Programme to prevent mother to child transmission of HIV: some concerns

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The National AIDS Control Organisation (NACO) has embarked on an ambitious programme aimed at controlling paediatric AIDS in the country. NACO has reason to believe that HIV prevalence among antenatal women is more than one per cent in the high-prevalence states of Maharashtra, Tamil Nadu, Karnataka, Andhra Pradesh, Manipur and Nagaland. The Prevention of Mother to Child Transmission or PMTCT programme is directed at preventing transmission of the virus from pregnant woman to foetus or breast-feeding infant. Feasibility studies involving the use of anti-retroviral (ARV) prophylaxis and therapy are underway with the longer objective of making it a nation-wide programme. NACO estimates that there are 3.86 million HIV-infected persons in the country and 20,304 AIDS cases as of March 2001.

In January 2000, NACO embarked on a pilot study in the Obstetrics and Gynaecology departments of 11 institutions in Maharashtra, Tamil Nadu, Manipur, Karnataka and Andhra Pradesh. The objective, according to a NACO report titled 'Combating HIV/AIDS in India, 2000-2001', was to assess the feasibility of administering AZT or Zidovudine to prevent mother to child transmission of HIV-1 infection in pregnant mothers.

All pregnant women attending the antenatal clinics in these instititutions were offered a group education-cum-counseling session on HIV, supported by a video film session. Written informed consent was obtained from the women and blood samples for the HIV test taken from them. Post-test counseling was also provided. After thirty six weeks of gestation, women who tested positive for HIV were given AZT 300 mg orally twice a day. During labour, the same dose was given every three hours. (This is a shorter and cheaper version of the AZT regimen followed as standard practice in the US.) Following delivery a Polymerase Chain Reaction test was done at 48 hours and at two months to determine the HIV status of the infant. The mother was given the option of breast feeding after being counselled on the risks and benefits of the various infant feeding practices. It is significant that only 658 of the 751 women who accepted AZT in the study were followed – the rest did not return and the institutes did not monitor them further.

The study completed one year in March last year. It established that PMTCT was a cost-effective strategy for prevention and control of the epidemic, and recommended that NACO expand the strategy to the level of a national programme. It noted that this would require a massive training exercise to cover 600 districts in the country in a phased manner. The 11 centres where the study was conducted would be nodal training centres and their technical expertise used for "scaling up PMTCT activities".

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The study further recommended undertaking operational research, especially of a single-dose regimen of Nevirapine which, it was felt, could be a more feasible option than AZT. The first phase of a feasibility study involving a single-dose application of Nevirapine was concluded recently and the second phase has been launched. The PMTCT strategy, using either AZT or Niverapine, is now expected to be expanded to a national programme.

Questions about the drugs

However, this programme does not taken into account the serious side effects of these drugs, and the possible development of resistant strains. Organisations like the Joint Action Council, Kannur, argue that the government is disregarding the findings of several studies bearing testimony to the ill-effects of Niverapine and AZT. Not only do they have established side-effects, they are also very expensive. Further, mothers and children taking the drugs need to be monitored. However, the system for monitoring in the Indian situation has not been thought out. It is feared that PMTCT will be another top-down programme dissociated from public health realities and people's needs.

In response to such criticism, J V Prasada Rao, then director of NACO, said the interventions should not be looked at only as a HIV prevention programme. Since the programme would be implemented through voluntary counseling and testing (VCT) centres, many pregnant women would counselled about reproductive health issues. Further, Rao said, it was only in a prolonged regime that drug resistance developed and side-effects could emerge. The single dose of Nevirapine was not likely to develop resistance among the recipients, he said. He said that the feasibility studies of Nevirapine conducted between October and December of 2001 had shown no adverse reactions.

