protection and are poorly prepared to build a life for themselves. Attempts to survive often lead to their trading any type of assistance (emotional and/or physical) for sexual favours, prostitution and criminal activities. Child abuse is a serious problem that demands broad multidisciplinary and inter-sectoral approaches. *Recovery*, a publication from the practical ministries and KwaZulu-Natal Programme for the Survivors of Violence, reports that in 1995, 16.2% of HIV-positive people were reported to be under the age of 19 years.[20] The number of children affected by political violence in KwaZulu-Natal alone is reported by them to be 26 790 (and these figures do not reflect child abuse). In addition, *Recovery* states that in South Africa ± 14.3 million children under the age of 15 years are living with caregivers who earn or receive less than R800 per month. The impact of ongoing community violence on children has been neglected in historically disadvantaged communities.[21] Substance abuse, mainly alcohol, is a contributing factor in many cases of violence, including child abuse.[22] Populations of children evaluated for suspected child sexual abuse are probably at a greater risk of exposure to the HIV virus than are other children.[23] The subservient role of women in society, temporality of bonding and other gender issues, plus family fragmentation, are important contributing factors in cases of child abuse.[24]

In our profession we sometimes encounter these children in hospitals, or know of them as names on laboratory forms or as anonymous bodies on autopsy tables. If they are physically presented to us we feel a mixture of indignation, outrage, involvement, voyeurism, frustration, reluctance and immeasurable pity. When they come in for examination with their J88 forms we would rather be somewhere else. But they are here, rivalling the prose of Hugo and Dickens, they are here. And, for the majority of these child victims in South Africa, there is no place of safety.

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Debate

Preventing perinatal HIV transmission in developing countries — do we know enough?

The article by Matchaba and Chapanduka[1] calls for the urgent need for antiretroviral therapy in HIV-infected pregnant women to reduce mother-to-infant transmission in developing countries. They largely make use of the results of the AIDS Clinical Trials Group Protocol 076 (ACTG 076) study to make their point.[2] However they do not take into account the realities of the health care situation in developing countries, nor do they discuss the logistics of applying this regimen in countries such as our own. These realities include the following facts.[1]

1. The majority of women only attend antenatal clinics very late in pregnancy, too late to receive the ACTG 076 regimen.[3]

2. A significant proportion of prenatal care and delivery occurs in primary health care settings where facilities for providing intravenous therapy may be lacking.

3. There is poor compliance due to infrequent visits both before and after delivery.

4. The ACTG 076 regimen costs approximately US$1 000 per month: introduction of this regimen includes the cost of routine screening, employment of counsellors and the establishment of laboratories where costly new techniques are used for the early diagnosis of HIV infection in infants. Severe financial constraints in South Africa and other developing countries preclude the use of this regimen.

5. The ACTG 076 study was conducted on women who were not breast-feeding their babies. The efficacy of the 076 regimen in breast-feeding communities has not been tested, and the financial costs and effect on infant morbidity of alternative feeding methods, such as subsidised formula feeds, in developing countries need to be assessed if women are to be advised against breast-feeding.

Matchaba and Chapanduka have also misinterpreted the results of a short-regimen antiretroviral study from Durban (submitted for publication), which they quote as showing a significant reduction in mother-to-infant transmission. This

was not an efficacy study, but rather a pharmacokinetics and safety study of zidovudine (AZT) and lamivudine (3TC) for 14 days in 20 mothers in late pregnancy, and in their neonates for a week. The lower rate of mother-to-infant transmission in a study of 20 women in comparison with the vertical transmission rate in a retrospective cohort study cannot be used as argument for the routine use of antiretroviral therapy in HIV-positive pregnant women.

The World Health Organisation and the Joint United Nations Programme on HIV/AIDS (UNAIDS) have recognised that the ACTG 076 regimen is not applicable in those parts of the world where most mother-to-infant transmissions occur, and have called for placebo-controlled trials as the best option for obtaining rapid and scientifically valid results. These trials should include antiretroviral agents given for short durations in late pregnancy, in labour, and to neonates for 1 or 2 days; oral therapy in labour only; and combinations of different antiretroviral drugs. An ongoing trial, PETRA (perinatal transmission), supported by UNAIDS but designed in conjunction with African scientists, is currently in progress in a number of African centres, including Durban and Johannesburg. The aim of this placebo-controlled trial is to evaluate whether shorter regimens, which can realistically be implemented in test countries, are better than no treatment at all. Subanalysis of the ACTG 076 study has shown that less than 12-week regimens are as effective as those of more than 12 weeks. This, however, does not give any indication of the efficacy of a 2 - 3-week regimen.

Another debatable issue not included in the article by Matchaba and Chapanduka but that needs to be mentioned is the ethical considerations of placebo-controlled trials in developing countries.[4] Critics maintain that nearly all such trials violate accepted international ethical standards because participating control groups are only offered placebos, as opposed to being given antiretroviral therapy that is known to be effective.

The debate has led to comparisons with the Tuskegee study, in which effective treatment was withheld from some 400 African Americans without their knowledge in order to establish the natural history of syphilis. This study has been described as a 'metaphor for racism in medicine.' Comparison with vertical transmission HIV studies in pregnancy, however, is unfair. Trials in Africa are frequently conducted by African scientists who have contributed significantly to the design of the studies and who are concerned for the welfare of their particular communities. In addition, local government authorities are informed of all such studies and ethical permission, usually from university ethical committees, will have been obtained. Subjects are informed of the existence of a placebo arm and give written consent. They are not intentionally deceived or deprived of treatments that are affordable, readily available and known to be effective, as was the case in the Tuskegee experiment. Placebo-controlled antiretroviral trials in developing countries will continue until a short applicable regimen is found to be effective in reducing mother-to-infant transmission.

The level of information provided to participant women and consent procedures are two further criticisms of these studies. Certainly in the trials conducted in South Africa, women were fully informed regarding the benefits and disadvantages involved, including the placebo component.

Criticism of HIV trials in developing countries has raised the question of whether these studies could be undertaken in the First World. The question of double standards, however, lies not in the way the trials are being conducted, but in unequal access to medicines in different countries.

It is our conclusion that before demands are made for the immediate use of antiretrovirals in pregnancy, an interaction is urgently needed between researchers, health authorities, pharmaceutical companies and global institutional programmes such as UNAIDS. This interaction would help prepare the infrastructure for the application of a short and cost-effective antiretroviral regimen when proven effective in developing countries.

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Preventing perinatal HIV transmission — now is the time to act!

We thank Moodley *et al.* for their response to our paper.[1] We are pleased to note that they concur that the major intervention in the prevention of perinatal HIV transmission is AZT use. In our paper we stated the need for the development of local protocols, outlined the reasons for this and certainly did not recommend that protocol ACTG 076[2] be used here. We believe that all the 'realities of the situation in respect of health care in developing countries' referred to by Moodley *et al.* in their response were sufficiently addressed in our original paper. The breast-feeding issue was also addressed at length.

They seem, however, to have missed two important issues raised by ourselves. Instead they focused on the issue of placebo-controlled trials, which we elected not to raise in our editorial[1] because of the volatile nature of the topic. We did not want to distract from the main thrust of our editorial, namely that 'now is the right time to act' in dealing with perinatal HIV transmission using zidovudine (AZT) as part of the national maternal and child health care (MCHC) programme. We will, however, address the issue of placebo trials in perinatal HIV transmission later in this article.

The first point they overlooked was the length of time it is taking to get protocols or interim results from the local studies being done. During this time perinatal transmission of HIV continues unabated.