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ORIGINAL CONTRIBUTIONS

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. AIMS: 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. SETTINGS 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 quardians 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. Fortysix 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 were assessed for reporting of assent; eight (14.81%) reported that children's assent was obtained. Only four (7.41%) eligible studies reported ethics committee's approval, informed consent, as well as assent. 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 assent.

Key words: Children, publication ethics, research, voluntariness

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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.^[1] Research should be conducted

that addressed these ethical processes.

The study protocol was submitted to the

institutional ethics committee for clearance. The

committee opined that its permission was not

necessary as it did not constitute biomedical

research. Research articles published in the

issues of Indian Pediatrics (IP) and Indian

Journal of Pediatrics (IJP) during the calendar

year 2006 were reviewed. Research studies

(including original articles and brief articles)

were enrolled for analysis if they satisfied

the criteria for 'biomedical research.' Review

articles, case reports, medical audits, and

case series were excluded from the study. The

type of study design employed (prospective or

retrospective) was noted. The definitions used

References to ethical clearance (by institutional

or independent ethics committee or review

board) and to obtaining of consent from

guardians or parents and/or assent from

research participants made in the article were

recorded. Ethical review was considered

relevant for all clinical study designs (whether

prospective or retrospective), provided the study

constituted biomedical research. Obtaining

written informed consent was considered

relevant for studies that enrolled subjects and/

or controls in a prospective manner. Assent

was considered relevant for those prospective

for various terms are provided in Table 1.

MATERIALS AND METHODS

in a scientifically and ethically correct manner, and this is ensured by independent ethics committees and regulators. The World Medical Association (WMA), through its Declaration of Helsinki^[2] and subsequent amendments and updates,^[3] has identified two protection measures to be implemented during research involving human subjects: that all participants voluntarily enroll in the research study, by providing informed consent after having understood risks and benefits associated with the study; and that the study protocol be evaluated and sanctioned by a disinterested body termed as Institutional Ethics Committee or Review Board. The Declaration of Helsinki expects publishers not to publish reports of experimentation that do not follow the principles laid down in the declaration^[3] The journal editors can ensure this, at least to some extent, by requiring authors to report regarding ethical approval and written informed consent. In fact, the International Committee of Medical Journal Editors (ICMJE)^[4] expects the authors to indicate whether the procedures followed were in accordance with the ethical standards laid out by the responsible committee on human experimentation (institutional or national) and with the Declaration of Helsinki. Although these aspects have been studied the world over,[5-12] there is hardly any data emerging from India, especially concerning studies carried out in children. Hence a study was carried out to determine the proportion of research studies published in the two Indian pediatric journals

Table 1: Definition of terms used

 Prospective study Retrospective study Institutional or independent ethics committee/ Institutional Review Board Approval (ECA) A study in which th A study that looks to The study/study pro- committee or Institutional 	e subjects are identified and then followed forward in time
 Retrospective study Institutional or independent ethics committee/ The study/study procommittee or Institutional Review Board Approval (ECA) 	
 Institutional or independent ethics committee/ The study/study processing of the study study s	ackward in time
 Institutional Review Board Approval (ECA) committee or Institu 	tocol was approved by the hospital's/institution's ethics
	tional Review Board or independent ethics committee
 Written informed consent (IC) Written consent for 	participation was obtained from parents or lawful guardians
Assent Assent was obtained	d from children aged 7 years and above

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studies that enrolled children over the age of 7 years. $^{\left[13,14\right] }$

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 about ethical clearance, consent, and assent were expressed as percentages.

RESULTS

The issues of IP and IJP had 132 articles that reported on clinical research studies. These included 98 prospective and 34 retrospective studies.

Ethics committee's approval (ECA)

As shown in Table 2, 39/132 (29.53%) reported ethical approval. The corresponding figures for prospective and retrospective studies were 36/98 (36.73%) and 3/34 (8.82%) respectively. Twenty-seven (27.55%) articles with prospective studies reported both ethics committee's approval and written informed consent. One study each reported approval from senior medical officer or hospital authorities. This was not considered to be equivalent to ethics committee's approval. In addition, one article mentioned that ethical approval was obtained for a larger survey of which the study reported was a part. This too was not considered equivalent to ECA.

