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COMMENTARY

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Better reporting quality for improved pediatric investigation: Application of health research reporting guidelines

Xiaoxia Peng[1] | Xiaolu Nie[1] | Xin Ni[2]

[1]Center for Clinical Epidemiology and Evidence-Based Medicine, Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, Beijing, China
[2]Beijing Key Laboratory for Pediatric Diseases of Otorhinolaryngology, Head and Neck Surgery, Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, Beijing, China

Correspondence
Xin Ni, Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, Beijing, China.
Email: nixin@bch.com.cn

Clinical research on the accuracy of diagnostic tests, the power of prognostic markers, and the efficacy and safety of interventions are the cornerstone of evidence-based health care.[1] Transparency and sufficient reporting are important for conveying research findings to the public, practitioners, and students in medicine because insufficient reporting of results would hinder assessment for a study's strengths and weaknesses and thus hamper integration of evidence, even from well-conducted research.[2] However, the reporting quality of articles in most healthcare journals remains inadequate.[3-6] Many publications lack clarity, transparency, and completeness on how the authors actually carry out their research. Therefore, the validity of research cannot be accurately evaluated. An example of such situation is that determining whether randomization is sufficient is difficult if authors do not report important information (eg, generation of random sequences and the method of random concealment in therapeutic assessment studies).[7] Reviewers and readers will not make an information-based assessment on research quality and the risk of bias if the reporting quality is insufficient as well as reviewers and readers could not get linkage to a research protocol.

EVOLUTION OF THE INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS TO REPORTING GUIDELINES

The International Committee of Medical Journal Editors (ICMJE) published a set of recommendations for conducting, reporting, editing, and publication of scholarly work as early as in 1979. This committee required that manuscripts should be prepared according to the basic reporting standards.[8] However, the requirements issued by the ICMJE are universal and applicable to all medical studies. The guideline of the ICMJE for authors does not take all the details of various research designs and research fields into account, although different research designs in different fields have their specific characteristics. Examples of this situation are randomization in randomized, controlled trials (RCTs), confounding factors of analytical research, linkage of databases in observational studies using routinely collected data, and genetic polymorphism in genetic association studies.

With the development of evidence-based medicine, critical appraise as a basic concept of selecting and synthesizing evidence was also improved, and it depends on adequate reporting of research. Therefore, refining the ICMJE guideline and developing reporting guidelines according to different major points for research designs in different study fields are urgent and necessary. Since 1996, reporting guidelines for various types of research have been developed in succession. These guidelines are in the form of a checklist and include a flow diagram or explicit text. In fact, reporting guidelines provide advice on how to sufficiently report the research, especially on methods and results by specifying a minimum set of items. Reporting guidelines can remind researchers to report what was performed and what was found in the research in a clear and transparent manner. In particular, these guidelines can emphasize the issues that might introduce bias to the research. Work groups that developed types of reporting guidelines have declared that reporting guidelines are recommended for researchers, but not to be demanded. However, researchers can improve the research design by referring to the checklists of a reporting guideline. Moreover, we must be aware that reporting guidelines do not recommend how specific studies should be designed,

conducted, and analyzed. Therefore, the guidelines should not be regarded as standards of research design, as well as tools to assess study quality, although the checklists of reporting guidelines often provide a basis to assess the risk of bias.

The first reporting guideline was the Consolidated Standards of Reporting Trials (CONSORT), which was developed by the ICMJE in 1996, and aimed to strengthen the reporting quality of RCTs.[9] Subsequently, on the basis of development of CONSORT, a variety of extended versions of CONSORT reporting guidelines were developed and published. With increasing expansion of types of study designs and research fields, corresponding reporting guidelines have also been created.

The well-known Enhancing the Quality and Transparency of Health Research (EQUATOR) is an academic organization that was developed from CONSORT and other workgroups of reporting guidelines. EQUATOR is dedicated to research, and for developing, collating, and promoting reporting guidelines for medical research. At present, more than 300 reporting guidelines have been collated and included in the EQUATOR collaboration network (http://www.equator-network.org/reporting-guidelines/). These reporting guidelines have the following characteristics. First, these guidelines cover a wide range of research, including original research, secondary research, and transformation studies, involving basic research, animal research, clinical research, and epidemiological research. Second, the content of these guidelines is comprehensive, including the reporting of study protocols, abstracts, search strategy, statistical analysis methods, and full text. Third, the fields of these guidelines are varied, covering internal medicine, surgery, obstetrics and gynecology, imaging, and other specific clinical fields. The development and application of reporting guidelines have become one of the important achievements of evidence-based medicine globally.

