

## Editorial policies aimed at improving the transparency and validity of published research

T. S. Sathyanarayana Rao, Prathap Tharyan<sup>1</sup>

Department of Psychiatry, JSS University, JSS Medical College Hospital, M. G. Road, Mysore, Karnataka, <sup>1</sup>South Asian Cochrane Centre, Prof. BV Moses & ICMR Centre for Advanced Research and Training in Evidence-Informed Healthcare, Christian Medical College, Vellore, Tamil Nadu, India

Research published in local and national journals, such as the *Indian Journal of Psychiatry*, is as important as research published in international journals, in order to contextualize the evidence on which healthcare and health policy needs are to be based.<sup>[1]</sup> However, the quality of research published in local and national journals, particularly those from low and middle-income countries, is often considered inferior to that of research articles published in international journals.<sup>[2]</sup> If these research findings are used to guide clinical practice, health outcomes may be adversely affected. Editorial policies, and adherence to these policies, determine to a large extent the quality of reporting of research published in journals.<sup>[3]</sup>

The duties of medical journal editors include, among others, safeguarding the rights of the study participants; establishing policies of submission, review and acceptance of manuscripts; and working towards improving the quality of the conduct and publication of research.<sup>[4]</sup> These can be aided by the unambiguous endorsement of standards that improve transparency in reporting research and by the provision of clear instructions to authors about what is expected of them. The instructions to authors in the *Indian Journal of Psychiatry* have therefore been amended to endorse internationally accepted reporting standards that are appropriate for the research design used. Authors of manuscripts are expected to adhere to these instructions when preparing manuscripts for submission in order to increase the chances that their manuscripts will be accepted. These amendments will also aid peer reviewers to readily identify whether the submitted manuscript meets the criteria for transparency in research reporting.

**Address for correspondence:** Dr. T. S. Sathyanarayana Rao, Department of Psychiatry, JSS University, JSS Medical College Hospital, M. G. Road, Mysore - 570 004, Karnataka, India.  
E-mail: [tssrao19@yahoo.com](mailto:tssrao19@yahoo.com)

How to cite this article: Sathyanarayana Rao TS, Tharyan P. Editorial policies aimed at improving the transparency and validity of published research. *Indian J Psychiatry* 2011;53:183-6.

### ENDORISING THE ICMJE UNIFORM REQUIREMENTS AND USE OF DESIGN-SPECIFIC REPORTING STANDARDS

The *Indian Journal of Psychiatry* continues to endorse the submission of manuscripts in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors (ICMJE);<sup>[5]</sup> the web-link to the ICMJE requirements has now been provided to enable authors to access the requirements in their entirety. The Uniform Requirements endorse design-specific reporting standards, and the revised instructions to authors now provide links to the appropriate guidance for interventional observational studies, and qualitative research, and for reports comparing the accuracy of diagnostic tests.

### CONSORT 2010

Authors of randomized clinical trials are now required not only to prepare and submit their manuscripts in accordance with the CONSORT 2010 statement,<sup>[6,7]</sup> but also to use the appropriate extensions of the CONSORT statement for trial designs that differ from the standard parallel-group trial or that use herbal interventions, and on reporting harms.<sup>[8-13]</sup> Authors are also expected to submit, along with the manuscript, the CONSORT checklist and participant flow diagram. The web-links to templates for both that can be downloaded and appropriately modified have also been provided. The former will not be published with the trial report but will aid effective peer review by stating exactly where in the manuscript the required CONSORT element can be found. The latter will be published and will provide information that will aid interpretation of the

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<b>Website:</b> <a href="http://www.indianjpsychiatry.org">www.indianjpsychiatry.org</a>	<b>Quick Response Code</b> 
<b>DOI:</b> 10.4103/0019-5545.86793	

generalizability of the results by disclosing details of those excluded from the trial so that the reader can evaluate the proportions excluded, particularly for not fulfilling inclusion criteria. It will also disclose the proportions in each trial arm that completed the various stages of the trial, thus making it possible to evaluate if the analysis of the results was complete.

