

Survey Study

Reporting ethics committee approval and informed consent:
Review of an Ayurvedic journal

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Abstract

Introduction: Reporting of ethical approval and informed consent in clinical research articles involving human subjects is necessary as per the International Committee of Medical Journal Editors (ICMJE). **Aim:** To assess the reporting of ethics committee approval and informed consent in clinical research articles published in AYU journal. **Materials and Methods:** This was a retrospective analysis of published articles in AYU from 2012 to 2014. All original articles (clinical research) were included. Data was collected to note – Ethics Committee approval and written informed consent (assent from children when applicable). Descriptive statistics was used to report the findings. **Results:** A total of 104 articles were included in this analysis. Of these, 38 articles included children. Ethics committee approval was reported in 53 (51.0%) articles and consent was also reported in 51 (49.0%) articles. Thirty-eight (36.5%) articles reported both ethics committee approval and consent, whereas 38 (36.5%) articles did not report both. Only five articles reported consent from guardian or parent whereas none of the articles were reported assent. **Conclusion:** Findings from this study demonstrate that Ayurvedic clinical research articles lack in reporting ethics committee approval and written informed consent.

Key words: Ethics committee approval, publication ethics, written informed consent

Introduction

Protecting research participants is reflected in the principles that are used to define ethical research. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, which also guides on ethics committee approval and informed consent.^[1] It suggests that the research protocol must be approved by the ethics committee, and voluntary informed consent must be obtained from each participant before participation. In addition, when participant is minor and considered incapable to provide informed consent, an assent must be obtained in addition to the consent from guardians or parents (the legally acceptable representative [LAR]). The Declaration of Helsinki obligates researchers, authors, sponsors, editors, and publishers to publish reports of their research, including negative and inconclusive and expects publishers not to accept papers where the research is not in accordance with the Declaration of Helsinki.^[1]

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The International Committee of Medical Journal Editors (ICMJE) offers recommendations and ethical standards in reporting of research, helping authors, editors, and others involved in peer review and biomedical publishing.^[2] The ICMJE recommendations have recently (December 2015) been updated and are now known as “Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.” The ICMJE expects all reports/publications involving human data to “indicate whether the procedures followed have been assessed by the responsible Review Committee (institutional and national), or if no formal Ethics Committee is available, were in accordance with the Helsinki Declaration..... when informed consent has been obtained, it should be

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indicated in the published article.” The ICMJE expects journals to include these requirements in instructions to author section.^[2]

Journal editors play an important role in adherence to these ethical requirements in all submitted and published research papers in their journals^[3] including AYU, an international quarterly journal of research in Ayurveda. AYU, in its instructions to the authors, included these requirements and expects authors to adhere to the same. The aim of this analysis was to assess the adherence to reporting of ethics committee approval and informed consent in research articles published in AYU.

Materials and Methods

This was a retrospective analysis of published articles in AYU from 2012 to 2014. All papers published under “Original Articles – Clinical Research” category were included. All other publications including review articles, case studies, pharmaceutical standardization, and pharmacological study were excluded from this analysis. This analysis did not need ethics committee approval as it did not constitute biomedical research. However, reporting is consistent with all ethical requirements.

An electronic version of each article was obtained, and data were collected to note-ethical clearance (by Institutional Ethics Committee or Independent Review Board), whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Declaration of Helsinki, written informed consent from study participants, and wherever applicable assent from children aged over 7 years in addition to consent from guardians or parents (LAR). Interventions were also noted which was defined as patients/participants who received any form of medication or underwent any procedure.

Descriptive statistics was used to report the result. The number of research articles reporting ethics committee approval, consent, and assent were expressed as percentages.

Observations and Results

A total of 104 clinical research articles published in AYU from 2012 (volume 33) to 2014 (volume 35) were included in this analysis. All included studies were deemed to have ethics committee approval or ethical clearance. Studies reporting that the consent was obtained before operation (presurgical consent; $n = 2$) were not considered as consented as it was not clear whether consent was obtained for participation in the study.

Among these, in 38 (36.5%) articles study participants were children (2014, $n = 9$; 2013, $n = 14$; 2012; $n = 15$); 32 studies included both adults and children and six studies included only children.

