We’re Trying to Help Our Sickest People, Not Exploit Them

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Every day, like the beat of a drum heard throughout Africa, 1,000 more infants here are infected with HIV, the virus that causes AIDS. At Old Mulago Hospital, we are trying to educate people about AIDS, as well as study new therapies to prevent the disease’s rampant spread. Recently, some of these studies have been attacked, with comparisons made to the notorious Tuskegee experiment in which black men in the United States were denied treatment for syphilis. Tuskegee? Is this really what is happening here in our mother–child clinic?

Our country lies in the heart of Africa, along the Great Rift Valley and Lake Victoria. It is one of those hardest hit by the AIDS epidemic. A few years ago, visitors here in the capital were greeted by the macabre sight of empty coffins for sale – piled in pyramids from adult to baby size – along the main road. These grim reminders have since been removed by city authorities, but the AIDS epidemic is omnipresent. In this city of 1 million, about one out of every six adults is infected with HIV. Hospitals and clinics like ours, which provide free medical care and therefore serve the poorest communities, are stretched beyond their resources.

At the Mulago Hospital, where more than 20,000 women deliver each year, we are trying to find effective therapies to stop transmission of HIV from pregnant women to their babies. About one in five babies becomes infected with HIV during pregnancy and delivery. If the mother breast-feeds her baby, there is an additional 15- to 25-percent chance that the baby will later become infected. There is no available treatment for the disease in Uganda. After careful consideration among researchers from developing and developed countries, the World Health Organization (WHO) recommended in 1994 that the best way to find safe and effective treatment for sufferers in countries in the developing world is to conduct studies in which new treatments, better tailored to the local population, are compared with placebos (inactive pills).

Women who enroll in our studies undergo intensive education and individual counseling. They are given a comprehensive consent form, written in the local language, which they are encouraged to take home and discuss with their families. It describes the potential risks of participating in the study and their chances of receiving a placebo. Only when they and their counselors are satisfied that all questions have been answered are they asked to sign the form. Our careful attention to these measures has consistently met the standards of national and international ethical review committees.
Results from a clinical trial in the United States and France, known as the ACTG 076 protocol, showed as long ago as 1994 that, if a mother takes zidovudine (AZT) daily from the middle of her pregnancy until delivery, receives intravenous AZT during delivery, gives her infant oral AZT for the first six weeks of life and does not breast-feed, the transmission of HIV from mother to child can be reduced by two-thirds. The ACTG 076 protocol immediately became the recommended therapy in the United States. But it is not possible to simply transplant this protocol to Uganda for three main reasons: At a cost of between $800 and $1,000 per person, it is far too expensive; it requires treatment to begin in the middle of a pregnancy; and it means mothers must abstain from breast-feeding.

Some critics in the United States have asserted that we should compare new therapies with the ACTG 076 protocol rather than with a placebo. But, in Uganda, the government health expenditure is $3 per person per year, and the average citizen makes less than $1 per day. We think it is unethical to impose expensive treatment protocols that could never be used here. The situations are not parallel. In America, for instance, antibiotics are often over-prescribed; but here in Uganda we have difficulty even obtaining many needed antibiotics – to treat common complaints like ear infections. It is also naive to assume that what works for Americans will work for the rest of the world. Differences in nutrition, economics, societal norms and culture, and the frequency of tropical diseases make such extrapolations dangerously ethnocentric and wrong.

Many pregnant women here never show up for prenatal care and, of those who do, 70 percent make their first visit after the 30th week of pregnancy – too late for the US treatment protocol. Should we make a study available only to the minority of women who come early for care and tell the others, sorry, you came too late? We need to find treatments that will reach the most women possible – ones that can be given late in pregnancy or during labor.

There is also a huge gap between the United States and Uganda in breast-feeding practices. Should we apply the ACTG 076 protocol and tell women in the clinic not to breast-feed and instead give their babies infant formula? Access to clean water is a formidable challenge here, and we still remember the shocking epidemics of infant diarrhea and mortality in the early 1970s, when multinational companies shamelessly marketed formula in Africa. Despite the known risks of transmitting HIV through breast milk, the Ugandan Ministry of Health, UNICEF and WHO still encourage African women to breast-feed, as the nutritional benefits outweigh the risks of HIV transmission.

There are other factors we need to take into account. Every day, we treat both mothers and infants for malaria and iron deficiency. Both diseases contribute to anemia, which is also a major side effect of AZT. We are worried that AZT will exacerbate anemia in women and infants here. If we are to find out whether the new treatments are safe, the best way is to compare them with a placebo. How could we evaluate the safety of a new treatment if we compared it with the treatment used in America – one that has its own side effects? Could we really tell Ugandans that we had evaluated a new therapy for side effects using the best possible methods?

The AIDS epidemic has touched all our lives. Each of the 90 staff members in the mother–child health clinic has lost a family member, a loved one or a close friend. There is no dividing line between patients with HIV and those of us who care for them. A few years ago, we all chipped in money when a staff member needed to pay for the burial of a loved one, but recently we realized that we were all giving and receiving the same.

The ethical issues in our studies are complicated, but they have been given careful thought by the local community, ethicists, physicians and activists. Those who can speak with credibility for AIDS patients in Africa are those who live among and know the people here or have some basic cross-cultural sensitivity. We are suspicious of those who claim to speak for our people, yet have never worked with them. Callous accusations may help sell newspapers and journals, but they demean the people here and the horrible tragedy that we live daily.

In the next several months, we expect to see results from our study and others like it in Ivory Coast, South Africa, Tanzania and Thailand. We hope they will help bring appropriate and safe therapies to the people of the developing world. That hope is the driving force that brings us back to our work in the clinic after each of the all-too-frequent burials.