



*Or how to get the
results you want from a
trial provided you have
no scruples at all*

Imagine you work for a pharmaceutical company who has a new drug. It was very expensive to develop, so lots of pressure to show it works & is safe

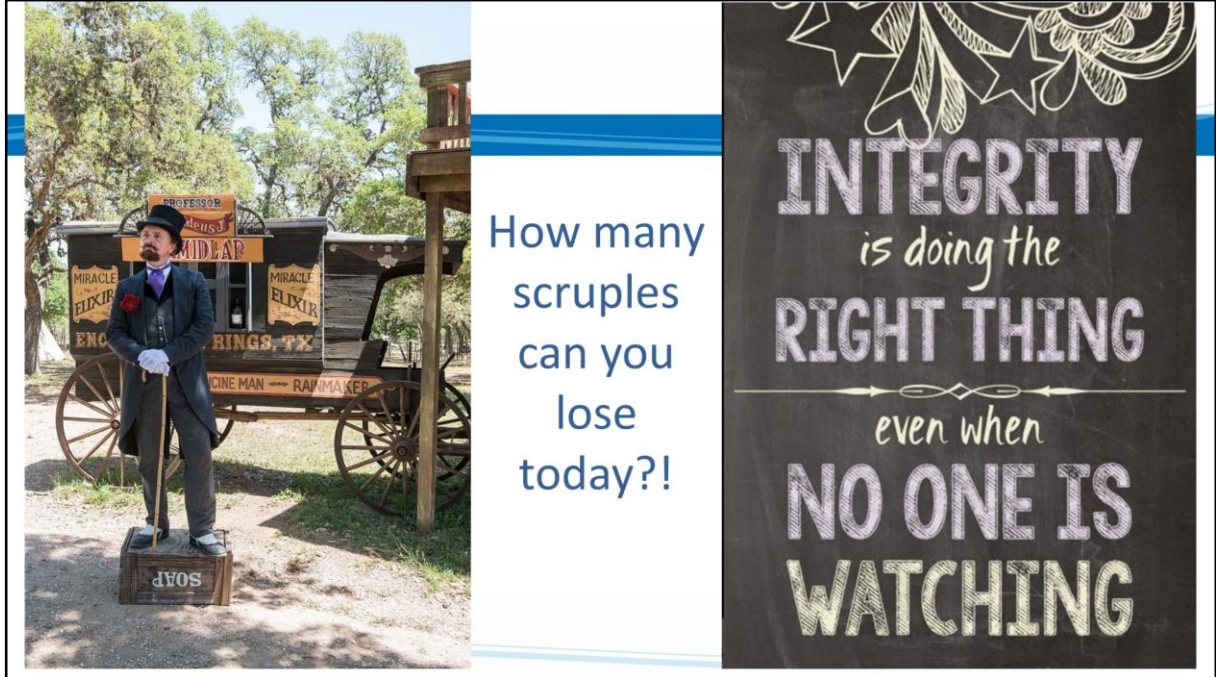
Step this way to 'encourage' positive results....



Inspired by a blog post on Students4best evidence,
<https://s4be.cochrane.org/blog/2016/12/09/get-result-want-study/> and the mighty Ben Goldacre

Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: MR000033. DOI: 10.1002/14651858.MR000033.pub3. Accessed 21 June 2023.

“Sponsorship of drug and device studies by the manufacturing company leads to more favorable efficacy results and conclusions than sponsorship by other sources. Our analyses suggest the existence of an industry bias that cannot be explained by standard 'Risk of bias' assessments.”



Bias is a big problem in research – it can affect the results significantly and make the entire study invalid.

When you're looking at an article, it's important to bear in mind how the outcome could have been influenced by decisions made in the methodology used, either consciously or unconsciously.

So, as an exercise in spotting bias, what would it be like if you consciously set out to influence the results of your research?

Meet Professor Thaddeus Schmidlap, resident snake oil salesman at the Enchanted Springs Ranch in Boerne, Texas. He'll be your guide to having absolutely no scruples and getting your drug to market by fair means or foul

Gameshow questions

1. **What type of participants to should I use?**
2. What to give your control group (comparison drug)
3. When to stop your trial
4. Should you publish the results?
5. **What to do about drop-outs? People are probably getting side effects**
6. Would cleaning up your data help? What about outliers?
7. Use a different statistical test
8. The results are still looking bad for the new drug – what now?
9. **Where to publish?**



There is value in debating how bad bad really is – the good option is usually obvious!

Can also do this on quiz platforms like Menti, works well when doing virtual training but then just go for the “worst” for ease.

1. What type of participants to should I use?

- a. Random bunch of people
- b. Bunch of people most likely to respond well to the drug even if they aren't the ones it is aimed at e.g. young, healthy
- c. Bunch of old people (after all, they're cheap & have plenty of free time to do the study, don't worry about their polypharmacy and co-morbidities)
- d. Bunch of people who've already tried the regular treatment & failed to respond



Looking for the way that's likely to put the product in the best light, and also the most ethical one.

