CORRESPONDENCE

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Breastfeeding in HIV-1-positive mothers

Sir—Ruth Nduati and colleagues (May 26, p 1651)¹ claim to show that breastfeeding strikingly increases mortality among HIV-1-positive mothers. In her May 26 commentary, Marie-Louise Newell² discusses some of the study's limitations and compares it with research by Coutoudis and co-workers³ that draws very different conclusions. We have concerns about some additional issues.

Balanced randomisation is essential in clinical trials. We believe Nduati and colleagues' randomisation was not successful. In a more detailed description of the trial,⁴ at birth only two of the babies in the formula-fed group were believed to be HIV-1 positive, compared with nine assigned breastfeeding. Obviously, method of feeding cannot have any impact on HIV-1 status at the time of birth, and these results suggest important differences between the mothers in the treatment groups that were not detected by the researchers nor balanced by randomisation.

The inability to mask feeding methods introduces a potential source of bias. In addition, the formula-feeding mothers might have had more extensive contact with researchers for education about the correct way to prepare formula.⁴ These women might have, if only indirectly, received more health-care interventions than those in the breastfeeding group.

Unlike Coutoudis, Nduati and colleagues do not distinguish between partial and exclusive breastfeeding, and do not precisely define exclusive breastfeeding. 9% of mothers were exclusively breastfeeding by 6 months, which is a much higher proportion than the 3.5% at 4–5 months in the general population in Kenya.⁵ This difference might be due partly to the WHO definition of exclusive breastfeeding not being used by Nduati and colleagues. Adherence to exclusive formula feeding was only 71%, meaning that 29% of the mothers practised partial breastfeeding. Given that adherence was based on self-reporting, this proportion is probably an overestimate.

Because the analysis was done by intention to treat, differences between

the two groups in actual feeding practices are unclear, since they both contained substantial proportions of mixed feeders. Some mothers in the formula-feeding group might have breastfed more than some mothers in the breastfeeding group.

Nduati and colleagues claim they have no reason to believe that dropouts (which were greater in number than deaths) differed between groups, but there is no reason to believe that they are the same. For example, a seriously ill woman might find formula preparation too great an effort and drop out. Conversely, some of the healthiest mothers with highest socioeconomic status in the breastfeeding group might have believed that their babies were at a disadvantage and left the trial to change to formula feeding.

We are concerned that Nduati and colleagues' policy recommendations may be based on their conclusions that there is no risk to the health of mother or child from exclusive breastfeeding. An additional concern is the lack of written witnessed consent for participation. Surely, even if verbal information was given, women could still sign their names.

Policy decisions based on this information may seriously impact the lives of millions of mothers and children. We believe the raw data need reanalysis.

Phyll Buchanan, David Crowe, Ted Greiner, George Kent, Tessa Martyn, Valerie McClain, Pamela Morrison, Denise Parker, Magda Sachs, and Karen Zeretke contributed to the writing of the letter.

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1 Nduati R, Richardson BA, John G, et al. Effect of breastfeeding on mortality among HIV-1 infected women: a randomised trial. *Lancet* 2001; 357: 1651–55.

2 Newell ML. Does breastfeeding really affect mortality among HIV-1 infected women? *Lancet* 2001; 357: 1634–35.

3 Coutoudis A, Coovadia H, Pillay K, Kuhn L. Are HIV-infected women who breastfeed at increased risk of mortality? *AIDS* 2001; 15: 653–55.

4 Nduati R, Richardson BA, John G, et al. Effect of breastfeeding and formula feeding on transmission of HIV-1: a randomized clinical trial. *JAMA* 2000; 283: 1167–74.

5 Kenya Central Statistical Bureau and Macro International. Demographic and health survey. Calverton MD: Macro International, 1998.

Sir—Nduati and colleagues¹ note an association between breastfeeding and a three-fold rise in maternal mortality in women infected with HIV-1. This link may prove useful in reducing deaths among such mothers.

Our main concern is about the ethics of this study. Randomly assigning women breastfeeding with no consideration of the risk of HIV-1 transmission to infants is unethical, according to the Council for International Organisation of Medical Sciences' guidelines.² A link between HIV-1 transmission and breastfeeding was suspected in 1985.³ Further evidence was available to support this theory in 1992.⁴

We agree with Nduati and colleagues that universal formula feeding in less-developed countries is difficult for cultural and practical reasons. Perhaps there is no ideal alternative to breastfeeding in Kenya. Since the study involves HIV-1-positive mothers, the researchers should have provided antiretroviral treatment to prevent maternal-infant transmission or should even have considered a different study design. Despite the difficulties of data collection and validity, a retrospective case-control study would have been a more ethical way of doing this essential research.

We believe that in the future there should be greater awareness of the standards of such research before publication. Even though the emphasis is currently on evidence-based medicine, the ethics should never be compromised.

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1 Nduati R, Richardson B, John G, et al. Effect of breastfeeding on mortality among HIV-1 infected women: a randomised trial. *Lancet* 2001; 357: 1651–55.

2 Council for International Organisations of Medical Sciences-World Health Organization. International ethical guidelines for biomedical research involving