Written informed consent

As shown in Table 3, 46/98 (46.94%) prospective studies reported that informed consent was obtained from parents or lawful guardians. Studies that reported recording verbal consent (n = 2) or did not clarify if the consent was a written one (n = 1) were not deemed to have obtained written informed consent. Neither ethical approval nor informed consent was mentioned in 45 (34.10%) of the published articles reporting prospective studies.

Assent

A total of 54/98 (55.10%) studies enrolled children aged 7 years or more and hence were assessed for reporting of assent; eight (14.81%) reported that children's assent was obtained. Four (7.41%) eligible studies reported ethics

Table 2: Reporting of ethics committee's approval by authors

	Indian Pediatrics		Indian Journal of Pediatrics		Total	
	Required	Mentioned	Required	Mentioned	Required	Mentioned
Prospective	42	20 (47.62)	56	16 (28.57)	98	36 (36.73)
Retrospective	16	2 (12.5)	18	1 (5.56)	34	3 (8.82)
Total	58	22 (37.93)	74	17 (22.97)	132	39 (29.53)

Table 3: Reporting of informed consent and assent

Journal	Written info	rmed consent	Assent		
	Required	Mentioned	Required	Mentioned	
ndian Pediatrics	42*	21 (50.00)	28	6† (21.43)	
ndian Journal of Pediatrics	56*	25‡ (44.64)	26	2 (7.69)	
Fotal	98	46 (46.94)	54	8 ^{§†} (14.81)	

*Includes one study that stated that verbal consent was obtained. This was not considered to mean 'written informed consent'; [†]Includes one study that mentioned that the study was conducted as per ICH-GCP guidelines; [‡]Includes a study where consent was reported to be taken from subjects in 'study group' without any mention about consent from subjects in 'control group'; [§]Includes four studies that reported 'consent' from older children, in addition to consent from parents and lawful guardians

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committee approval (ECA) written informed consent (IC) as well as assent

The manuscripts contained 21 articles with foreign authors or collaborators that reported prospective study designs. Nine (42.86%) of them reported on ECA and 8 (38.10%) reported on written informed consent from parents or guardians. Eight studies included children over the age of 7 years. However, only 2 (25%) reported of having obtained assent from eligible children. Five manuscripts written by foreign authors/collaborators used retrospective study design. Three (60%) reported about ECA.

Instructions to authors

Till 2006, neither IP nor IJP provided any guidance to their authors regarding the reporting of ethical processes such as ECA, written informed consent, and obtaining assent from child participants. The IP now advises its authors to indicate if the study was approved by the institution's ethics committee and if informed consent was obtained from the study participants.

DISCUSSION

The observations made in the study indicate that a vast majority of articles published in the two peer-reviewed Indian pediatric journals do not mention about ECA, written IC, and assent procedures. ICMJE recommends that authors mention about human experimentation being done in accordance with standard ethical procedures and Declaration of Helsinki.^[4] Although these two journals are not a signatory to this policy, the importance of mentioning these details cannot be overemphasized. Provision of these details assures readers that studies have been carried out adhering to these two most important components of ethics involving human studies. It also serves as an informative or educational tool for prospective researchers.

It has been found that 24% to 84% of articles published in various scientific journals do not mention about ECA, while 22% to 75% of published studies do not inform readers about written informed consent being taken^[5-12] Table 4. The journal, the year of publication, and the type of study design influence the proportion of published studies mentioning about these ethical aspects. Generally it has been observed that over the years, there has been an increase in the proportion of studies reporting on these details.^[5,10] Most of these studies have included randomized controlled trials^[6,10,12] or prospective study designs for analysis.^[5] Our study unearthed a relatively less reported fact: the proportion of articles with retrospective study design reporting about ECA was abysmally low (just over 8%). One possible reason for this could be that researchers and reviewers might not be aware that such clearance is necessary even when data is being analyzed retrospectively.

