JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
415 N. Washington Street, 2nd Floor
Baltimore, Maryland 21231

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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: The opaque trialist

As a trialist, I feel like Jimmy Swaggart when he gave his tear-filled "I have sinned" speech, 21 February 1988[*].

I did not always feel that way.

When I started in trials, before there was electricity, I felt wholesome. Sin free.

The first dose of reality came in the 10th year of my first trial, the University Group Diabetes Program (UGDP), when we were accused of "switching outcome" in relation to stopping one of the study treatments because of excess mortality.

Indeed.

The study was designed to detect differences in morbidity between the treatment groups. Mortality did not enter into the design rationale because investigators did not expect a difference in mortality.

"Switching outcome" implied something nefarious on our part without any appreciation by the people complaining that mortality trumps lesser outcomes. Even a farmer from Sleepy Eye knew we could not continue a treatment in the presence of a mortality excess, even if mortality was not designated as the primary outcome measure in the trial.

Carolyn Ball (Professor of public administration, University of Maine), in her publication, "What is transparency?" (Public Integrity; 2009; vol 11; pp 293-307), defines transparency as metaphors for (1) a public value or norm of behavior to counter corruption; (2) open decision-making and free flow and access to relevant information; and (3) a tool of good governance in programs, policies, and organizations.

Most of the demands for "transparency" in clinical trials relate to the 2nd metaphor.

Transparency, in this 2nd sense means: readily understood characterized by viability; accessibility of information.

"Transparency" in government was a promise of Obama in his first campaign but largely forgotten after he was elected.

The seeds for transparency in government were sown decades before Obama with the passage of the Freedom of Information Act in 1966 and the Watergate saga that started with a burglary of the Democratic National Committee headquarters, 17 June 1972.

The desire for transparency appears in the 16 September 2004 edict of the ICMJE (NEJM 351:1250-51) calling for registration of trials.

> *Registration is only part of the means to an end; that end is full **transparency** with respect to performance and reporting of clinical trials.*

The term in its noun form appears in the Food and Drug Administration Amendments Act of 2007:

> *Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall improve the **transparency** of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site*

The 2010 CONSORT statement (BMJ 2010;340:698-702) includes nine uses of the term in its various forms:

> *To assess a trial accurately, readers of a published report need complete, clear, and **transparent** information on its methodology and findings.*
>
> *Along with the CONSORT statement, we have updated the explanation and elaboration article, which explains the inclusion of each checklist item, provides methodological background, and gives published examples of **transparent** reporting.*
>
> *Diligent adherence by authors to the checklist items facilitates clarity, completeness, and **transparency** of reporting.*
>
> ***Transparent** reporting reveals deficiencies in research if they exist.*
>
> *Thus, investigators who conduct inadequate trials, but who must **transparently** report, should not be able to pass through the publication process without revelation of their trial's inadequacies.*
>
> *We strongly recommend using the explanation and elaboration in conjunction with the checklist to foster complete, clear, and **transparent** reporting and aid appraisal of published trial reports.*
>
> *The Enhancing the Quality and **Transparency** of Health Research (EQUATOR) Network will facilitate development of reporting guidelines and help disseminate the guidelines*
>
> *CONSORT urges completeness, clarity, and **transparency** of reporting, which simply reflects the actual trial design and conduct.*
>
> *However, with wide adoption of CONSORT by journals and editorial groups, most authors should have to report **transparently** all important aspects of their trial.*

The SPIRIT (Standard Protocol Terms: Recommendations for Interventional Trials; Ann Intern Med. 2013;158:200-207) includes eight mentions of the term in its various forms:

> *Adherence to SPIRIT would also enhance the **transparency** and completeness of trial protocols for the benefit of investigators, trial participants, patients, sponsors, funders, research ethics committees or institutional review boards, peer reviewers, journals, trial registries, policymakers, regulators, and other key stakeholders.*
>
> *A **transparent** audit trail with dates of important changes in trial design and conduct is an essential part of the scientific record.*
>
> *Finally, the intent of SPIRIT 2013 is to promote **transparency** and a full description of what is planned— not to prescribe how a trial should be designed or conducted.*
>
> *Protocol Representation Group, and Pragmatic Randomized Controlled Trials in HealthCare, to align international efforts in promoting **transparency** and high-quality protocol content.*

*Improved protocol content relevant to **transparency**, accountability, critical appraisal, and oversight (fr Table 2)*

*Improved **transparency** and interpretation of trials by readers (fr Table 2)*

*As a **transparent** record of the researchers' original intent, comparisons of protocols with final trial reports can help to identify selective reporting of results and undisclosed amendments, such as changes to primary outcomes.*

*Widespread adoption of the SPIRIT recommendations can help improve protocol drafting, content, and implementation; facilitate registration, efficiency, and appraisal of trials; and ultimately enhance **transparency** for the benefit of patient care.*

The trouble with the word is that it comes across to trialists as "preachy" and self righteous.

The reality is that the term is vacuous. Devoid of content.

As a trialist, I have no idea what the ICMJE, in its 2004 edict on registration of trials, means by "full transparency". Nor do I have any idea what CONSORT means by "transparency of reporting" or what the SPIRIT means by a "transparent record".

We would be better served if document producers deleted the word from their vocabularies and replaced it with words that have meaning.

The UGDP brouhaha was upsetting, but it did not make me feel like Jimmy Swaggart. That feeling is recent with the ever increasing demands for "transparency" without knowing how to achieve it.

The "transparentologist" have convinced me, like Jimmy Swaggart, that I have sinned. But at least Jimmy Swaggart knew what his sin was. I am not certain of mine, but I am certain that as a trialist I have failed to be "fully transparent".

Therefore I beg the Great Trialist in the Sky for forgiveness even if I do not know how I have failed.

Forgive me Great One for being opaque.

Please make me a transparent trialist.

I am grateful to Betty Collison, Gillian Gresham, and Jill Meinert for reference help.

[*] Jimmy Swaggart is a television evangelist with a career spanning six decades. He got defrocked by the elders of the Louisiana presbytery of the Assemblies of God when he was discovered to have been cavorting with a prostitute. After that event Swaggart continued his ministries as an independent non-denominational Pentecostal, based in the Family Worship Center in Baton Rouge, Louisiana, and broadcasting on the Sonlife Broadcasting Network (SBN).