Of 104 studies, 61 (58.7%) included vulnerable population (children [aged <18 years], $n = 38$; elderly [aged >60 years], $n = 33$; pregnant women, $n = 2$; students, $n = 2$; Note: Vulnerable population may not be exclusive in particular study). A total of 96 studies

had some intervention whereas other eight studies were non-interventional (surveys/questionnaires) [Table 1].

Reporting of ethics committee approval and consent

Ethics committee approval was reported in 53 (51.0%) articles, and consent was reported in 51 (49.0%) articles. Both ethics committee approval and consent were reported in 38 (36.5%) articles; however, 38 (36.5%) articles did not report both ethics committee approval and consent. Only two articles reported that the study was in accordance with Declaration of Helsinki. The percentage of reporting of ethics committee approval was improved from 33.3% (2012) to 78.6% (2014) and reporting of consent from 35.7% (2012) to 57.1% (2014). Higher numbers of articles were observed reporting both ethical approval and consent from 2012 to 2014 [Figure 1].

Reporting of consent from guardians/parents and assent

Only five (2014, $n = 2$; 2013, $n = 3$) articles reported consent from guardians or parents (LAR); however, none of the articles reported assent from participating children. In studies, where both adults and children participated ($n = 32$), consent was obtained in 15 articles (including LAR, $n = 1$).

Phrases used to report consent

Various phrases were used to report consent. The most commonly ($n = 20$, 39.2%) used phrase was “informed

Table 1: Summary of observations

	2014 ($n=28$)	2013 ($n=34$)	2012 ($n=42$)
Number of participants in study, median (range)	60 (15-1095)	46 (10-138)	50 (6-138)
Interventions, n	26	32	38
Vulnerability, n	15	20	26
Children (<18 years)	9	14	15
Elderly (>60 years)	4	11	18
Pregnant women	2	0	0
Students	0	1	1

Vulnerable population may not be exclusive

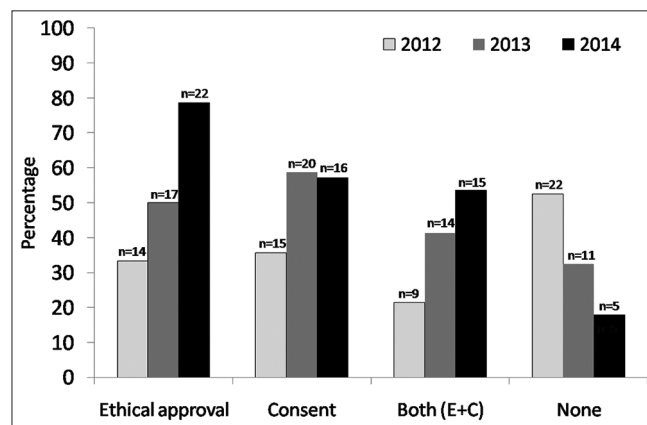


Figure 1: Reporting ethics committee approval and consent (2012-2014)

consent,” followed by “written consent” ($n = 14$, 27.5%), “consent” ($n = 9$, 17.6%), “written informed consent” ($n = 5$, 9.8%), “signed informed consent” ($n = 2$, 3.9%), and “ethical consent” ($n = 1$, 2.0%). One article reported consent in the abstract and not in the body of the article. Few notable statements concerning consent were (1) “patients.... were selected, who have been informed about the details of the trial in brief,”^[4] (2) “Every selected patient was explained about the procedure of hemodynamic observations upon him, its benefits and thereby was obtained with consent.”^[5]

Discussion

This retrospective analysis assessed reporting of ethics committee approval and consent in AYU. Overall, observation is poor adherence in reporting of ethics committee approval and consent in published clinical research papers in AYU; however, the reporting practices were improved over the period of time from 33.3% to 78.6% in ethics committee approval and from 35.7% to 57.1% in consent. Reporting of studies that they were conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and local requirements was lacking. In addition, it was observed that the absence of reporting of assent in addition to consent from parents or guardians in studies where participants were more than 7 years of age despite this was clearly stated in journal instructions to authors of AYU.

