

Lingua Franca and Beyond

Some thoughts on statistics and a bit more...

In this issue of *Medical Writing*, I would like to recommend two articles. Szymon Musiol shares with us his thoughts on a statistician's role in research overall and also in the process of preparing publications. He takes a medical writer's perspective and convinces us that the risks for creating a mutual relationship between the author, the medical writer, and the statistician can be minimalised. Personally, I fully agree with Szymon, but on the other hand I understand that often communication between

authors and statisticians can be very challenging. The former speak their clinical language and the latter – statistical *Hocus Pocus*; no way do they get into mutual communication. Here comes in or at least should come in the medical writer, just to translate so that the statistician understands the clinical question and the author comprehends the statistical answer. Not an easy task... The second article is from dear *Hotspur* – welcome back with your funny stories and observations.

SECTION EDITOR



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In the March 2016 issue, we read about the unpredictable aspects of choosing a collaborator. Now, we can look further into refereeing mechanisms... Please, bear in mind the final conclusion! Very true!

Have a nice reading ☺

Maria

Statistics – are we doing it right?

Statistics has probably been a bone of contention of medical academia since the first time someone decided to calculate a p-value in support of their findings. Beloved by few, and dreaded by many, it remains a necessary evil for those wishing to engage in scientific endeavours of high quality. The mutual relationship between the author, the medical writer, and the statistician (not to mention the sponsors) is often underpinned by a power struggle, with each of the parties striving to vindicate their own agenda. I think resentment towards statistics by the non-statisticians has an important part to play here.

In my personal experience, the statistician is frequently involved too late in the process of research. The first person to mention it to me was a professor of statistics who tried to hammer this point home at every opportunity. At the time I thought he was merely bitter at missing out on dinners, but now I understand his advice was invaluable. Time and again, the statistician is approached with an often meticulously collected set of raw data and is curtly asked to 'run some stats on it'. Often

the feedback states something along the lines of the study being underpowered by an order of magnitude to show the expected potential effect. Disappointment is followed by *plan B*, as the authors now ask the statistician to employ some mathematically dubious sorcery to shrink that p-value. The medical writers find themselves in an equally uncomfortable position having to word far-fetched conclusions from exotic maths they barely understand. One objectionable trick is to generate hypotheses *a posteriori*, based on the sample available.

By chance alone, if enough putative correlations are tested, some of them will be statistically significant. That's all we want, isn't it? A positive result with a nice p-value. Except, such data are not reproducible. If someone applies our devised model to their sample of the population, most likely there will be no correlation. And now no one

wants to cite our paper.

That being said, *a posteriori* generation of hypotheses isn't always bad. I recently came across a report on Google being granted access to approximately 1.6 million patient records in the UK for the purpose of identifying predictors of *acute kidney injury*. Putting aside the Orwellian connotations this might

prompt in some, it could lead to significant scientific advances. Why should it work then? Simply because of the enormous sample size. Any correlation identified, even based on a post hoc hypothesis, is very likely to hold true for the entire population. Most of us sadly can't dream of this level of statistical power, and to keep publishing high quality material we must adjust our methods appropriately.

All this stems from pressure to publish positive results only, something anyone ever applying for funding will be acutely aware of. The tabloid-like obsession with headlines has led to significant publication bias in the literature. Fortunately, awareness of the problems it poses is now beginning to trickle into the minds of academics, reviewers, editors, and sponsors alike. With many meta-analyses laying bare this skew, The International Committee of Medical Journal Editors now advises periodicals to require pre-registration of clinical trials as a necessary condition for publication. This means hypotheses have to be devised *a priori* and negative results are also likely to be published. This spares the statistician having to dredge the data, and the medical writer the job of describing it. With a few exceptions, we may all remain in the safe sandbox of undergraduate level statistics with good old t-tests, linear regression, and correlation coefficients dominating the scene. Perhaps every now and then Mann and Whitney will pay us a visit. But all in all

it shouldn't be too bad, provided we abide by those ground rules.

My final advice is to always design the hypotheses to be tested in advance. Invite the statistician for coffee well before

collecting the first batch of data. Let them explain what sort of sample size is needed to have sufficient power for the result you desire, and what statistical methods suit the purpose. Register your research whether

original or secondary. And finally, unless you're Google, don't mine your data.

