

[EDSTAT-L] HIV Trial: Control group drop out

In 5/25/2013 6:28 PM, Milo Schield wrote:

I recall a story an early test (1986?) of an HIV treatment (AZT?) in > the US (San Francisco?). With help from pharmacists, the subjects were able to find out which group they were in. Those subjects in the control group (placebo) tended to drop out. Finally, after convincing > subjects to stay "blinded" the trials were able to give meaningful results. Is this story true or is this an urban legend? I can't find any match using Google. If so, where is a good account?

It is true, and even more. It took me a long time to confirm that this was not an urban legend. The break came when I found the following book:

Epstein, S., 1996. *Impure Science: AIDS, Activism, and the Politics of Knowledge*, University of California Press.

It is a fascinating look at how AIDS activists changed how clinical trials were run by taking on many of the roles that were normally reserved for scientists.

I have the Kindle version, so I'm not sure about page numbers, but I think the account starts around page 203.

The first few AIDS trials were placebo controlled and this was not (in my humble opinion) a good idea. You are facing a rapidly fatal disease (at least that's what AIDS was before the era of AZT), and you want to enroll in a trial where there is a 50% chance of getting a placebo?

It turns out that the drug being tested (AZT) had a bitter taste and you could tell whether you were on the placebo by just opening up the capsule and taking a quick taste test. After the drug company changed the composition of the placebo to match the bitter taste, AIDS patients would take one of the pills to a local chemist for analysis.

I'm speculating, but if you found out you were in the placebo group, you would probably drop out and then re-enroll under a different name.

Still other patients pooled their pills with others figuring out that a 100% chance of getting a dose at 50% potency was better than a 50% chance of getting a dose at 0% potency.

Now Epstein does admit that much of this was "rumor" and that the actual level of "abuse" (if you can call it that) was very low.

You should read the book because it talks in detail about how these incidents might make [or] cause you to lose faith in the objectivity of the double blind placebo controlled trial.

There's also extensive discussion of the controversies associated with surrogate outcomes.

The book looks at an even broader theme. What does it mean to be a scientist? Who decides what research should be done? Who decides when there is sufficient evidence to establish something as a scientific fact? The first half of the book talks about the controversy over whether the HIV virus was the cause of AIDS. The second half of the book talks about the controversy associated with early trials of AZT and other closely related drugs.

If you didn't already know it, some of the things we think of as perfectly objective have a subjective aspect to them that hides just beneath the surface. This sounds like post-modernism, but you don't have to embrace this philosophy in order to recognize that many aspects of research have some wiggle room in them. Reading the Epstein book helps you to see this much more clearly.

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