### **STROBE**

Most research published in this journal are observational in nature and authors are required to follow the guidance provided in the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for reporting observational studies, typically cross-sectional studies, case-control studies and cohort studies.<sup>[14,15]</sup> Authors of these manuscripts should also include in their submission the STROBE checklists, for which a link has been provided, to aid the peer-review process.

### **STARD**

Studies that evaluate the sensitivity, specificity, and other characteristics of a diagnostic test (including clinical criteria or a diagnostic scale) against a reference standard should follow the guidance provided in the STARD statement that aims to improve the accuracy and completeness of reporting of studies of diagnostic accuracy, in order to assess the potential for bias in the study (internal validity) and to evaluate its generalizability (external validity).<sup>[16]</sup> Manuscripts of diagnostic accuracy studies should also include the STARD checklist and a flow diagram for which a web-link has been provided. The flow diagram will be published with the report.

### **COREQ**

Qualitative research in psychiatry is common, but the quality of reporting of the results of surveys and focus group discussions is seldom uniform. The *Journal* now expects authors of manuscripts that describe qualitative research obtained from in-depth interviews and focus group discussions to follow the guidance found in the consolidated criteria for reporting qualitative research (COREQ criteria), and to submit the COREQ checklist with their submissions.<sup>[17]</sup>

### **PRISMA AND MOOSE**

Systematic reviews are reviews with clearly formulated questions and that use systematic and explicit methods to identify, select, and critically appraise relevant research and to extract and analyze data from the studies that are included in the review. Meta-analysis refers to the use of statistical techniques that may (or may not) be used in a systematic review to integrate the results of included

studies. Manuscripts of systematic reviews of interventional studies should follow the guidance provided in the PRISMA statement.<sup>[18]</sup> Authors of manuscripts should include in their submission, the PRISMA checklist and flow diagram that can be downloaded from the web-link provided and that should be used in conjunction with the PRISMA explanation and elaboration document. If the systematic review and meta-analysis primarily includes observational studies, then the manuscript should be prepared in accordance with the MOOSE guidelines.<sup>[19]</sup>

### **ENHANCING THE QUALITY AND TRANSPARENCY OF HEALTH RESEARCH: THE EQUATOR NETWORK**

The Equator Network is an international initiative that aims to improve the reporting of health research, and their website (<http://www.equator-network.org/>) provides up-to-date resources aimed at empowering authors, editors, peer reviewers and developers of guidelines to improve the value and reliability of their research by improving transparent and accurate reporting. All the reporting standards endorsed herein, as well as many more resources aimed at improving the quality of research, can be accessed from the site. Research funders, research ethics committee members, individuals and organizations involved in research education will also find the resources collated in this site educative and informative.

### **USING REPORTING GUIDELINES TO IMPROVE THE QUALITY OF PUBLISHED RESEARCH**

Systematic surveys have demonstrated that the adoption and implementation of the CONSORT statement and checklist by international journals had improved the quality of reporting of randomized controlled trials over time, compared with journals that did not do so.<sup>[20-22]</sup> However, an analysis of the instructions to authors and of randomized controlled trials published in 65 Indian medical journals in 2004–2005 revealed that only a third of the journals endorsed the CONSORT statement and the quality of reporting of key CONSORT items, particularly those aimed at reducing the risk of bias in these trials, was sub-optimal. Adequacy of reporting was not related to whether the journal endorsed either the CONSORT statement or the ICMJE requirements.<sup>[23]</sup> It is hoped that adherence to the CONSORT requirements would improve if the CONSORT checklist is made essential for authors to submit, and for peer-reviewers and editors to use while evaluating the manuscripts.

