CASE STUDIES

CASE STUDY 1

Background

THE "OVER-RESEARCHED COMMUNITY": A SEMI-HYPOTHETICAL CASE.

Doug Wassenaar PhD & Mike Bennish, MD.

The case focuses on an impoverished rural community in an African country. In the mid 1990's, an internationally funded HIV vaccine preparedness study was commenced in a specific geographic region, with the formal support and agreement of national health authorities and applicable RECs/IRBs. A demographic surveillance project was conducted, and regional HIV antenatal clinic seroprevalence studies were conducted which found a regional HIV prevalence of 28% for antenatal clinic attendees. About 1.2 million persons reside in this large geographic area. The area is characterised by high male migrancy to remote urban areas in search of employment. As part of the vaccine preparedness project, community education initiatives were launched from various community-based sites after extensive negotiation with local stakeholders who were enthusiastic about the prospects of a phase III HIV vaccine study being initiated in this region at some future date.

The phase III vaccine trial was not conducted because of the failure of suitable candidate vaccines in Phase I and Phase II studies. The vaccine preparedness personnel made this information known to stakeholders and gradually withdrew from the area. Local persons employed by the preparedness project lost their employment. At this time ART was not generally available from government health clinics in the region.

After the withdrawal of this initiative, various other health research initiatives took place in this region, all in close communication with representatives of the local community, and all approved by relevant local and international Ethics Committees (REC)/IRBs.

Current Problem

In 2003, an arm of an international HIV preventative microbicide initiative identified the region, on the basis of its high HIV prevalence, as an ideal site for a Phase III microbicide trial. The initial component of this study proposed an extensive microbicide preparedness plan to ensure that participants clearly understood key elements of the proposed microbicide trial. The preparedness study would be followed by a randomised placebo-controlled study of an active microbicide. Both arms of the study were to receive intensive VCT, risk-reduction counseling and free condoms. A guarantee was made that if the eventual Phase III microbicide trial was successful, the effective product would be made available to the region for 10 years after the trial. Some preliminary

contact was made with community representatives through community-based organisations (CBOs), and through CABs attached to other health studies ongoing in the region. This community support was documented in the submission to the REC/IRB. By now VCT clinics were well established in the region, and ART for a limited number of patients was available through government clinics and a local hospital.

In their letter to the investigator, the local REC/IRB declined permission to commence the microbicide preparedness study on the grounds that they regarded the region as "over-researched".

Questions:

1. How should the investigator respond to this decision?
   Do international guidance documents provide any guidance for the investigator in this situation?

2. a. What ethical considerations, if any, are implied in the wording ("over-researched") of the REC/IRB's letter to the investigator?

   b. Based on your answer to 'a', is the REC/IRB decision ethically defensible?

3. What sociological issues are implied in the REC's letter and how might the investigator respond to these?

4. What scientific issues, if any, are implied in the REC's letter, and how might the investigator respond to these?

5. If you were a member of the REC/IRB, would you have reached the same decision?
   If 'yes', justify this ethically.
   If 'no', justify this ethically.