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TAC Electronic Newsletter

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- TAC comment on the termination of two microbicide trials
- "What excites me the most is that I can call a doctor my colleague" - a community story told to TAC trainee journalist Nokulanga April by Alfreda Brinkhuis.

TAC comment on the termination of Ushercell microbicide trial

Last week, two clinical trials of the microbicide Ushercell were halted after it was found in one of the trials that the product possibly increased the risk of contracting HIV. The trial that showed this result was being conducted in Benin, South Africa, Uganda and India. The other trial was being conducted in Nigeria. The trials were in Phase III, which is usually the final phase before the manufacturer of a product can apply for it to be registered with medicine regulatory authorities, such as the Food and Drug Administration (FDA) in the United States or the Medicines Control Council (MCC) in South Africa.

Microbicides are compounds, applied to the vagina or rectum, to prevent the sexual transmission of HIV and other sexually transmitted infections. They can be gels, creams, films, or suppositories. No microbicide has yet been shown to be effective.

Several other Phase III microbicide trials are ongoing or due to start this year. The development of a successful microbicide is an important goal for HIV prevention. Often women do not have the power to compel their male sexual partners to use condoms. A successful microbicide could give women the means to reduce the risk of HIV transmission.

The termination of the Ushercell trials is a setback for microbicide research. It is unlikely that a successful microbicide will be found in the next few years and it is possible that other ongoing microbicide trials will fail. Nevertheless, science advances by learning from failures and ethical trials of the most promising microbicides should continue because the development of a successful microbicide will likely prevent many HIV infections and save many lives.

Another promising line of research is chemoprophylaxis. If successful, this would involve an HIV-negative person taking an antiretroviral to prevent HIV transmission during or after sex. Unfortunately promising chemoprophylaxis trials of an antiretroviral called tenofovir (which is used for HIV treatment) were terminated controversially in 2005, after disputes between the researchers and some people in the communities in which the trials were conducted. Community HIV activists and clinical trial researchers need to negotiate with each other to remove the obstacles to these and similar trials being carried out.

Ethics of Microbicide Trials

TAC believes any woman infected during a microbicide trial should be guaranteed free HIV medical treatment and care.

However, there is a commonly held myth about microbicide trials which needs to be dispelled. This myth has been perpetuated by at least two senior South African politicians and we have encountered journalists who have mistakenly believed it. The myth is that participants in microbicide trials (as well as vaccine trials and the recently conducted circumcision trials) are encouraged to have unprotected sex or, in the myth's most extreme version, exposed to HIV by researchers. This is false. On the contrary, participants in these trials must be counselled about safer sex. If a trial is conducted properly, participants are arguably at less risk of contracting HIV than the general population, because they have all been through a standardised comprehensive counselling session, approved by a regulatory ethics committee.

City Press on Sunday reported that the Medical Research Council (MRC) is contacting the participants in the South African arm of the Ushercell trial to return their gels. It is critical that the MRC moves quickly to do this. City Press also reports a number of other allegations made about the trial. Undoubtedly the details of the trial are in the public interest and should be reported. However, City Press sensationalised the story. It referred to the fully informed and consenting trial participants as guinea pigs, and reported unsubstantiated serious allegations against the trial researchers without verifying whether these allegations were true. This unfairly undermines public confidence in science as well as the future of essential clinical trials that will likely save many lives.

As a consequence of these allegations, the Minister of Health has ordered an investigation into the ethics of the trial. This investigation should give the MRC researchers an opportunity to demonstrate that they conducted the trial ethically. Science must be conducted ethically and also be seen to be conducted ethically.

[END OF MICROBICIDE STATEMENT]

"What excites me the most is that I can call a doctor my colleague"

As told to TAC trainee journalist Nokulanga April by Alfreda Brinkhuis

My name is Alfreda Brinkhuis. I am 27 years old and I live in Langa Location, Uitenhage in the Nelson Mandela Metro District (in the Eastern Cape). I am on the executive committee of the TAC Langa Branch and a lay counsellor at Uitenhage Provincial Hospital. I found out about my status in February 2005 at Rosedale Clinic because I had TB and shingles. Finding out about my status gave me purpose in life.

I started antiretrovirals in October 2005 when my CD4 count was 158. I was excited when I got antiretrovirals at first but I have faced a lot of challenges with them. My first-line regimen was lamivudine, stavudine (d4T) and nevirapine. I experienced joint and abdominal pains. I also got lipodistrophy: I lost fat in my face and gained fat in my abdominal area. My legs and arms got thinner. The doctor told me this was caused by d4T. He changed it to AZT.

Then after a little while on my new regimen, there was no improvement in my viral load. I was suffering virological failure. So my doctor changed my regimen to AZT, ddI and lopinavir/ritonavir /[better known by its brand-name, Kaletra - Ed]. /I am still taking this regimen. I meet my doctor every month or when I have a problem.

Good things have happened to me since being diagnosed with HIV. I have met the love of my life. I have got experience working with people and have a positive attitude. I am also computer-literate now and part of a committed team of workers. What excites me the most is that I can actually call a doctor my colleague. Sometimes I find myself overqualified for my job and educating sisters and nurses about HIV concepts such as VCT, mother-to-child transmission prevention and opportunistic infection treatments.

My future plans are to get married this year, adopt a child and to carry on doing what I love - helping others. HIV has been no stumbling block for me. It is a wake up call to look after your health and treasure your life and body.

[END OF COMMUNITY STORY]

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- Treatment Literacy

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