### **SCIENCE AND ETHICS IN RESEARCH**

Research that is not free from bias and confounding is likely to lead to erroneous results; such research is unethical as it betrays the trust of participants and those using the results of research to guide policy and practice. Similarly,

research involving humans that do not adhere to ethical principles is inexcusable. In accordance with the ICMJE Uniform Requirements, the *Indian Journal of Psychiatry*, in its expanded section on ethical issues in the instructions to authors, now provides web-links to the 2008 revision of the Declaration of Helsinki<sup>[24]</sup> and to the ethical guidelines of the Indian Council of Medical Research.<sup>[25]</sup> Authors are expected to have obtained ethical clearance from an authorized committee that has evaluated the scientific and ethical aspects of the proposed research, and that may be contacted directly, if thought necessary, for further clarifications. In adopting the ICMJE requirements, the *Journal* also endorses internationally approved policies on plagiarism, duplicate publications and research misconduct; declaring competing interests and funding sources; and on claiming authorship, that authors of manuscripts need to be cognizant of.<sup>[5]</sup>

### **FACILITATING IMPROVEMENTS IN THE DESIGN OF RESEARCH PROTOCOLS**

Deficiencies in the quality of published research reports may reflect a poor understanding of research design; the reporting standards endorsed herein provide guidance on the elements considered essential to improve the internal and external validity of the study that will differ according to the research question and the study design adopted, apart from improving the transparency of the published report. As part of its editorial mandate to facilitate improvements in the quality of published research, the *Journal* advises authors to refer to the reporting guidelines specific to the design of the proposed study, particularly their elaboration and explanation documents, at the time the study is being designed. This will ensure that these elements were prospectively ascertained and hopefully would lead to better conduct, and better quality of reporting of the methods and the results of research.

### **PROSPECTIVE REGISTRATION OF CLINICAL TRIALS**

Apart from biases that arise due to flaws in the design and execution of research, reporting biases (wherein what is reported and how they are reported are determined by the study results, and what authors wish to conceal, reveal, misdirect, or highlight) also contribute to the erroneous interpretation of research results.<sup>[26]</sup> In February 2008, the editors of 11 Indian medical journals published a statement<sup>[27]</sup> endorsing the ICMJE and WHO position on expecting that all clinical trials assigning participants to one or more pharmacological or non-pharmacological interventions in order to improve health outcomes be prospectively registered before recruiting any participant, and essential details of the protocol be disclosed in a trials registry approved by the WHO. This statement set a deadline for January 2010 after which these journals intended to refuse

manuscripts of interventional studies that had not been prospectively registered. The CONSORT 2010 checklist also requires prospective trials registration as a pre-requisite.<sup>[6,7]</sup> The 2008 revision of the Declaration of Helsinki also requires, in clause 19, the prospective registration of clinical trials.<sup>[24]</sup> The Clinical Trials Registry – India (CTRI; [www.ctri.nic.in](http://www.ctri.nic.in)) is a primary register of the WHO International Clinical Trials Registry Platform and all trials prospectively registered in the CTRI will be accepted as fulfilling the ICMJE requirements.<sup>[28,29]</sup> The Drug Controller General of India has made prospective registration of clinical trials in the CTRI as a regulatory requirement from July 2009, and this has led to an increase in the prospective registration of industry-sponsored trials.<sup>[30]</sup> The Clinical Practice Guidelines of the Indian Psychiatric Society on ethical issues in research recommended the prospective registration of clinical trials in India.<sup>[31]</sup> An analysis of trials registered in the CTRI indicated that the quality of reporting of items affecting internal validity was significantly better than that in reports published in Indian medical journals, suggesting that prospective trials' registration has the potential to not only detect reporting biases, but also improve the design of clinical trials by providing a template that researchers can use to improve trial protocols.<sup>[32]</sup>

In keeping with these international and national requirements, the *Indian Journal of Psychiatry* joins the fraternity of international and Indian journals that require authors to prospectively register clinical trials and to submit the registry identification details along with the manuscript. If the trial has recruited participants from sites in India, the *Journal* expects that the trial would have been prospectively registered in the CTRI. This requirement would become mandatory for all fresh submissions from January 1, 2013.

This slew of initiatives will help ensure that the standard of research published in the *Indian Journal of Psychiatry*, in its current avatar, reflects the aspirations and intentions of the editorial board of the *Journal* and the members of the Indian Psychiatric Society and serves as a vehicle for the publication of research on all aspects of mental health from India and around the World that is valid, transparent and relevant. This can be reliably used to improve clinical care, formulate clinical practice guidelines and health policies and improve the health outcomes of our patients.

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Source of Support: Nil, Conflict of Interest: None declared