

## **"Would You Kill the Fat Man? The Trolley Problem and What Your Answer Tells Us about Right and Wrong"**

**David Edmonds, 2014, 220 pages, Princeton University Press, \$14.95**

**Review by Norman M. Goldfarb**

"Would You Kill the Fat Man? The Trolley Problem and What Your Answer Tells Us about Right and Wrong" is an illuminating romp through an ethical minefield with direct application to human subjects protection in clinical research.

Consider the following scenario:

You are standing on a pedestrian bridge over a trolley line. You look down to the right and see five people tied to the tracks. You look down to the left and see an approaching trolley that will surely kill them. But standing next to you is a large man, so large that if he were to fall onto the tracks, he would stop the trolley but be killed himself. You could jump but you are too small to stop the trolley. You have to make a quick decision: push the large man off the bridge to save the lives of five people tied to the tracks, or do nothing, and let the five people die. There are no clever solutions or extenuating circumstances. What should you do?

This is the basic "trolley problem," one of hundreds of variations that ethicists have studied in the field of trolleyology (gotta love that name) to probe people's ethical beliefs. For example: Now imagine that the large man will allow you to push him. Or, that the large man is about to jump, and you must decide whether to stop him. Or, that the large man will die of cancer within the week. Does your decision change in these scenarios?

If the question is to sacrifice one person in a clinical research study to save five (or 5,000) patients, the clinical research answer is clear: do nothing and let the patients die:

...no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. (21 CFR 50.20)

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. (21 CFR 56.111)

In other words, even if you could obtain the large man's consent to being pushed off the bridge, you would never obtain IRB approval.

However, consider this situation, based on an actual study:

Acme Pharmaceuticals will conduct a study in your country with 400 neonatal infants on a disease that kills about half of those afflicted. Half the infants will receive the study drug and most will live. However, the other half will receive a placebo and about 100 of them will die. In other words, the study will save the lives of about 100 Ruritanian infants. If you refuse the study, it will be conducted elsewhere, sacrificing the lives of those 100 Ruritanian infants. Medications currently on the market can save all the infants' lives, but they are too expensive for your country. The study could employ an active control, but Acme, if forced to use an active control, would conduct it in the United States for legitimate scientific and business reasons. If the study is successful, the new medication will be far too expensive for Ruritanian

citizens, even with the 90% discount that Acme can afford to offer. As the benevolent ruler of your country, should you approve this study? <sup>1</sup>

Now consider this hypothetical situation:

The Zika virus has mutated to a virulent, airborne form that kills 10% of people infected and is spreading fast. A new vaccine will probably stop the disease, but before it can be deployed, it must be tested on 100 volunteers, half of which will surely die. You are a member of the IRB that must decide today whether to approve the study. The federal government has granted a waiver of the relevant human subjects protection laws. No other information is available. Do you vote for approval?

The above scenarios are extreme, but IRB members deal with mild forms of the trolley problem when they decide whether "risks to subjects are reasonable in relation to...the importance of the knowledge that may be expected to result." IRBs should pose various trolley scenarios and develop a consistent policy for dealing with them.

The book includes 16 chapters:

- Churchill's Dilemma
- Spur of the Moment
- The Founding Mothers
- The Seventh Son of Count Landulf
- Fat Man, Loop and Lazy Susan
- Ticking Clocks and the Sage of Konigsberg
- Paving the Road to Hell
- Morals by Numbers
- Out of the Armchair
- It Just *Feels* Wrong
- Dudley's Choice and the Moral Instinct
- The Irrational Animal
- Wrestling with Neurons
- Bionic Trolley
- A Streetcar Named Backfire
- The Terminal

The book is available in bookstores.

## Reference

1. "Is This Study Exploitative?" Norman M. Goldfarb, *Journal of Clinical Research Best Practices*, April 2011

## Reviewer

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