartum period. Presently only oral formulations are available in India. Combination regimens using AZT and NVP in a modified regimen with AZT at 300 mg orally BD from 28 weeks of gestation and intrapartum 300 mg orally 3 hourly till delivery followed by 8mg/kg/day in two divided doses to the baby for 1 week in addition to single dose NVP to baby and mother was shown to reduce transmission to as low as 1.9%(3). Highly active antiretroviral therapy (HAART) with three drugs (AZT, Lamivudine (3TC) and NVP) further reduces transmission to <1%(4).

The WHO issued new guidelines in 2006 recommending 3 drug combination therapy as the first choice to prevent mother to child transmission when the drugs are indicated for the mother's own

health, based on clinical and immunological staging. When there is no indication for 3-drug HAART, an ARV prophylactic regimen with AZT should be started at 28 wks. Peri-partum, in addition to single dose NVP the mother needs to receive AZT and 3TC which is continued postnatally for one week as a tail to reduce chances of NVP drug resistance. The baby has to receive a single dose of NVP and a week's course of AZT. This strategy not only reduces transmission to a significant extent but also reduces the problems of NVP resistance. When mothers present for the first time in labour, the same protocol is followed peri-partum and postpartum. However, the baby has to receive AZT for one month along with single dose NVP(5).

Possible difficulties in up-scaling the PPTCT program as per WHO guidelines could be related to logistic problems, compliance and monitoring side effects when the mother is on multiple drugs. At the present time there is expertise available in the country for HAART therapy. With a referral network to access these services when HAART is indicated for pregnant women and enhanced training on the use of the WHO ARV prophylactic protocol, it seems possible to extend this treatment to expectant mothers with the provision of two or three drugs as indicated. This will enhance protection to babies from a preventable life-threatening disease and at the same time preserve the mother's future treatment options.

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Tuberculosis Infection in BCG Vaccinated Children

- A good number of BCG vaccinated children do not develop a scar. In Kerala, BCG coverage is above 95%. But in the present study(1), only 59% of children have a BCG scar. This clearly shows that the BCG scar alone, to identify the vaccinated children, is an irrational and misleading criteria. This study ideally should have been conducted as a prospective study(2,3).
- Tuberculin induration measured, should be interpreted without any prejudice, whether the children are vaccinated or not. But this study probably brings out that the interpretation of Tuberculin induration differentially in vaccinated and unvaccinated children is baseless.

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Reply

- We disagree. Studies have demonstrated >90% scar formation post-vaccination with BCG(1-5). These data indicate that a BCG scar is indeed a sensitive and reliable indicator of BCG vaccination. However, we do concur with Dr. Kartha that a prospective study could have had more validity but temporal and resource limitations ruled this out.
- We do not deny that the use of a differential cut-off is unconventional. The multiple reasons for using this strategy have been described in detail in the article. Our hypothesis is that, despite tuberculin reactions appearing similar in both groups (as suggested by the data and pointed out by Dr. Kartha), vaccinated and unvaccinated children, ipso facto, have different risks of acquiring tuberculosis and developing disseminated disease that necessitates a different tuberculin cut-off reading for each group. It is an