

Ethics guidance for HIV prevention trials

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International trials of HIV prevention strategies are necessary to end the AIDS pandemic, but they present complex ethical challenges that are not uniformly or adequately addressed in existing guidance documents. The HIV Prevention Trials Network has developed ethics guidance that incorporates best practices and emerging consensus on four areas:

- General principles
- Meeting local needs and priorities
- Care and prevention
- Informed consent.¹

Further discussion of these issues is available on bmj.com. The guidance emphasises concern for communities as well as participants and grounds obligations within a participatory process. It outlines procedures for balancing obligations and stresses the importance of creativity, persistence, and partnership in meeting ethical challenges.

The HIV Prevention Trials Network is funded by the National Institutes of Health, one of the major sponsors of research into prevention of HIV in both the United States and international settings.² A survey of network members identified several ethical challenges for which clear guidance does not exist, including establishing acceptable standards of care for research participants, defining the relevance of research to host countries, reducing risks associated with stigmatisation, determining who has ethical authority and accountability in international collaborative research, designing research that meets local needs without bolstering an inadequate status quo, ensuring informed consent for complex research with potentially vulnerable participants in highly variable contexts.

The guidance reflects the network's commitment to conduct scientifically and ethically sound research that is grounded in a participatory process.³ It directs that research should be implemented only in settings where

it clearly meets the needs of the local population. For clinical trials, the guidance requires selection of comparison or control arms that reflect best practices in HIV prevention while generating scientifically valid results and useful data for developing locally responsive prevention programmes. Whenever possible, researchers are directed to seek ways to improve local access to care rather than contribute to the creation of a dual standard that privileges research participants. The informed consent process outlined in the guidance requires explicit consideration of community and individual level obligations before and during enrolment and, where needed, during ongoing research.

The guidance reflects procedures and strategies that are already being used within the network by at least some researchers. Implementing those procedures more broadly and consistently will require additional effort, and we are exploring the means to accomplish this.

No guidance document can eliminate the necessity of identifying relevant issues on the ground and then engaging in a process of description, analysis, and balancing of the ethical tensions inherent to them. The goal of establishing this guidance is to ensure that ethical decision making is of the highest quality, in keeping with the network's scientific agenda. It will continue to be refined as experience is garnered, new research is designed, and important events occur that affect research already underway or in the pipeline.

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- 1 HIV Prevention Trials Network. *Ethics guidance for research*. www.hptn.org/Web%20Documents/EWG/HPTNEthicsGuidanceFINAL15April2003.pdf (accessed 1 July 2003)
- 2 HIV Prevention Trials Network. www.hptn.org
- 3 MacQueen KM, Sugarman J. Back to the rough ground: working in international HIV prevention research as ethical debates continue. *IRB: Ethics Hum Res* 2003;25(2):11-13. (Accepted 23 June 2003)



The Doctor's Visit by Gabriel Metsu (1629-67), Hermitage Museum, St Petersburg, Russia (www.hermitage.ru)

Images of the good doctor in Western medicine: the doctor-patient relationship (part 2)

Metsu is perhaps most famous for his painting *Music Lesson*, but I prefer *The Doctor's Visit*, which contrasts with Naiveu's painting (*BMJ* 2002;325:1003) in showing a less caring image of a doctor visiting an equally wealthy patient.

The relationship between the subjects is intriguing. The young girl patient is obviously the daughter of a wealthy family. The chamber pot in the foreground indicates she has provided a urine specimen, a sample of which the doctor inspects. It was believed that by such an inspection pregnancy could be confirmed. A small dog, of a breed favoured at the time by upper class prostitutes, provides a visual metaphor for sexual activity.

The cavalier pose of the doctor indicates a degree of detachment and disapproval of the girl's behaviour. The expression of the maid, however, indicates a satisfaction that her suspicions are confirmed and a certain amusement at the predicament of the girl, aware that this will mean ruination for the girl and shame for the family. Only the dog shows any sympathy or concern for the girl.

So, what lesson can be learnt from this 17th century scene? Perhaps it is that when dealing with someone of whose activities you may disapprove, remember the image of the dog and try to show as much sympathy. Oh, and get the maid out of the room before you start.

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