as per ICMR guidelines.

Postgraduate courses are now also conducted at hospitals/institutions other than those affiliated to medical colleges i.e., Diplomate of National Board (DNB), which often do not have a valid or set process for granting ethical clearance. Also, if a private practitioner contemplates research on an individual basis, what is the process or facility for obtaining ethical permissions?

THE WAY FORWARD

Editors of biomedical journals should ensure appropriate reporting of ethical processes prior to accepting articles for publishing. The policy of the journal on this aspect should be clearly spelt out and widely disseminated. Reviewer pro forma should have a specific column for commenting upon ethical processes; similarly, checklist for authors should be augmented by adding a checklist for this purpose. Reviewer comments should be made specific and widely disseminated. Reviewer comments should be made specific and widely disseminated. Reviewer comments should be made specific and widely disseminated. Editors of biomedical journals should ensure that ethical clearance and informed consent/assent.

Words/ Group of words/ Corrections that need to be checked/ verified have been highlighted or commented upon.

REFERENCE


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EDITORIAL POLICY STATEMENT

The registration of clinical trials will help improve reliability of data generated, help clinicians interpret research, minimize duplication of trials and prevent exposure of volunteers to potential risks.[1] The Clinical Trial Registry India (CTRI; www.ctri.in) hosted at the National Institute of Medical Statistics (NIMS), Indian Council of Medical Research (ICMR), New Delhi, was formally launched on July 20, 2007. This is a free online registry of clinical trials established with the aim to encourage all clinical trials conducted in India to be prospectively registered before the enrollment of the first participant and to disclose details of the 20 mandatory items of the WHO International Clinical Trials Registry Platform (ICTRP) dataset and a few additional items.[2] Thus, the CTRI becomes a WHO’s ICTRP and ICMJE compliant Primary Register for India. Clinical trial has been defined by the ICMJE.[3]

Within about 3 months of its launch, the response received has been overwhelming with over 90 clinical trials already registered. But registration of trials is just a beginning. Active steps are on to sensitize researchers who actually conduct trials, funding agencies, ethics committee members, pharmaceutical companies, health professionals and medical journal editors on the need to register all trials that need registration. The WHO’s ICTRP and ICMJE have drawn up clear guidelines on these issues.[4-6] However, only prospectively registered clinical trials will be considered for publication.

While participants of clinical trials volunteer with an altruistic motive, it is too obvious that all is not well in experiments involving human subjects.[7] There have been reports that trials have failed in their objective to carry out experiments fairly, report honestly and follow the ethical principles in India and abroad.[8] There have been several instances of selective reporting or not reporting at all, depending upon the outcome of the trial and when financial interests are at stake. Despite best efforts to ensure transparency and honesty, most initiatives to discourage the conduct of unethical trials have largely been unsuccessful.

Attempts to regulate clinical trials through system of record keeping at a public registry that would provide access to data on trials being carried out have not been very successful, as trial registration is voluntary and there is reluctance of pharmaceutical companies to disclose data. As a step to ensure complete awareness of trial details, the ICMJE proposed comprehensive registration for clinical trials submitted for publication for the 12 member journals [Annals of Internal Medicine, British Medical Journal, Canadian Medical Association Journal, Croatian Medical Journal, Journal of the American Medical Association, The Dutch Medical Journal (Nederlands Tijdschrift
With this background, the CTRI in association with the Indian Journal of Medical Research (IJMR) organized a meeting of editors of Indian biomedical journals to evolve a policy to be followed for publication of clinical trials in Indian biomedical journals. The meeting held at the ICMR headquarters on October 9, 2007, was attended by 12 editors of Indian biomedical journals. It was unanimously decided that the editors have the responsibility to promote the registration of all clinical trials being conducted in India and to urge researchers to register their trials within a stipulated time, to make the clinical trial data transparent and to enable results to be published in good journals.

On behalf of all biomedical journals published from India, we urge to all those who are either conducting and/or planning to conduct clinical trials involving human subjects, to register their trials in CTRI or in any primary clinical trials registry. The meeting at the ICMR headquarters on October 9, 2007, was attended by 12 editors of Indian biomedical journals. It was unanimously decided that the editors have the responsibility to promote the registration of all clinical trials being conducted in India and to urge researchers to register their trials within a stipulated time, to make the clinical trial data transparent and to enable results to be published in good journals.

The joint statement is being published simultaneously in the journals listed in the byline.

For more information, please visit: http://www.icmr.org/clin trial07.pdf.

REFERENCES


ORIGINAL ARTICLES

REPORTING ETHICAL PROCESSES IN TWO INDIAN JOURNALS

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ABSTRACT

BACKGROUND: In biomedical journals, authors are expected to report if the study was carried out in accordance with international and national ethical guidelines and inform readers if approval from ethics committee was obtained and if written informed consent was taken from the participant or legal guardian. AIM: To determine the proportion of research manuscripts in two pediatric journals published from India reporting on ethical clearance, obtaining of informed consent and/or assent. SETTING AND DESIGN: Retrospective study for analysis of research articles published. MATERIALS AND METHODS: Research articles published in the issues of Indian Pediatrics and Indian Journal of Pediatrics in 2006 were reviewed for reporting regarding ethical clearance, obtaining written informed consent from guardians or parents, and obtaining assent from research participants. STATISTICAL ANALYSIS USED: Descriptive statistics was used. The number of articles according to their types; the number of research designs employed according to their types; and the number of research studies mentioning ethical clearance, consent, and assent were expressed as percentages mentioning ethical clearance, consent and assent were expressed as percentages. RESULTS: Of the 132 manuscripts reporting biomedical research, 39 (29.53%) reported having obtained approval from the ethics committee. Forty-six of the 98 (46.94%) manuscripts reporting on prospective studies indicated that informed consent was obtained from parents or lawful guardians. Neither ethical approval nor informed consent was mentioned in 45 (34.10%) published articles reporting prospective studies. A total of 54/98 (55.1%) studies enrolled children aged 7 years or more and hence consent was obtained from parents or law guardian. Neither ethical approval nor informed consent was obtained in four (7.41%) manuscripts reporting prospective studies. A total of 54/98 (55.1%) studies enrolled children aged 7 years or more and hence consent was obtained from parents or lawful guardians. Neither ethical approval nor informed consent was obtained in 45 (34.10%) published articles reporting prospective studies. A total of 54/98 (55.1%) studies enrolled children aged 7 years or more and hence consent was obtained from parents or lawful guardians. Neither ethical approval nor informed consent was obtained in four (7.41%) manuscripts reporting prospective studies. A total of 54/98 (55.1%) studies enrolled children aged 7 years or more and hence consent was obtained from parents or lawful guardians. Neither ethical approval nor informed consent was obtained in four (7.41%) manuscripts reporting prospective studies.

CONCLUSIONS: A significant proportion of research articles published in the two pediatric journals did not provide information regarding ethical approval, written informed consent, and obtaining of consent.

Key words: Children, publication ethics, research, voluntariness

INTRODUCTION

India has become an important hub for clinical research. It is estimated that by 2010, India will be the destination for one-fifth of all the global clinical trials. Research should be conducted...