Registered reports: prospective peer review emphasizes science over spin

Scientific studies are typically considered for publication after they are completed and the results are available. Consequently, the decision to publish is based not only on the importance of the research question and the quality of the methods used, but also on the novelty and statistical significance of the authors’ findings. This in turn creates perverse incentives for researchers to seek surprising, positive results, and to prioritize creative interpretation of data over accurate discovery.

It is now known that the scope for creativity in the collection and analysis of research data is considerable if the methods are not precisely defined in advance (1). It is also recognized that this flexibility makes it easy to arrive at statistically significant results (typically, those with a P value less than .05) that are false positives. This phenomenon has been dubbed ‘P-hacking’ (1). In the presence of P-hacking, P values obtained from statistical tests of hypotheses do not have their conventional meaning, and it is unclear whether they have any intelligible interpretation at all. These problems are compounded by the fact that many studies are unlikely to detect genuine effects using statistical significance as a criterion due to weak study design. For example, a recent review of randomized controlled trials in fertility has shown that research in this field lacks power to detect anything other than unrealistically large effects (2). Under these circumstances, many published statistically significant results are expected to be false.

The routine practice of publishing results of P-hacked analyses would not be problematic if they were clearly presented as being exploratory or hypothesis-generating in nature. Exploratory research is important to science, but results obtained in this manner should generally be viewed as tentative pending confirmation in an independent experiment with a prespecified hypothesis. What typically happens is that results of exploratory analyses are described as though they had been predicted based on some theory, giving the false impression of being confirmatory in nature (called ‘HARKing,’ or hypothesizing after results are known). This is possible because there is typically no expectation that researchers publish their predictions before conducting the study. But it is now clear that results obtained from post-hoc analyses are fragile. For example, after being tested in recent large-scale replication studies, many influential findings in the field of psychology now appear to have been illusory (3).

An additional consequence of the traditional publishing model is that studies with negative results are less likely to be published at all. Typically, this is because researchers, peer reviewers, or journal editors do not consider negative studies to be important or interesting. Thus, negative studies are more likely to be omitted from systematic reviews and meta-analyses. This leads to publication bias, where interventions appear to be more effective than they are. It is clearly problematic if fertility treatments are bought and sold based on a flattering evidence base.

Because these problems stem from the link between statistical significance and the likelihood of being published, one solution would be to sever that link. This is precisely the motivation for a new type of journal article, the registered report, which is offered by 165 peer-reviewed journals at the time of writing (4). Registered reports upend the traditional sequence of conducting a study, writing up the results, and then submitting the resulting article for peer review. Instead, registered reports are submitted before a study has been initiated. They articulate, in detail, the importance of the study question and the methods and analyses that will be employed to answer it (5). If the research question is of sufficient interest to the journal editors, the registered reports can be sent for peer review. At this stage, the study is assessed based on its design and analysis plan, and peer reviewers and editors can suggest amendments to the study protocol. In their response, the authors may choose to accommodate these suggestions, or to offer arguments against them (on the grounds of necessity or feasibility, for example). The journal will then decide whether to offer in principle acceptance (IPA) of the study. This means that, if the authors of the registered reports conduct the study per the approved protocol, the journal guarantees publication of the finished article. The need to obtain statistically significant results to be published is therefore removed. Instead, researchers are incentivized to execute a high-quality realization of the registered reports, knowing that the reward will be a publication. Following completion of the study, the authors can then submit a manuscript describing the results of their prespecified analyses, as well as any additional, exploratory analyses, which are clearly labelled as such. This manuscript will undergo a second round of peer review. Ideally, this is undertaken by the same reviewers who critiqued the pre-study proposal, with an emphasis on evaluating whether the protocol was followed.

The advantages of registered reports for the scientific literature are clear, since results obtained from preregistered analyses cannot be easily gamed. However, there are also benefits for other stakeholders. Researchers can feel more confident in the validity of their results, and are less likely to be fooled into performing fruitless follow-on studies based on artefactual effects. Prospective peer review also means that their work will be judged based on their ability to identify and answer an important research question, rather than on whatever that answer turns out to be. Moreover, peer review of a detailed protocol may result in improvements to the study, where these are practicable within the bounds set out by the ethical approval. Benefits to journals include the fact that published results are far less likely to be exposed as artefacts. Both journals and peer-reviewers are given the opportunity to suggest alterations to the design of the study, and in this way, might forestall missed opportunities. Ultimately, patients are likely to benefit from more rigorous evaluations of reproductive medical interventions than are currently performed (2).

Considering these advantages, Fertility & Sterility is introducing the registered reports format for randomized controlled trials. Studies will be evaluated on their aims and methods. It will be a requirement that studies have high power (typically, 90% or greater) to detect realistic, meaningful effects. The
submission process will require investigators to declare that the research could begin immediately following IPA (meaning that funding and ethics approvals are in place). A condition of IPA will be that the research is prospectively registered in a trial registry prior to commencement and institutional review board approval has been obtained. All trials must be reported per the Consolidated Standards of Reporting Trials including, for sub-fertility trials, the Improving the Reporting of Infertility Trials extension. We believe that this format, by emphasizing rigorous methodology over surprise and spin, will produce high quality research that will stand the test of time.

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