Ethics of HIV

Modern medical systems thrive on their mythopoiesis. The January 1998 issue of *Issues in Medical Ethics* has two articles on the unethicality of denying multi-drug treatment to HIV-positive and AIDS patients. This is a classical example of the truism that the pathway to iatrogenic hell is paved with impeccable therapeutic intentions.

Sandhya Srinivasan's lament (1) is that some mothers were denied anti-retroviral drugs in the name of clinical trials. Her espousal of the cause is in the teeth of the facts that (a) as yet no one can say whether HIV-positivity implies HIV carriership, (b) no one knows whether the drugs are genuinely anti-HIV, and (c) the drugs are well-known cytotoxic and cancerogenic agents. In fact the need for a controlled trial arises when the efficacy and worthwhileness of the (so-called) specific therapy are not above board. Hence the placebo-treated women who were denied AZT were indeed spared the assault from a positively dangerous drug.

Just a few weeks ago the media were agog because the *BMJ* turned down an AIIMS paper on the grounds that the trial involved denying curative surgery to women with cervical precancer. It needs to be emphasised that (a) precancer as yet remains undefined, (b) treatment of precancer or cancer precipitates cellular and metastatic crises worse than the original disease.

Dr Sanjay Pujari's article (2) harps on the back-breaking cost of drugs against HIV and AIDS, taking for granted the efficiency and the advisability of the drugs, both of which are as yet sub-judice. The fancy price tags betray the profit potential of the drugs making anti-retrovirus against the drugs of the future for the drug pushers.

Suffice it to say that ethicists of the like of Srinivasan and Pujari should first check whether the therapy denial is in any way inferior to the therapy administration. In the absence of that, the mythopoiesis surrounding HIV/AIDS will tilt the world view in favour of must-treatism with obvious disastrous results. If the much-taken-for-granted Swan-Ganz catheter can reveal its adverse side many years after its usage, then what of dangerous drugs? The bottom line is that in all likelihood, HIV-positiveness implies antibody positiveness and therefore virus negativeness. One day we will compliment the person who tests HIV positive.

Manu Kothari, Lopa Mehta, Vatsal Kothari, department of anatomy, GS Medical College and KEM Hospital, *Mumbai 400 054*

References

(1) Srinivasan S: Physician, do no harm. *Issues in Medical Ethics. 1998* 1: 22-23.

(2) Pujari S: Anti-retrovirals in India. *Issues in Medical Ethics.*1998 1: 24-25.

Sanjay Pujari replies:

The subject of HIV medicine is continously evolving and so are the new treatments. Intensive research in the hope of a cure is in progress and it would be a great disservice to the tire less workers all around the world if we criticise the efficacy of currently available drugs.

Drug development essentially is based on an increasing understanding of the life cycle of HIV and its immuno-pathogenesis. After recognising the various enzymes responsible for replication of the virus, drugs are developed to inhibit these enzymes. At present computer modelling is extensively used to do this and also to determine, beforehand, to which molecules the virus develops easy resistance. Only those molecules which satisfy anticipated efficacy and delayed resistance are put into in-vitro studies. After successful in vitro studies, animal studies are performed to assess toxicities at doses many times more than that would be used in humans. After that Phase I trials are carried out to assess safety in humans and only then do they progress to efficacy studies *viz.* Ph[illegible]ha[illegible]ic[illegible] III. After completing Phase III studies, the drugs get approval to be used in practice. Hence there is no question that any of these drugs are being tried out on a trial and error basis. Rather, all combinations are extremely rational.

It is true that we do not know the long-term toxicities of these drugs but only extensive use in the coming years will resolve the issue. Till then it would be inhuman to withold such efficacious drugs from infected individuals. At the same time as more and more efficacious drugs are developed current treatments may become obsolete in the recent future. However, based on current understanding a 'current standard of care' is developed and implemented. Let us accept also that there is no ideal drug in this world (100% effective, no side effects etc.) for any disease, leave aside HIV.

For the first time in the history of the AIDS epidemic, the CDC reported a decline in AIDS related deaths by 13-20% in the US and also a decline in the hospital admission rates. Also, for the first time the number of children born with HIV infection declined last year. This has been possible because of antiretrovirals. Let us stop criticising the basic issues about efficacy of these drugs and look ahead as to how we can make them more accessible and affordable to our people and improve their quality of life.

Sandhya Srinivasan replies:

It is not necessary to debate the efficacy of HIV drugs to examine the ethics of placebo-controlled trials. It is enough that the clinical trials, supported primarily by the US Centers for Disease Control and the National Institutes of Health, deprived the control group of a treatment that is *recognised* in the funding country, the US as standard treatment for pregnant HIV-infected women, and is *believed* to prevent a large proportion of vertical transmission. It is this action that is being challenged as