

Ethics of HIV research in children

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In their Personal View, Seema Shah and colleagues¹ addressed ethical issues to be considered in paediatric HIV cure research.¹ The recent rebound of HIV RNA in the so-called Mississippi baby dispelled hopes of a cure, and cautions against use of the term cure.² In a subsequent Correspondence,³ the same investigators accepted the limits of our knowledge and the complexity of the scientific questions that remain unanswered, including the optimum time to interrupt antiretroviral therapy (ART) to assess whether therapy initiated in acute infection can eradicate or prevent long-term HIV reservoirs. Shah and colleagues first proposed that therapy be maintained “until ample time has been given for the strategy to work on the basis of existing data”,¹ and then conceded that “how long treatment should be given for the strategy to work is unclear”.³ We wish to emphasise that, although some data exist on the possible safe interruption of ART,⁴ current data does not inform the optimum time to interrupt infant treatment, which depends on the postulated mechanisms responsible for clearing infection—ie, post-exposure prophylaxis or decay of acutely infected cells.

These intricate questions can probably only be answered in prospective, experimental studies and not in observational research as suggested. Such studies entail intensive, invasive, and specialised monitoring of infants who test positive for HIV infection and necessitate lengthy and complex informed consent documents (ICD), and education of most eligible families will probably be needed. We propose that research be done only in infants at high risk of mother-to-child-transmission (MTCT); that the initial ICD should only consent for maternal or infant treatment during labour and until HIV diagnostic test results are known; and that subsequent ICDs cover research in infants with positive HIV diagnostic tests to elucidate the mechanisms of treatment effecting or failing to effect a cure, and issues pertaining to the interruption of ART. In view of the uncertainties surrounding the interruption of ART [A: edit OK?], adequate time and repetition should be allowed to ensure satisfactory comprehension.

Finally, we caution that the hope and hyperbole invoked by the term cure does not distract from efforts to improve prevention of MTCT and antenatal services across the world.

Since only 63% of the 1.5 million pregnant women infected with HIV in low-income and middle-income countries received effective ART in 2012,⁵ we support global efforts to expand and improve prevention-of-MTCT services, coupled with research and interventions directed at the social contexts that allow MTCT to continue in these communities.

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References

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