Children constitute a vulnerable population that is enrolled in research studies. The World Medical Association recommends that greater care should be taken while enrolling such a population and advocates provision of additional safeguards.^[3] It is ironical that, as noted in our study, research publications involving children report lower, and not higher, figures for ECA and IC documentation.^[7,9] It is also worth noting that the issue of documenting assent Table 4: Publications regarding nonreporting of ethics committee's approval, informed consent, and assent^[5-12]

First author,	Journal and total number	Nonreporting of	Nonreporting of	Nonreporting
Year of oublication	of manuscripts studied	clearance by an ethics committee	informed consent	of assent
Dison <i>et al.</i> ^[5]	Articles on resuscitation retrieved from Medline [47]	23 (48.9)	35 (74.47)	Not applicable
Ruiz-Canela ^{[6]*}	BMJ, Lancet, JAMA, NEJM [767]	224 (29.2)	155 (20.2)	Not applicable
Bauchner ^{[7]†‡}	APAM, JAMA, NEJM, Pediatrics, J Pediatrics [561]	221 (39.39)	Information not provided	Information not provided
Sifers <i>et al.</i> [8]†‡	JPP, JCCP, CD, JACP [260]	Information not provided	152 (58.46)	211 (81.2)
Neil et al. ^{[9]†‡}	Pediatrics, APAM, J Pediatrics [379]	182 (48.02)	215 (56.7)	Information not provided
rank <i>et al.</i> ^[10] *	AIM, BMJ, JAMA, Lancet, NEJM [600]	147 (24.5)	132 (22)	Not applicable
Harrison et al.[11]	AJODO, JO, EJO [155]	130 (83.87)	116 (74.83)	Information not provided
Schroter et al.[12]†	AIM, BMJ, JAMA, Lancet, NEJM [370]	104 (31.23)	168 (46.93)	Not applicable
Present study [‡]	IP, IJP [132]	93 (70.47)	52 (53.06)	46 (85.18)

Figures in box brackets [] indicate total number of manuscripts studied; Figures in parentheses () indicate percentages; AIM - Annals of Internal Medicine; AJOD - American Journal of Orthodontics and Dentofacial Orthopedics; APAM - Archives of Pediatrics and Adolescent Medicine; BJJ - British Medical Journal; CD - Child Psychology; EJO - European Journal of Orthodontics; JACP - Journal of Abnormal Child Psychology; JAMA - Journal of American Medical Association; JCCP - Journal of Child Psychology; J Pediatrics - Journal of Pediatrics; JPP - Journal of Pediatric Psychology; JO - Journal of Orthodontics; NEJM - New England Journal of Medicine; *clinical trials; †Research papers; *studies involving pediatric subjects, exclusively

was not referred to in some of the publications related to studies done in children;^[7,9,11] and when this aspect was examined, the proportion of nonreporting of assent was very high.^[8] As stated under 'Results,' although IP advises authors to report regarding ECA and obtaining of informed consent, it does not still provide any guidance regarding assent to be obtained. All these facts indicate that the concept of obtaining assent from a child participant is yet not given the attention it deserves.

Children are not a homogeneous population. Older children and adolescents, depending upon their cognitive abilities, might be able to understand important aspects of research and hence their assent is required to be taken. There is no unanimity amongst various authorities regarding cut off date for mandating an assent from a child for participation in the trial.^[14-16] This absence of a consensus could have contributed to the low rates of assentreporting found in our study.

Our study has its limitations. We have looked at only a year's data. However, this is likely to represent the best possible picture, given the worldwide trend of improvement in reporting ethical procedures over the years.^[10] Experts might question the generalizability of our results since articles published in only two pediatric journals have been studied. However, these two are peer-reviewed journals that are being published for the last 40 years and most research carried out in children in India is published in these two journals. They have been indexed in PubMed for several years. One of them is the oldest subspecialty journal published from Asia, while the other is the official publication of the Indian Pediatric Society. Thus, these two journals are likely to represent the best practices followed with regards to publications. Another limitation is that we did not contact the individual authors to determine if they had obtained ECA prior to commencing the study and/or informed consent and/or assent prior to enrollment. This did not matter since the primary objective was to

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Despite the limitations cited, the study findings demonstrate that a significant proportion of articles involving biomedical research and published in the two Indian pediatric journals do not provide information regarding ECA, IC procedure, and assent. The journals can improve on these aspects by ensuring that reporting these procedures is made mandatory and included in 'Instructions to Authors.' A checklist could be devised that would remind authors, reviewers, and editors about reporting ethical procedures. There may also be a need to educate researchers and reviewers regarding the importance of reporting on these issues, especially with regards to retrospective studies. Journals could also provide links to sites providing national and international guidelines concerning conduct and reporting of research.

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Source of Support: Nil, Conflict of Interest: SBB and NJ have acted as investigators for several research studies involving children and have been associated with various journals as members of the editorial be and associated editor and editor.

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