There are previous similar analyses in other streams of medicine where ethics committee approval was not reported in 24–84% of articles whereas consent was not reported in 20–75% of articles.^[3,6-12] However, in previous reports, the assent was not reported in 81–85% of articles.^[6,13]

It was also observed that various phrases were used to report ethics committee approval and consent, and the most common were “informed consent” and “written consent.” More clear and standardized statements could help reader whether fully written informed consents were obtained. One of the articles reported that patients were informed “about the details of the trial in brief,” whereas the Declaration of Helsinki expects all participants must be adequately informed.^[1] Another article reported that “its benefits” were explained; however, Declaration of Helsinki suggests that “the anticipated benefits and potential risks of the study and the discomfort it may entail” should be adequately explained.^[1]

To the best of author’s knowledge, this was the first time when adherence to reporting of ethics committee approval and consent was assessed in any Ayurvedic journal. The results of the present study provide current status of ethical publication practices concerning protection of research participants in Ayurvedic clinical research and may provide direction or early guidance on the need to report ethical approval and consent. The high proportion of articles lacking reporting of ethics committee approval and informed consent in this report demonstrates that there is a need to raise awareness on this topic for better and complete adherence.

It is important that editor enforces these ethical standards in all submitted manuscripts. If a manuscript does not meet these requirements, editor may inform authors that it could be rejected, due to unsatisfactory ethical non-adherence. It

could also be helpful if mandatory steps are added to online submission portal so that during submission authors can confirm to each of these components. Following such high standards will also help building journals credibility and confidence of readers.

Author also acknowledges limitations of this analysis. The present analysis only assessed articles published in clinical research category, and articles published in issues before 2012 were not included. Generalizability could be limited as the author has only assessed articles from one journal; however, these results could provide insights on ethical reporting practices among Ayurvedic researchers.

Conclusion

Overall, the present analysis demonstrates that a significant proportion of articles involved in Ayurvedic clinical research lack in reporting ethics committee approval and written informed consent; however, improvements have been observed over time. Articles were completely lacking in reporting whether assents were obtained from children whenever applicable, along with consent from guardians or parents. Additional training may be necessary to raise awareness regarding the importance of reporting ethics committee approval and written informed consent.

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Conflicts of interest

Author is an employee of Tata Consultancy Services, Mumbai, however the views presented in this paper are of the author and not necessarily of his employer.

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हिन्दी सारांश

'आयु' जर्नल में प्रकाशित लेखों में नैतिक और सहभाग अनुमोदन का आंकलन

प्रविण एम. बोलशेटे

मेडीकल जर्नल संपादकों की आंतरराष्ट्रीय (आई.सी.एम.जे.ई.) अनुसार वैद्यकीय संशोधन लेखों में नैतिक और सहभाग अनुमोदन का लिखना अनिवार्य है। इस अध्ययन का उद्देश्य 'आयु' जर्नल में प्रकाशित लेखों में नैतिक और सहभाग अनुमोदन की रिपोर्टिंग का आंकलन करना है। इस अध्ययन में 'आयु' में प्रकाशित (२०१२ से २०१४) मूल लेख (क्लिनिकल रिसर्च) शामिल किये गये। प्रकाशित लेखों से नैतिक अनुमोदन - लिखित सहमति पत्र और बच्चों से सहमति (जब लागू हो) का परिणाम एकत्रित किया गया। निष्कर्षों को रिपोर्ट करने के लिए वर्णनात्मक सांख्यिकी का इस्तेमाल किया गया। इस अध्ययन में कुल १०४ लेख शामिल किये गये। इनमें से ३८ लेखों में बच्चों का सहभाग था। ५३ (५१%) लेखों में नैतिक अनुमोदन रिपोर्ट किया गया था और ५१ (४९%) लेखों में सहमति पत्र रिपोर्ट किया गया था। ३२ (३६.५%) लेखों में दोनों चीजें रिपोर्ट नहीं की गयी थीं। आयुर्वेदिक चिकित्सकिय लेखों में नैतिक अनुमोदन और सहमति पत्र की रिपोर्टिंग का अभाव है, यह निष्कर्ष प्रस्तुत अध्ययन से प्राप्त हुआ।