

How Unexpected Closures Can Affect Other Trial Sites: The Cellulose Sulfate Trial Closure in South Africa

In January 2007, a study in South Africa on cellulose sulfate (CS), a potential microbicide, closed prematurely after its Independent Data Monitoring Committee identified a safety concern during a review of preliminary results and recommended that enrollment stop at trial sites. The research team at the HIV Prevention Research Unit at the South African Medical Research Council (MRC), which managed several sites around Durban, and CONRAD, the trial sponsor in the United States, worked quickly to plan how to share the news with local, national, and international stakeholders, including trial participants. In South Africa, the MRC released a press statement and contacted a well-respected South African health journalist, hoping her article on the closure would set a balanced tone for press coverage to follow.

Meanwhile in Mtubatuba, a small town in KwaZulu-Natal 200 kilometers north of Durban, a research site affiliated with the Africa Centre for Health and Population Studies was conducting a separate large-scale microbicide study testing a different product called PRO 2000 gel. On Friday of the week of the MRC's public announcement of the CS study closure, the Africa Centre contacted members of its community advisory board (CAB) in Mtubatuba to invite them to an urgent meeting. The Centre's staff planned to brief CAB members the following Monday about the sudden closure of the CS trial and reassure them that their PRO 2000 microbicide study was not affected.

That weekend, however, a journalist from Durban posing as an insurance official with the health department traveled to Mtubatuba, hunting for the inside 'scoop' on the closure. He located a CAB member for the Africa Centre's PRO 2000 trial in Mtubatuba who—convinced by this guise—took the journalist to the home of a PRO 2000 trial participant. Other participants joined and were encouraged by the undercover reporter to share their perceptions, unaware that they were being interviewed by a journalist (Gafos 2009).

The next day, the *City Press*, a national newspaper, ran the headline, "Women used as AIDS guinea pigs" (Hlongwa and others 2007). The article claimed that hundreds were feared to have contracted AIDS during the CS study and that women were selling their gels in the townships as AIDS cures. More articles by the same journalist followed, accusing the CS study of unethical conduct and claiming that women were instructed to have promiscuous unprotected sex and that the researchers had purposely infected participants with HIV. Not only were these assertions not true, the article was based on interviews with participants from a completely different trial than the CS trial that was prematurely halted.

While coverage of the CS trial closure remained balanced and accurate in the United States, a wave of negative press and sensational headlines followed in local press in South Africa as well as in Uganda (where another CS trial site was located). These articles painted a picture of poor, uneducated, and vulnerable women taken advantage of by researchers and duped into participating in clinical trials.

The closure of the CS study in South Africa and related concerns about safety had snowballed into a narrative of exploitation, affecting perceptions among the community and the entire microbicide field of the ethical conduct of microbicide trials. The research organizations directly involved in the South African CS study and a related CS study in Nigeria implemented intensive communications efforts to respond to the events. Other research and stakeholder groups also offered technical assistance and support behind the scenes, both locally and internationally, including the Microbicides Media and Communications Initiative, which set up teleconferences and worked on coordinating messaging.

Advocacy groups, such as the Global Campaign for Microbicides and the African Microbicide Advocacy Group, facilitated civil society calls and online discussions, while South Africa's Treatment Action Campaign and Gender AIDS Forum wrote articles and statements of support to refute the rumors and myths.

These combined efforts were successful in calming the waters and promoting more accurate news coverage. The participation of local groups introduced African voices into the media coverage. While these "damage control" efforts improved the situation, the experience highlighted for all that what happens in one trial can easily affect other trials. Investigators, research groups, and communities in this area have put these lessons learned into action. They now plan ahead to avoid controversy, develop integrated communication strategies, and work collaboratively to discuss messaging for trials and results.