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Refereeing: a humour-free occupation

Sometimes you find yourself in a mess through no fault of your own; on other occasions, the problem is self-inflicted because of character traits that have troubled you in the past and no doubt will do so again in the future. One such character trait that I possess is a tendency to be flippant and a little silly when feeling completely relaxed.

Well, I was very relaxed on a lovely summer evening a year or two ago in North America, the day's work was over, and I was in happy hour mode; I sensed upregulation of my flippancy gene. The purpose of my visit was to attend the annual meeting of the American Endocrine Society (AES); as far as I could tell, my presentation had been well received, and I was now enjoying myself at a dinner held for a small constituent society of the AES that always arranges a social function to coincide with the annual meeting.

I was searching for my second pre-dinner cocktail when I spotted Mike, an American colleague (the name has been changed to protect the guilty); I had known him for years. He was lively, intelligent, a man of strongly-held beliefs, and equipped with a great sense of humour. We had sparred many times before in a jocular good-hearted fashion. Furthermore, I was certain that he had just refereed one of our articles for *Clinical Endocrinology*; the style, the manner of expression, and the content of the referee's argument all pointed to Mike. The article was a tricky one and I have to admit that I was amazed that my research fellow had ever been able to conjure a manuscript out of such raw data; nonetheless, he had done a very professional job and no other data exist in the literature on this topic. So we were in the position of the one-eyed man in the land of the blind, and I anticipated that the journal would accept the manuscript.

Referee one, whom I guessed was Mike, started down the first page of his report by not liking the article and by the end of the page he hated it; boy, did he hate it! Vitriol was pouring from his pen as he became

more and more agitated by our efforts. The journal behaved impeccably and allowed us to rebut the criticisms and comments, eventually accepting and publishing a revised version of the manuscript.

I had to pass in Mike's direction to get to the bar so I paused to greet him;

'How are you?'

'Fine', he said

'Tell me why did you hate our work with such intensity?'

'What are you talking about?' said Mike (my pulse rate quickened)

'You know, our recent manuscript for *Clinical Endocrinology* on pituitary disease.'

'I don't know what you are talking about, I have never refereed any manuscript of yours'.... (beads of sweat appeared on my forehead)

... 'but you refereed an article of mine recently that I sent to the *Journal of Clinical Endocrinology and Metabolism*' said Mike abrasively (my legs felt very heavy)

'Did I?'

Scrambling thoughts together; is he right? Oh god, I do seem to remember an article, the article presumably (brain no longer driving my side of the conversation).

'What happened to that article?' I queried

'Oh, it was rejected on your recommendation' he replied (now I was in desperate need of that drink)

'How do you know it was me that refereed your article?' (my legs were no longer capable of movement in any direction).

'The journal sent me the referee's comments with your name on the fax.' he stated.

Well, for the remainder of the AES meeting, as luck would have it, I ran into Mike every day, and without fail he reminded me that I had rejected his

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article. Even if on escalators moving in opposite directions, and too far apart for dialogue, he would simply look across at me

with a baleful eye and then, Roman-style, give me a thumbs-down sign.

I was upset that my ability to referee-spot was not as good as I thought. In the past, I used to recognise the typeset, e.g. dropped 's' on typewriter in endocrine department of a famous London teaching

hospital, an unhelpful talent in the computer era, but I had always told myself that I could identify the referee by the style and language used in the review. Thus, my illusion was shattered and self-esteem reduced.

Some 2 to 3 months had elapsed when out of the blue I received a fax from Mike; 'I have been reviewing my refereeing records and find that I have refereed two articles of yours, including the one on pituitary disease.'

Referee-spotting self-esteem restored instantly; I felt happier than if I had had a manuscript of my own accepted. More seriously, I was deeply impressed by his actions; he must have lain awake for a few nights tormented that he had been economical with the truth and driven by his conscience responded in the manner that he had.

From that whole experience, I advise all readers to avoid all attempts at humour where the refereeing of manuscripts is concerned. When an article is criticised, pain of varying intensity and duration is felt by the author however senior or junior.

I still relax after a day's work and remain a little silly but I am fonder of Mike, and I now understand that refereeing is a humour-free occupation.

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