Ethics & Medical Research

The Standard of Care & Reasonable Availability

As you read the material for the next class, keep the questions below in mind. To answer these questions you will have to reflect critically on what you have read and possibly re-read important passages. Keep in mind that there are two basic kinds of information that you need to look for in the readings:

1. What are the main points or conclusions that an author accepts with respect to a particular issue?
2. What are the reasons, important considerations, and evidence that lead the author to accept that conclusion?

For our purposes, *it is information of the second sort that will be our primary concern* since our most basic task is to *evaluate the reasons and evidence* that are offered to support accepting one possible conclusion about an issue, rather than another.

Although I strongly suggest that you write out brief answers to these questions, you do not have to turn in written responses. You do, however, need to be prepared to speak intelligently to these issues in the next class meeting.

Readings

- Robert Crouch & John Arras, "AZT Trials and Tribulations" (PDF on webpage).
- Søren Holm & John Harris, "The Standard of Care in Multinational Research", pp. 729–736.

Questions

1. When it comes to the placebo-controlled trial of AZT in Thailand, what is Crouch and Arras' justification that (a) the trial had both scientific and social value, and (b) the participants in the control group were not entitled to receive the full 076 protocol (the standard of care in developed countries) instead of placebo? Does this mean that they wholehearted approve the ethics of this study?
2. Much of the analysis by Holm and Harris is based on the idea that researchers have obligations to both the subjects of research and those not participating in research. What are these obligations and why do researchers have them? What implications follow from these obligations?
3. Holm and Harris also argue that all members of society have certain obligations concerning research. What are these obligations? Why do we have them? What is the moral problem with being a "free rider"? What implications follow from these obligations?
4. In their final analysis, what prescriptions do Holm and Harris make for determining the proper standard of care?
5. Guideline 10 of the *2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects* by the Council for International Organizations of Medical Sciences (CIOMS) says that every effort must be made to ensure that the fruits of the research are made "reasonably available" to benefit the host community. Crouch and Arras defend this guideline as a necessary condition against exploitation, whereas Holm and Harris declare it morally irrelevant. What are the arguments for defending their respective positions? Given that they reach different conclusions, they cannot all be right. Where exactly in their respective arguments do they disagree? Which position is supported by the strongest and most compelling argument?