Correspondence

AIDS 2006, **20**:000–000

Concerns regarding a randomized trial of two postexposure prophylaxis regimens

I would like to raise the following issues regarding your recent article by Gray *et al.* [1].

Perhaps as a result of the small sample size, exclusive and mixed breast-fed infants were combined into the same group. For some of the outcomes examined, keeping these groups separate is otherwise preferable.

Although the risk of mother-to-child transmission of HIV was twice as high in breast milk-exposed (BME) infants in multivariate analysis when the entire sample was included, the data for those receiving nevirapine, the option the authors clearly and with good reason suggest is preferred showed no statistically significant difference in the rates of mother-to-child transmission between BME infants and those not so exposed.

Among infants who received nevirapine, there was a 6.3% rate of transmission in the BME group at less than 10 days; the exclusively formula-fed group was 44% higher at 9.1%. This was not tested for significance but sample sizes were small.

There has previously been speculation that early breast milk may be protective against transmission, which otherwise can occur at or near labor [2]. Perhaps a meta-analysis should be performed to examine the possibility in a larger sample size.

Rates of transmission in the BME group treated with 6 weeks of zidovudine increased rapidly: from 5.1% at less than 10 days to 14.5% at 6 weeks to 20.6% at 12 weeks. Because this is more rapid than has been seen in untreated infants [3], the possibility that longer-term postnatal dosing with zidovudine actually increases breast milk transmission rates cannot be ruled out. This possibility urgently needs to receive further research, given the

World Health Organization's recent decision to recommend the use of 4 weeks of zidovudine treatment to infants born to HIV-positive women who did not get prophylaxis during pregnancy [4].

The authors stated that there was 'no increased mortality in the formula-fed group' based on the lack of statistical significance of that group's 72% higher death rate (3.8 versus 2.2%). This strikes me as a statement far beyond what the data support, given that the sample size was not adequate to measure mortality differences if they were indeed occurring.

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