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The Everson trial protocol is only available if you sign a confidentiality agreement. This is unacceptable.

Posted on March 29, 2016

Ben Goldacre, Henry Drysdale

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Conflict of Interest: None Declared

We are writing to raise serious concerns about lack of transparency and rigour in Annals' processes to identify outcome switching in clinical trials, and Annals' apparent complicity in avoidable secrecy around trial documents. We have provided extensive documentation of outcome switching in Annals [1]. Disappointingly, Annals' editors have avoided open discussion [2]. They have also explained that Annals checks protocols itself in secret, undermining decades of progress towards better standards in trial reporting and transparency through registers [3].

When we initially assessed the Everson trial, we used the pre-specified outcomes posted by the trialists to the trial registry, the only publicly accessible date-stamped source for this information. Annals' editors have attempted to argue [4] that protocols are a better source of information, despite registries being specifically set up as a publicly accessible source of prespecified outcomes, with extensive endorsement from ICMJE and journals.

The protocol for the above trial is not publicly posted. The trial report in Annals states: "Reproducible Research Statement: Study protocol: Available from Dr. Everson (e-mail, greg.everson@ucdenver.edu).\" We therefore emailed Dr Everson to request the protocol. Our request was forwarded to a representative from Gilead Sciences, the trial's commercial sponsor, who replied: \"I regret to say that these protocols are confidential documents, but we would be happy to send you the original and both amendments if you sign a confidentiality agreement.\"

If we signed this document, and found discrepancies or problems in the protocol, we would not be allowed to share this information with the doctors or patients it affects. This is plainly unacceptable. Protocols are routinely published, and should be, especially when Annals' editors are now arguing that they regard protocols as a better source of information than the trial registers explicitly set up as publicly accessible sources of the same information.

Correction

Posted on April 12, 2016

Christine Laine, MD, MPH

Annals of Internal Medicine

Conflict of Interest: None Declared

Annals require authors of original research articles to include a "Reproducible Research" statement with the article that indicates whether the authors will share the protocol, statistical code, and data with interested readers (1). At the time of publication, this policy did not mandate sharing, but did mandate inclusion of a statement about willingness to share and conditions of sharing. The "Reproducible Research" statement accompanying the article was incomplete. It indicated that the protocol was available by contacting the authors but should also have stated that signature of a confidentiality agreement was necessary to obtain the protocol. The corrected statement is "Reproducible Research Statement: Study protocol: Available from Dr. Everson (e-mail, greg.everson@ucdenver.edu) after signature of confidentiality agreement. Statistical code and data set: Not available."

1. Laine C, Goodman SN, Griswold ME, Sox HC. Reproducible Research: Moving toward Research the Public Can Really Trust. *Ann Intern Med*. 2007;146:450-453. doi:10.7326/0003-4819-146-6-200703200-00154

Correction on the research reproducibility statement

Posted on April 19, 2016

Ben Goldacre and Henry Drysdale

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Conflict of Interest: None Declared

We are grateful to Dr Christine Laine, Editor in Chief, for issuing a correction on the misleading reproducibility statement accompanying this trial. Unfortunately this correction has not been made. The text in the PDF as at 19th April 2016, one week after Dr Laine's comment above, still reads exactly as before. There is no correction on the full text or abbreviated page for the paper. We hope this important correction will be made appropriately and clearly flagged to readers of the paper.

Ben Goldacre and Henry Drysdale, on behalf of the COMPare trials team.

Correction Issued

Posted on April 21, 2016

Christine Laine, MD, MPH

American College of Physicians

Conflict of Interest: None Declared

The corrected article is now published. The publication of corrected article requires interaction with external vendors, and this necessary interaction and review of the corrected material accounts for the time difference between posting of the correction in the comments and the publication of the corrected article.

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