
Originating Department: A&S Political Science Research (4013104)  Submitting To: Morningside
Title: Does Registration Reduce Publication Bias? Evidence from Medical Sciences.
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Study Description

1. Study Purpose and Rationale

There is broad recognition that reporting and publication biases operate at scale in academic scholarship. For example, published results in our field, political science, are much more likely to report p-values just below the 0.05 critical value than just above it. This could be due to publication practices or to researcher degrees of freedom that allow them to select models that produce significant results. There are discussions inside the discipline, and more broadly in social sciences, about whether the introduction of a registration system like that prevailing in medicine would mitigate these effects. In 2005, the International Committee of Medical Journal Editors (ICMJE) started requiring that all clinical trials be registered in order for results to be considered for publication. Researchers would be obliged to register their trials and publicly catalogue information related to the design, treatment, and empirical strategy of a given project. After two years, the ICMJE conducted a review of registration and noted that while registration “precipitated much angst” in the field, it had ultimately been quickly and widely adopted.

Though the arguments are strong for registration, there is surprisingly little evidence that it makes any difference. Do registration requirements really change reporting norms and statistical practice? To contribute evidence to the debate, we seek to assess levels of bias before and after critical registration dates for journals that required and did not require registration. Conscious of the difficulty of establishing a causal effect of registration we nevertheless seek at least to assess whether things have improved following the adoption of registration norms in those journals that adopted those norms.

2. Study Design and Statistical Procedures

We employ two strategies in this study: 1) a strategy used to assess critical threshold bias on publicly available data, and 2) a survey of medical experts on their beliefs about registration.

For the first strategy, we assess critical value bias, we build on the “caliper test” employed by Gerber and Malhotra (2006). We implement this statistical test on publicly available data from Jager and Leek (2014) which records the p-values for medical journals published between 2000 and 2010.

For the second strategy, we invite members of the editorial board of 10 medical journals that initially adopted registration requirements to complete an online survey in which they estimate the impact that registration had on publication bias.
3. Study Procedures

Two types of data are used: 1) data on p-values reported in medical publishing and 2) data from an expert survey. The first data is not human subjects data and is publicly available for analysis from the published record. To collect the second type of data, we will field an online survey with the editorial boards of 10 medical journals. The survey includes a consent script and provides the contact information of the PIs. Respondents are invited to but are not required to leave their names and contact information.

4. Study Drugs or Devices

Not applicable.

5. Study Instruments (e.g., Questionnaires, Interview Outlines, Focus Group Guides)

One study instrument has been uploaded for review (“20141220 – Survey”). The survey instrument only includes questions on the estimated impact of registration on publication bias and 3 short questions about the individuals (occupation, whether they read medical journals, and how they heard about the survey).

6. Study Subjects

Subjects can self-select to take part in the survey (which is set up as a holiday quiz). In addition we will encourage members of the current editorial board of the 10 journals that initially adopted registration requirements in the medical sciences to take part.


7. Recruitment

Recruitment will be conducted online via e-mail and blog postings. The e-mail addresses of the encouraged participants editorial boards will be taken from publicly available online information and e-mails with a link to the online survey will be sent to the subject pool.

8. Informed Consent Process

Informed consent will be obtained from all subjects prior to the interview and administered online. Subjects will be able to stop the survey at any time without any repercussion. The script for the consent process is attached as “20141220 – Consent Text”.

9. Confidentiality of Study Data

We anonymize all data from responses to this survey publicly available. There are no risks or individual benefits (beyond the prize) and no deception is used. Respondents also have the choice to report their name or not. Data will be maintained on password protected computers that only PIs have may access.

10. Privacy Protections
Privacy will be maintained at all stages of the research and respondents have the choice to report their name or not. All interviews will be conducted online at the respondent’s choice of time and place.

11. Potential Risks

There are no risks or individual benefits (beyond winning the prize) and no deception is used.

12. Data and Safety Monitoring

All surveys will be conducted online and data will be anonymized and saved on a password-protected computer that only the PIs can access. Contact information for the Co-PIs will be provided to all respondents to report any issues.

13. Potential Benefits

The only individual benefit is the chance to win a 200 USD prize for the closest guess to the true estimate. Prizes will be distributed once the final analysis is conducted.

14. Alternatives

The alternative to participation in this study is non-participation.

15. Research at External Sites

This study will be conducted online.

16. Columbia as Lead Institution

This is not a multicenter study.