EDITORIAL

Need for Uniform Guidelines for Submitting Adverse Event Reports for Publication in Biomedical Journals

Vishal R. Tandon

Published Adverse Drug Reaction (ADR) related case reports are important resource of early drug safety signal for pharmacovigilance program of India (PvPI). Poor quality of case reports published in biomedical literature may fail significantly to serve their purpose. They may not prove to be use full to PvPI to identify signals early in comparison to conventional approach of spontaneous reporting system. Moreover creating database out of good quality published ADRs due to new drugs, medication error, drug interaction, rare, unusual, serious, severe or fatal reports can be very useful for drug regulatory authorities. They also are useful for educational purposes at individual levels to enhance drug safety in clinical practice.

However, In spite of availability of Joint Recommendations /Guidelines of the International Society of Epidemiology (*ISPE*) and the International Society of Pharmacovigilance (*ISoP*) as well as CARE guidelines for submitting adverse event reports for publication, they continue to get published in medical journals. (1, 2)

Often information on Naranjo, WHO/UMC scale, severity scale and preventability scale, temporal relationship, medical contents, dose response relationship, pictorial evidence, drug estimation, important relevant laboratory investigations and other offending drug or pathology which could have contributed to the ADE are lacking. The problem is expected to be more prevalent in non indexed, low impact factor and non peer reviewed, paid Journals.

CARE guidelines recommend to focuses the primary items like title, key words, abstract, introduction, patient information, clinical findings, timeline, diagnostic assessment, therapeutic interventions, follow-up and outcomes, discussion, patient perspective and informed consent. (1)

Whereas the Joint recommendations /Guidelines of the (ISPE) & (ISoP) beside asking to focus on detail medical contents of report also ask to provide enough details for either a differential diagnosis or provisional assessment of cause-effect association, or a reasonable pharmacological or biological explanation. (2)

Most biomedical journals from developing countries including India have no specific requirement for publishing ADR related case reports. It would be reasonable for the most of the editors of medical journals emerging from India to adopt any of these guidelines till a consensus is achieved by all medical journals and PvPI on this subject. Reviewers and authors are also required to be aware of these guidelines so that scientific quality of these valuable published ADR reports can be enhanced in the interest of drug safety.

References

1. Gagnier JJ1, Kienle G, Altman DG, Moher D, Sox H, Riley D; CARE Group. The CARE guidelines: consensus-based clinical case report guideline development. *J Clin Epidemiol* 2014 ;67(1):46-51.
2. Kelly WN1, Arellano FM, Barnes J, Bergman U, Edwards RI, Fernandez AM et al. Guidelines for submitting adverse event reports for publication. *Drug Saf* 2007;30(5): 367-73.

From the Department of Pharmacology, Govt. Medical College, Jammu J&K- India 1800001
Correspondence to : Dr Vishal R. Tandon, Editor In Chief, Department of Pharmacology, Govt. Medical College, Jammu (J&K) -India 180001