Ethical choice is A

Choice most likely to give positive results is B

D would be interesting to see if the new treatment works better, but not what we're looking for

2. What to give your control group (comparison drug):

- a. A drug you know works really well (but perhaps give a sub-therapeutic dose....)
- b. A drug you know works really badly
- c. A drug you know produces lots of side effects
- d. The drug that's usually given for this condition



Ethical choice is D

Choice most likely to give positive results is B or C – both would be good choices to make the control group look bad

Anyone choose A? Could be very convincing as it looks like you are pitting your drug against a effective one, especially if no-one remembers to check what the standard therapeutic dose ought to be.

3. When to stop your trial:

- a. As soon as your comparison drug is clearly showing better results
- b. After a duration decided before the trial takes place
- c. Suck it and see - give it another couple of months if the new drug results are showing late promise



Ethical choice is B

Choice most likely to give positive results is definitely C

Anyone chose A? Definitely NOT what we're after here – You're Fired!



*Or how to get the
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Now the trial is over – results are in.
It's not looking good for the new drug,
but do not despair – there are more tricks to try!



Decisions made during the trial are not the only ways to influence the results, there's a few more decisions to be made yet...

4. Should you publish the results?

- a. Yes – publish in full because science is best when all the available data is out there
- b. No, not a chance – bury the data. (and don't share it if asked by a diligent systematic reviewer in the future...)
- c. Yes, because you need the publication on your CV, but you can always massage the data



Publication bias is not all about pharmaceutical companies burying data, many publishers only want to publish papers which show interesting results, not dead losses.

Ethical choice is A

Choice most likely to give positive results is C with some data massaging

B is also a popular option, but won't help get the drug to market

5. What to do about drop-outs? People are probably getting side effects:

- a. Ignore everyone who dropped out, only do per-protocol analyses (count those who were still there at the end)
- b. Think about mentioning drop outs if they were getting the comparison treatment as it makes that drug look bad – otherwise 'forget' them
- c. Carry out intention to treat analyses (do your stats based on the number you intended to treat) and acknowledge drop outs, also account for everyone who took part and their reasons for dropping out



Ethical choice is C – everyone should be accounted for, and ITT analyses are pragmatic and reflect real world medicine where not everyone takes their prescribed medicine properly or at all.

Choice most likely to give positive results is B

A happens more than you think!

6. Would cleaning up your data help? What about outliers? Those rare people who do spectacularly well - or badly - compared to everyone else – skewing the average result

- a. Include some of them as long as they make your new drug look good; after all, data is data
- b. Remove them from the data if they make your drug look bad as they were probably not representative of normal people anyway
- c. Include all data regardless (and if the results look bad for the new drug that is just the way it is)



Ethical choice is C

Choice most likely to give positive results is A or B

7. Use a different statistical test.

- a. Choose whichever statistical test will give the most impressive result, even if the data didn't warrant it (who even reads that paragraph in an article anyway?)
- b. Invent a statistical test with a convincing complicated name, pretend you ran it, and make up some results. (Who is going to admit they never heard of a statistical test....?)
- c. Use the appropriate type of test for the data regardless of what the result will look like



Some statistical tests shouldn't be used if your data doesn't meet certain assumptions. But who cares about using an inappropriate statistical test if it means you get the result you want!

Ethical choice is C

Choice most likely to give positive results is A or B

8. The results are still looking bad for the new drug

- a. Prepare to publish anyway, warts and all
- b. 30-35yr old female cat owners did really well so just write about them (just don't mention they were a subgroup when you write your press release)
- c. Totally re-invent your data so that your drug looks golden.
- d. Bury the trial, and never speak of it again



Ethical choice is A

Choice most likely to give positive results is B

C would never happen – or would it? That's why replication is really important

D makes other people's systematic reviews less valuable, even dangerously so. That's why systematic reviewers are meant to go to quite some lengths to get hold of unpublished data.

9. Where to publish?

- a. The most prestigious, widely read, peer reviewed journal you can find (although they'll probably spot you mucked about with the data and will not publish. But then again, Andrew Wakefield.)
- b. The most obscure journal you can find, that way fewer people will read it (and lots of them won't read past the abstract...)
- c. Whack it on a pre-print server where nothing is peer reviewed. Then "forget" to submit the manuscript to an actual journal.



Choice most likely to give positive results is C, although B looks better on your CV

Ethical choice is A

Be aware – A didn't catch out Andrew Wakefield – his study linking autism to MMR vaccines was originally published in the *Lancet*, then retracted. Wakefield had highly selected his patients, fixed results and manipulated patient data, failed to get ethical approval for invasive tests on children, and lots more, including holding a patent for a single vaccine at the time he said combined vaccines were dangerous. The BMA struck off Wakefield. Check out *Lancet* MMR autism fraud on Wikipedia for the gory details.

"Preprints" are preliminary versions of scientific manuscripts that researchers share by posting to online platforms known as preprint servers before peer-review and publication in an academic journal. Preprint servers are publicly available online archives that host preprints and their associated data.

Write for Northern Lights!

What about ...

your best bits from today / new services / old services evaluated / co-operative ventures / outreach into new departments / sessions you've run / INCdocs has changed your life / funny things your users have said....literally anything that you think might be of interest to fellow health library staff

And while you are thinking about that,
why not join t'committee?

Northern Lights
needs you!

On behalf of Northern Lights Editorial Group



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