Editorial Policies of MEDLINE Indexed Indian Journals on Clinical Trial Registration

30 MEDLINE indexed Indian journals publishing clinical trials were identified and their editorial policies on trial registration were assessed. Trial registration number was required in 9 journals (30%).16 journals (53.33%) encouraged adherence to the CONSORT Statement, while 22 (73.33%) mentioned ICMJE Guidelines.

Key words: *Clinical trials, Editorial policy, Registration.*

With a myriad of clinical trials being performed, there is a growing demand [1-3] for prospective registration of clinical trials to reduce selective reporting and publication bias, and enhance transparency, validity, availability and public accessibility of trial results. The International Committee of Medical Journal Editors (ICMJE) has made registration of trials a prerequisite for consideration of publication in its member journals [4]. The updated Consolidated Standards of Reporting Trials (CONSORT) Statement [5] includes 'registration number and name of trial registry' in its checklist for reporting of randomized controlled trials. Prospective trial registration has been made mandatory by the Drugs Controller General, India in the Clinical Trials Registry-India [6].

The National Library of Medicine (NLM) Catalog was searched on July 16, 2012 using the search string "India [country of publication] AND currently indexed." A list of 48 journals was retrieved and each journal was manually reviewed. Eight journals published by India-based publisher(s) but not having editorial office in India were excluded. Nine more journals were excluded because they primarily do not publish clinical trials. One journal had to be excluded as neither its website nor the print version could be located. Thirty journals were included in the final analysis. The 'instructions for authors' were downloaded from the website/online issues of the journals and were reviewed independently by each author. In case of disagreement, final decision was reached by consensus.

Nine journals (30%) required clinical trial registration number (CTRN) compulsorily for submission. This includes two journals, which did not mention explicitly about CTRN, but required authors to complete the CONSORT checklist. Journals which required compliance to CONSORT Statement but did not require submission of CONSORT checklist were considered not compulsorily requiring CTRN submission. One journal which mandatorily required registration of trials but did not ask for submission of CTRN was also marked in negation. One journal stated that registration is 'desirable' but did not specifically require submission of CTRN. 7 (23.3%) journals mentioned the name of at least one eligible clinical trial registry.

16 (53.33%) journals (including two journals which required the submission of CONSORT checklist) encouraged authors to adhere to the CONSORT Statement. 7 (23.3%) journals encouraged adherence to the CONSORT statement but did not specifically require submission of CTRN or the CONSORT checklist. One journal which required compulsory trial registration did not mention CONSORT Statement. 22 (73.3%) journals mentioned ICMJE guidelines. Journals which encouraged CONSORT Statement adherence were more likely to require trial registration number for submission.

Out of the 11 signatories to the 'Statement on publishing clinical trials in Indian biomedical journals' [7], 9 journals were included in the present study (the other two were not currently indexed for MEDLINE). 4 journals (44.44%) required CTRN mandatorily for submission. One journal mentioned registration to be mandatory but did not mention about submission of CTRN. 6 journals (66.67%) encouraged adherence to the CONSORT Statement.

30% of the journals in our study mandatorily required CTRN. In a 2008 international survey [8], 37% of journals mentioned about clinical trial registration while 26.7% required registration as a prerequisite for submission. 53.3% of journals in the present study mentioned about the CONSORT statement compared to 38% in the 2008 study [8].

TABLE I ASSOCIATION OF ENCOURAGEMENT OF CONSORT ADHERENCE WITH CTRN REQUIREMENT

	CTRN required	*CTRN not required*
CONSORT adherence mentioned	9	7
CONSORT adherence not mentioned	0	14

CONSORT: Consolidated standards of reporting trials; CTRN; Clinical trial registration number.

The present study is limited by the fact that it includes only Indian journals which are currently indexed for MEDLINE. The present study highlights that a majority of the journals are yet to adapt their editorial policies with regard to the issue of clinical trial registration.

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Clinical Response to Antibiotics Among Children with Bloody Diarrhea

WHO recommends ciprofloxacin as the drug of choice for bloody diarrhea. We retrospectively analyzed antibiotic response in 100 children with bloody diarrhea admitted between 2006-2010. Cotrimoxazole (*n*=55) had higher chance of attaining improved appetite and normal activity in 48h, hospitalization of <3d, blood disappearance in ≤5d and not requiring a second antibiotic compared to others (*n*=45). Older antimicrobials should be tried in all possible situations.

Key words: *Antibiotic response, Bloody diarrhea, Children, Dysentry, India.*

WHO recommends ciprofloxacin as the drug of choice for treatment of bloody diarrhea [1]. In this context, we recorded clinical response to antibiotics in 127 children from case records, admitted with a clinical diagnosis of bloody diarrhea to Government Medical College, Thrissur between 2006-2010. Inclusion criteria were children 1 mo-12 y with visible red blood in loose stools at admission / during ward stay. Those with melena, blood streaks over formed stools, chronic hepatic / renal / bleeding disorders, surgical abdomen, those who left our hospital before satisfactory completion of treatment, and blood detected only on microscopy were excluded. We finally analyzed 100 patients. Data on demography, presentation, complications, risk factors, co-morbidities and antibiotics used were collected. Clinical response to therapy was based on 6 WHO parameters - disappearance of fever, fewer stools, less blood, less pain, improved appetite and attainment of normal activity [1]. Each parameter if achieved within 48 h was scored 1. Outcome measures were total score, duration of hospitalization, time taken for blood disappearance, and need for a second antibiotic from our ward.

89% had risk factors- infancy (20), non-breastfed (19), unconsciousness (6), hyperthermia (37) and malnutrition (48). 59% had complications- dehydration (43), metabolic derangement (11), seizures (19) and rectal prolapse (3). Presence of complications had 2.8 times higher chance of need for second antibiotic from our wards (P= 0.019, 95% CI=1.165- 6.730). 34% had co-morbidities. Two children who died had co-morbidities. Absence of co-morbidities had 3.5 times higher chance of attaining total scores 5 or 6