



(Tuesday) 2 April 2013

## Memorandum

To: Trialists

Fr: Curtis Meinert

Re: On publish first, present later

I am a "publish first, present later" person when it comes to treatment results of trials. My reasons are because:

- 1 The gold standard for dispersing results is via publication in peer-reviewed indexed medical journals and therefore because one should proceed to publication as quickly as possible
- 2 Presentation prior to publication is likely to slow publication and cause journals to reject results if editors regard prior presentation as equivalent to publication
- 3 Queries generated by presentations will be difficult to answer without data from a publication
- 4 Discrepancies between what is presented versus that which is published will erode trust in the results; discrepancies likely if database for presentation different than for publication
- 5 Prior presentation can result in negative imprinting if results are controversial

Presentation in this context means at a public scientific forum. It does not refer to presentations in closed forums like department seminars or at closed investigator meetings.

The thing about presentations is that they do things to your head. The allure is in the five minutes of fame that comes from presenting.

Typically, investigators want to present because:

- 1 The results are too important to wait for publication  
**Comment:** If they are so important get on with publishing them. Don't waste time presenting. Presentation at scientific forums, no matter how large the forum, reach only a small fraction of those reached with publication and with slides that disappear as soon as the talk is finished. Publication cover the world. Presentation cover only those in the audience of the forum.
- 2 No one will be interested in presentations after publication; we should present first  
**Comment:** If interest is so thin why bother presenting
- 3 Presentation will speed paper writing  
**Comment:** Wrong. It will probably slow it down. The presentation will syphon away energies for paper writing. Further, the let down that comes after presentation will delay or even derail paper writing.
- 4 The feedback will make for a better paper  
**Comment:** Maybe, but so will 15 iterations of the paper. In any case, if feedback is desired, that can be gotten in closed forums, like department seminars, or presentations to the investigator group closed to outside parties.

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- 5 We can have our cake and eat it too by orchestrating presentation to coincide with publication  
**Comment:** Don't kid yourself. Editors waltz to their own tune.
- 6 The publicity from presentation will increase interest in the publication  
**Comment:** That depends on the publicity.
- 7 The norm in science is to present before publication  
**Comment:** The trouble with the norm is that it produces myriads of presentations never published.

I got to be the way I am from my first experience in trials – The University Group Diabetes Program (see Ch 49; 2nd edition; Meinert's *Clinical Trials: Design, Conduct, and Analysis*; Oxford University Press 2012).

Investigators, early on, bought into "publish first, present later" in regard to treatment results. So when they stopped use of tolbutamide because of safety concerns in mid 1969 they started work on a pair of manuscripts; one describing the design and methods of the trial and another detailing treatment results leading to the stop.

Work on the manuscripts proceeded apace but, as usually the case, slower than expected. By the end of 1969 projections were that the two manuscripts would be ready for submission in late spring of 1970. That time schedule gave rise to a push by investigators to "present and publish at the same time". With publication anticipated in June, investigators opted to submit results for presentation at the American Association of Diabetes (ADA) annual meeting, scheduled for mid June.

Unbeknownst to investigators, the ADA made the results available to the press about a month before the meeting. That release led to a series of news story. The press coverage led to a flurry of calls from patients to their doctors to find out if they were on that "killer drug" discussed in news reports. Physicians were in the difficult position of answering questions regarding tolbutamide without data. As a result, study investigators faced a hostile crowd in St. Louis on the day of the presentation – the 14th of June 1970.

St. Louis was a blood bath. When investigators left town that evening, they were licking their wounds and had a tornado on their tail on the way to the airport.

The publication was nowhere in sight. It was five months before it appeared (so much for orchestrating presentation and publication!).

Study investigators were sitting ducks without a publication. When it finally appeared, it was too late. By then everyone knew the study was "flawed". The only thing that needed to be done was to find out where the trial went wrong.

One of the more astounding criticisms was that mortality was not a legitimate outcome since the trial was not designed with mortality as an outcome.

The controversy regarding access to raw study data raged 15 years. Ultimately, the case ended up in front of the U.S. Supreme Court. It was heard with a request for Henry Kissinger's telephone logs while Secretary of State.

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Suffice it to say, all concerned would have been better served if study investigators had foregone presentation before publication.

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