The PMTCT programme is to be expanded in three stages. All medical colleges in high prevalence states of Tamil Nadu, Andhra Pradesh, Karnataka, Maharashtra, Manipur and Nagaland would have to set up VCT centres, and laboratory technicians would be trained to deal with the demands of the programme. In the second stage, all district hospitals would be covered, and in the third, medical colleges in the rest of the country would come under the programme. "If need be, district level hospitals in the low prevalence states will also be covered but that would come later," said Prasada Rao. An estimated six to seven million mothers could be covered in a year. Of an estimated 25 million annual pregnancies, some six to seven million women deliver in government hospitals and institutions. The majority of them are poor and vulnerable and more prone to HIV, said Rao.

Unrealistic programme

The fact is that the target group for this programme consists of millions of poor, illiterate or semi-literate women for whom no choice of any kind exists. Breast feeding and

non-Caesarean deliveries are known to be conduits for virus transmission. But the HIV positive pregnant and working class woman cannot avoid breast-feeding. Nor can she afford a Caesarean.

Anju Singh and Puroshottaman Mulloli of the Joint Action Council are highly critical of NACO's proposal. Singh argues that given the stigma attached to HIV/AIDS, a woman not breast feeding her infant would be singled out. Second, the infant would be deprived of the immunity provided by breast milk. NACO is also unrealistic to 'leave the option' to the woman after counselling her on the various infant feed choices. One such option, the NACO director suggested was encouraging the consumption of 'diluted cow milk' for the infant. It is not clear who would pay for the diluted cow milk.

Drug toxicity

On February 5, 2001, US federal health authorities responded to emerging evidence of drug toxicity with new guidelines for ARV therapy. JACK points out that US guidelines now recommend that treatment for HIV be delayed as long as possible for asymptomatic people. The new guidelines have made treatment regimens very complex. The administration of these drugs demands a number of conditions including patient involvement and close medical supervision to constantly monitor the effects.

US scientists emphasise that not enough is known about HIV/AIDS for them to set hard and fast rules. They advise that each individual requires specific responses under the supervision of experts on the use of ARV drugs. According to a press statement issued by John G Bartlett, chief of infectious diseases at Johns Hopkins and co-chair of the panel that produced the new guidelines, "The updated guidelines recognise that we need to make definitive recommendations about the optimal time to start treatment. We highlight the uncertainty, allow for flexibility, encourage an individualised approach to treatment, and, at the same time, try to provide guidance."

Singh and Mulloli state that at the very least, the use of ARV drugs calls for very sophisticated medical supervision that the US has – and it should be more than obvious that this is not possible in developing countries. Countries like ours, with scarce medical facilities, surely call for a different approach to HIV/AIDS care altogether.

Singh and Mulloli note that South Africa stopped Nevirapine drug trials when five patients died. A report in the April 15, 2000 issue of the BMJ states that about 11 per cent of patients in the trial showed signs of severe liver toxicity. It was alleged that women involved in one site of the trial had not given fully informed consent.

In January last year, US federal health officials warned that health-care workers who take Nevirapine after possible occupational exposure to the AIDS virus risk potentially life-threatening side effects. The Centers for Disease Control and Prevention (CDC) said it found 22 reported cases of serious side effects among people who took the drug fearing exposure to HIV. The side effects included liver toxicity and severe skin reactions. In one case, a 43-year-old health-care worker needed a liver transplant after suffering liver failure.

The CDC stated: "In this (health care) setting, the risk of HIV transmission is very low and, in most cases, the risk of taking Nevirapine would outweigh the risk of using it for possible prevention of HIV." It also said the adverse reactions reported among health- care workers "do not, in any way, apply to the use of Nevirapine in other settings."

Need for transparency

What is required is a complete transparency on the part of NACO and the union health ministry regarding the trial methodology, and detailed results of the feasibility studies. The section on the feasibility study of AZT in the NACO report does not mention the words 'side-effects'. Neither are the details of the Nevirapine trials made available for scrutiny even by the public health community. It should be remembered that the constituency that NACO will be dealing with is not an informed, highly literate and empowered one. Accountability to this section should not be a casualty in the zeal to push anti-retrovirals as life-saving drugs.

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