

Case Study: Step Trial

One of the most common situations in biomedical HIV research, requiring a rapid response, is an unexpected closure of a trial because of no effect from the product being tested or concerns for the participants' safety. An important part of crisis communications planning is to anticipate such possibilities and to plan for them accordingly.

In September 2007, the United States' National Institute of Allergy and Infectious Diseases (NIAID) (part of the National Institutes of Health), the pharmaceutical company Merck, and the NIAID-funded HIV Vaccine Trials Network (HVTN) announced that immunisations in the HIV vaccine clinical trial, known as the Step trial, would be discontinued. The decision was based on recommendations made by an independent Data and Safety Monitoring Board (DSMB), which analysed early

data and concluded that the vaccine did not prevent HIV infection nor reduce the amount of virus in those who became infected with HIV, and early analyses suggested that the vaccine may actually increase the likelihood of HIV acquisition. The Step trial started in 2004 and was conducted in the USA, Australia, South America and the Caribbean. This trial had enrolled mostly men who had sex with men (MSM) and had enrolled 3000 participants in total.

Based on further review of the Step data, an independent South African DSMB concluded, that given the fear of increased risk for HIV, there was no basis for anticipating favourable results in the South African trial, known as the 'Phambili' trial, which was testing a similar product in South Africa. Therefore, this trial was also stopped in 2007.

Relevance to GPP

The Step results brought an unprecedented dialogue involving the US Government (NIAID, and its Vaccine Research Program), as well as the broader community of biomedical HIV prevention advocates like AVAC.

The finding of potential increased risk for HIV was of great concern to everyone involved in the trial and in vaccine research in general. The sponsors, Merck and the HIV Vaccine Trials Network were committed to communicating clear and transparent information as broadly as possible, according to their existing communications plans. The Step trial sites had all been required to develop and implement comprehensive community engagement plans including Communications and Issues Management planning.

The first priority was to communicate the results clearly to all trial participants. Then, the results were explained at an open, scientific session of the HVTN meeting, where discussions were conducted that included trial investigators and community stakeholder representatives engaged in HIV vaccine efforts. This forum provided the opportunity to share feedback and advice from diverse interested constituencies about potential message dissemination. Investigators then made themselves broadly available to press, advocacy groups, and other interests with clear messaging they had developed with the Step protocol team, which included community representatives, trial site community engagement officers, as well as investigators. And, at the local level, trial sites had plans prepared to take the reports back to their stakeholders.

Lessons Learned

Communications and issues planning and management are increasingly recognized as essential good participatory practices. Advocate, donors, and key stakeholders become partners in disseminating results, and they are an important bridge between scientists and civil society. Members of community advisory boards (CABs) and even trial participants can help to shape messages, rather than merely receive them.

Important lessons were learnt in both trials about how to communicate effectively with the media and in handling the potential fall-out as well as how stakeholder groups can work together around trial closures to create coordinated and consistent messages to the media. In the case of Step, this kind of planning and effort enabled positive, consistent messaging even in the face of uncertain and troubling news.