COMMONLY USED REPORTING GUIDELINES FOR CLINICAL RESEARCH

Most of the existing reporting guidelines of medical research are classified according to the study design. CONSORT and its extended version are used only for RCTs. However, considering special research fields or design, special CONSORT extended versions for RCTs are recommended for nonpharmacological interventions and herbal medicine interventions. Because the research designs of cluster RCTs and noninferior RCTs are not the same as traditional RCTs, specific CONSORT extended versions were developed for them. Considering that data sources and methods of individual participant data (IPD) meta-analyses are different from traditional meta-analyses, there is also a special Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) extended version. The extended versions retain most of the items in the original version to reflect the common methodological characteristics of RCTs, observational studies, and systematic reviews and meta-analyses. The extended version of

TABLE 1 Commonly used reporting guidelines for clinical research available from EQUATOR

Reporting guidelines	Study design
CONSORT[11]	Randomized controlled trials
CONSORT extension to cluster randomized trials[12]	Cluster randomized trials
CONSORT extension to noninferiority/equivalence trials[13]	Noninferiority/equivalence trials
CONSORT for TCM[14]	Trials of traditional Chinese medicine
CONSORT extension to nonpharmacological treatment[15]	Trials of nonpharmacological treatment
STROBE[16]	Observational studies
STROBE-ME[17]	Molecular epidemiology studies
STREGA[18]	Genetic association studies
RECORD[19]	Observational studies conducted using routinely collected health data
REMARK[20]	Tumor marker prognostic studies
STARD[21]	Diagnostic test accuracy
GRIPS[22]	Genetic risk prediction studies
CARE[23]	Case reports
PRISMA[24]	Systematic reviews and meta-analyses
PRISMA-P[25]	Protocols of systematic reviews and meta-analyses
PRISMA-IPD[26]	Systematic reviews and meta-analyses of IPD
SAMPL[27]	Statistical analyses and methods in all research

CONSORT denotes Consolidated Standards of Reporting Trials; CONSORT for TCM, Consolidated Standards of Reporting Trials for traditional Chinese medicine; STROBE, STrengthening the Reporting of Observational Studies in Epidemiology; STROBE-ME, STrengthening the Reporting of OBservational Studies in Epidemiology-Molecular Epidemiology; STREGA, STrengthening the REporting of Genetic Association studies; RECORD, REporting of studies Conducted using Observational Routinely-collected health Data; REMARK, Reporting Recommendations for Tumor Marker Prognostic Studies; STARD, Standards for Reporting of Diagnostic Accuracy; GRIPS: Genetic Risk Prediction Studies; CARE, CAse REport; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses; PRISMA-P, Preferred Reporting Items for Systematic Reviews and Meta-analysis protocols; PRISMA-IPD, Preferred Reporting Items for Systematic Reviews and Meta-analyses of individual participant data; SAMPL, Statistical Analyses and Methods in the Published Literature.

reporting guidelines also reflects the addition or modification of specific items to show the personality traits of particular research types. To date, reporting guidelines have been adopted by an increasing number of international medical journals, including The New England Journal of Medicine, The Lancet, British Medical Journal, Journal of the American Medical Association, and Annals of Internal Medicine.[10] The commonly used reporting guidelines for clinical research are shown in Table 1.

BETTER REPORTING QUALITY FOR IMPROVED PEDIATRIC INVESTIGATION

The problems of reporting can be subdivided into the following: missing or incomplete information (eg, missing details of intervention or exposure, or selective reporting of results); incorrect or misleading information (eg, misleading figures, incorrect statistical analysis, a change in primary outcome, or extended conclusion); inconsistent information (eg, differences between protocols and results reported in articles); poorly written text and poor use of figures and tables; and information presented in an obscure or less than optimum format.[10] A large systematic review that was updated in 2012 assessed the effect of journal endorsement of the CONSORT checklist.[28] This study critically reviewed 50 studies, including more than 16 000 RCTs and showed that despite improvements in the completeness of reporting (22 of 25 checklist items), there were still major reporting deficiencies in journal publications. Although adoption of reporting guidelines, such as CONSORT, STARD, and PRISMA, has helped to improve the quality of research reports, all guidelines remain much less adhered to than they should be. Reporting guidelines have been widely disseminated through publications in journals with a high impact factor and endorsements by several editors. Nevertheless, adherence of authors to these reporting guidelines remains low.[28,29]

Pediatric Investigation is a newly issued international journal that aims to improve the quality of pediatric research and to promote evidence-based practice. Therefore, requirements for authors publishing articles in *Pediatric Investigation* should keep consistent with those for authors publishing articles in international journals. Authors are recommended to provide a checklist according to a specific reporting guideline, which will be beneficial for editors and peer reviewers to rapidly review missing items recommended by reporting guidelines and to improve the quality of reporting. Therefore, authors will hopefully adhere to reporting guidelines when preparing and submitting their manuscript. Moreover, *Pediatric Investigation* will provide adequate training for authors, editors, and peer reviewers to understand and ensure that they adhere to reporting guidelines.

CONFLICT OF INTEREST

All authors declare that they have no competing interests.

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