Ethics of Medical Research: placebo trials

Placebo Trials

Hawkins is interested in cases that have the following five features:

(1) *Pre-Existing Treatment.* "[C]linical research is undertaken in an effort to develop a new treatment for some condition – call it A – even though other forms of effective treatment already exist for A.

(2) *Inferiority.* "[T]he control arm in the trial uses placebo or some other therapy known to be inferior to the best existing therapies."

(3) *Unavailability.* "[N]o treatment for A is generally available where the trial is to take place."

(4) *Sick.* "[T]he proposed subjects are not healthy volunteers, but individuals with condition A."

(5) *Serious.* "A is a serious condition, that is, one that if left untreated carries with it a high risk of disability or death, or is otherwise quite serious."

Question: Is it morally permissible for medical researchers to conduct Placebo Controlled Trials in such cases?

Answer 1: No. It's never okay for medical researchers to conduct PCTs in cases like these.

Answer 2: Yes. It's always okay for medical researchers to conduct PCTs in cases like these.

Answer 3: It depends. It is sometimes okay for medical researchers to conduct PCTs in cases like these but it is also sometimes not okay.

Hawkins defends *Answer 3* — she argues that medical researchers have a Good Samaritan obligation to treat the control group participants in a drug trial, but that this Good Samaritan obligation can be cancelled if, and only if, the following three conditions are satisfied:

1. **Importance:** The aim of the research is morally weighty. There is a great need for the information that might be gained from the study.
2. **Necessary:** A PCT (as opposed to an Active Control Trial) must be the only way to obtain the information.
3. **Local Benefit:** The community from which the subjects will be drawn must be a community that could greatly benefit (and is likely to benefit) from the information the might be gained from the study.

PCTs and Harm

In a PCT, the control group receives no treatment. In these cases, there exists an effective treatment for the condition, the condition is serious, but the control group is withheld treatment. Do medical researchers, by conducting such trials, *harm* the members of the control group?

> **Harm.** Person X *harms* person Y when X's actions directly cause person Y to be *worse-off*.

(a) Worse-off relative to the **status-quo**?

(b) Worse-off relative to how well-off person X is **obligated** to make you?

Because the effective treatment is *unavailable* in the community, medical researchers **do not harm** the members of the control group in a PCT in the sense that *they do not make them worse-off relative to the status-quo.*

Do the medical researchers have an *obligation* to make the members of the control group better-off? If so, then medical researchers **do harm** the members of the control group in a PCT in the sense that *they do make them worse-off relative to how well-off they are obligated to make them.*

Duty to Rescue. If I'm a Lifeguard and you are drowning, and I do nothing, then I *harm* you — but I don't make you worse-off than the status-quo; I make you worse-off than you would be if I fulfilled my obligations to you.

What Obligations do Medical Researchers Have?

1. **Professional Obligations.** Doctors have a moral obligation to their patients. Do medical researchers have the same obligations to their subjects as doctors have to their patients?

   (a) Medical researchers *are* doctors.

   (b) The same reasons that generate Doctor-Patient Obligations also generate Researcher-Subject Obligations? The *inseparability of Hats Argument*?

But there's a difference between *wearing your doctor hat* and *wearing your researcher hat*. Shouldn't your professional obligations track the particular role you are playing?

2. **Good Samaritan Obligations.** These are obligations that everyone has simply in virtue of being a moral agent.

   > It seems to me that a good argument can be made that researchers, just like the rest of us, have Good Samaritan obligations and that what is troubling about their actions [...] is that they are flouting a deeply important obligation to perform easy rescues.

   Good Samaritan obligations are "open-ended" and "indeterminate," so why do researchers have obligations to *their subjects* in particular?

Hawkins says: *distress avoidance* and *gratitude*.

Hawkins argues that Good Samaritan obligations can sometimes be defeated by other weightier moral considerations.

- In AZT, the obligations **are defeated** because "by hypothesis a PCT is the only way to prove an intervention that, if successful, would save thousands of lives."
- In Surfaxin, the obligations **are not defeated** because the data is not morally significant: it will merely help a company generate more of a profit.