

able to make sense of the PowerPoint handouts.

8. **Spend time developing an effective evaluation form.** If participants mark down any of the items, ask them to explain why. Also, importantly, ask them to suggest improvements. (Ignore impossible requests.)
9. **Be prepared for all eventualities.** Try to fill places when there are last-minute cancellations. There are waiting lists for our courses and we do our best not to waste any places. Guest speakers can drop out unexpectedly; untimely failures of audio-visual equipment can try everyone's patience; and, worst of all, the coffee and cake can fail to arrive! Hence you should have the mobile numbers of important contacts, including the IT department and the canteen, written in indelible ink on the back of your hand. (Many things can go wrong – if anyone would like a comprehensive list they are welcome to get in touch.)

10. **Finally, send out a follow-up email with useful links and answers to questions that have required extra research.** Request additional feedback; this can be used to make the course even better next time.

The Intensive Medical Writing Course currently runs in January and June. In addition, longer medical writing courses, consisting of eight sessions with 12 participants, run in the spring and autumn. As a new venture – at the request of former participants – a one-day follow-up course was successfully established last November and is now scheduled to run twice a year. It should be noted that the texts submitted for the November follow-up course were light years ahead of those submitted for the preceding full-length courses, which illustrates the positive effect the writing courses are having.

### Acknowledgements

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### Suggested Reading

1. Møller C. New medical writing course in Copenhagen: Increasing chances of publication for non-native speakers. *The Write Stuff*. 2007;16(1):8–9.
2. Møller C, Schoell M. Language revisers/translators/editors: is there anyone out there? *The Write Stuff*. 2008;17(2):85.
3. Schoell M. Working as a medical editor and translator in a university environment in Germany. *Medical Writing*. 2012;21(3):257–9.

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## Profile

# An interview with Professor Peter Jüni

## on methodology and statistics in scientific manuscripts

This issue of Medical Writing (MEW) is about statistics, so what is more appropriate than interviewing a research methodologist who focuses on epidemiology and statistics in clinical research? I am happy that we were able to win Professor Peter Jüni for this interview. Peter Jüni is a physician by education, has been a Professor of Clinical Epidemiology and the Director of the Clinical Trials Unit and the Institute of Primary Health Care at the University of Bern. In 2016, he moved to Toronto where he is a Professor of Medicine at the University of Toronto, and the director of the Applied Health Research Centre (AHRC) at the Li Ka Shing Knowledge Institute. The AHRC is a leading not-for-

profit academic research organization fully integrated with the Li Ka Shing Knowledge Institute of St. Michael's Hospital and affiliated with the University of Toronto.

Peter Jüni has authored more than 270 peer-reviewed publications. Amongst them were several landmark trials and meta-analyses, various international guidelines (such as the 2014 ESC/EACTS guidelines on myocardial revascularization), and several articles on statistical topics such as systematic reviews, meta-analysis, and propensity score techniques. He has been a reviewer for major journals such as *The Lancet*, and was listed as highly cited researcher by Thomson Reuters.

### SECTION EDITOR



**Beatrix Doerr**

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**Medical Writing (MEW):** You review many manuscripts. What are the most common mistakes you see?

**Peter Jüni (PJ):** The most common mistakes I see is that the perspective of the reader is ignored and the manuscript is not structured logically and coherently. Thus, this is much more about a basic lack of structure and logic than about fancy statistics. A caveat: my observations are mostly related to working with fellows, PhD or MD students – they might not apply, or only to a lesser extent, to medical writers.

The introduction should clearly lead to the main question. The main question should then be reflected in the methodology, including the statistical section. All

descriptions should be transparent, consistent, and easy to understand. Often, I find analyses in the results section, which have not been described in the methods section or vice versa. In other cases, I find that the content does not reflect the structure of the manuscript, descriptions of methods end up in the results section, results in the methods section and things get mixed up quite a bit. 'What was done' belongs into the methods section, 'what was found' should be reported in the results section and 'how this should be interpreted' can be stated in the discussion.

Frequently, protocol-specified outcomes are missing from methods or results, or new outcomes are reported that were inexistent in the protocol. Randomisation lacks an appropriate description, important elements are lacking, such as the generation of the random sequence, including stratification and blocking, and more importantly, the reader does not understand the mechanism of concealment of allocation. However, all the high level stats are completely futile if randomisation was messed up in the first place. The subsequent methodological steps following randomization (blinding, follow-up of patients, intention-to-treat analysis) are ultimately deemed to maintain the experimental momentum introduced by randomization and should be described meticulously.

The discussion section is often a wild, completely unstructured experience, when in fact it can be structured into separate paragraphs describing main findings, context, strengths, weaknesses, clinical and scientific implications of the work. Display items, i.e. tables and figures, should be completely self explanatory, with a legend that makes sure that the reader will not have to go back to the main body of the manuscript to understand what is being reported. Following the CONSORT 2010 and related guidelines (see <http://www.equator-network.org/>) will help a great deal to get this right. However, I would recommend using these guidelines like a cook book – don't follow it too slavishly, but make sure to include most ingredients.

**MEW: What are the most common mistakes you see related to statistics?**

**PJ:** Well, on a more conceptual level, many of the mistakes I see probably start with our trouble in accepting uncertainty. People ignore that the probability of hypotheses



depends on much more than just the p-value, and even worse, divide the world into significant and non-significant. Used in such a naïve way, statistics will not help us to quantify uncertainty appropriately.

Results of a trial should be interpreted in the light of the sample size consideration. So, a comprehensible and complete description of the power calculation, which is not too technical is crucial – simply copying and pasting the statements received from the statistician is not good enough. Reporting of results should include absolute numbers, percentages, estimated differences between groups with corresponding 95% confidence intervals. P-values would actually not be necessary, but if they are reported, they should be reported exactly, and not, as already stated above, as merely significant or non-significant. A frequently encountered tautology is the reporting of p-values for baseline comparisons in randomised trials – not really helpful at best, misleading at worst, please avoid! Other frequent mistakes include taking correlations as evidence for causation, choice of wrong statistical models, over-interpretation of secondary outcomes, over-interpretation of subgroup analyses and mixing up statistical significance with clinical relevance.

**MEW: How should an ideal cooperation between a statistician and a medical writer look like?**

**PJ:** Both parties need to understand clinical and biological context and basic statistical principles to properly interpret results from a statistical analysis – mere number crunching is not enough. Continued cooperation and mutual exchange is key.

The sophistication of a manuscript lays in its clarity, transparency, consistency and simplicity, and in its focus on the readers' perspective, not in complex writing styles.

**Conclusion:** Professor Peter Juni shared some of his experience with us. I hope this will be valuable not only for inexperienced writers, but also for experienced ones. The sophistication of a manuscript lays in its clarity, transparency, consistency and simplicity, and in its focus on the readers' perspective, not in complex writing styles. And let's not forget our clinical judgement when we interpret statistical analyses!