

Documentation of ethical considerations in published articles in Sudanese medical journals

Dya Eldin M Elsayed, MD

Assistant Professor, Department of Community Medicine, Alzaiem Alazhari University, Khartoum North, Sudan

Rabaah M Elamin, MD

Department of Chest Diseases, Omdurman Teaching Hospital and Faculty of Public Health, Alzaiem Alazhari University

Introduction. Guidelines for biomedical research involving human subjects require that research should be conducted in accordance with accepted ethical principles. The International Committee of Medical Journal Editors guidelines require authors to indicate that they have obtained ethical approval and informed consent. Sudanese scientific medical journals ask authors to declare informed consent and ethical approval by an ethics review committee (ERC) in published reports.

Methods. We reviewed 114 original research articles published in five peer-reviewed Sudanese medical and health journals to assess the extent to which ethical considerations had been reported.

Results. A subtitle indicating 'ethical considerations' was found in 5 (4.4%) articles, 35 (30.7%) stated that informed consent had been obtained from the study participants, and 13 (11.4%) stated that the study had been approved by an independent ERC. Although all five journals explicitly ask authors to document ethical approval and informed consent, 88.6% and 69.3% of the articles examined had failed to document ethical approval and informed consent, respectively.

Discussion. Failure to obtain or report ethical approval by an ERC and failure to obtain informed consent from study participants was the most prominent finding. Failure to report ethical approval or consent was seen to a similar extent in all study designs reported, so study design did not seem to influence the reporting of ethical considerations. However, failure to document ethical considerations, in particular ethics committee approval and obtaining of informed consent, does not necessarily mean that these were not done in the research reported.

Limitations. We reviewed only Sudanese journals, so do not know the practice of Sudanese authors in this regard when they publish in international scientific journals.

International ethical guidelines state that all research involving human subjects should be conducted in accordance with accepted ethical principles that focus on protecting human subjects and communities and with approval by an independent ethics review committee (ERC).¹ ERCs have been established in many countries at institutional and national levels, with the purpose of making sure that all research involving human subjects is reviewed and approved by an independent body. These committees are made up of clinicians, scientists, community members and patient representatives who review the research according to procedures set out at national or institutional levels.^{2,3} All human participants should receive relevant information on the study before it commences, and the investigators must obtain written informed consent from each individual participant enrolled (verbal consent is sometimes acceptable).^{4,5} The investigators should also specify how privacy and confidentiality have been addressed. Potential risks to participants must be stated, and the authors must list adverse events that occurred during the course of the study and how these were handled.⁶

The Declaration of Helsinki demands that ethical considerations be reported in published research, stating: 'Publishers have ethical obligations. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.'⁷ Ideally, research results should be published after independent scientific peer review to avoid the risk of disseminating false results.

The 1981 International Committee of Medical Journal Editors (ICMJE) guidelines require authors to confirm that their research has been reviewed by an independent ERC. In 1991 they added that researchers must also declare that they have obtained informed consent from study participants.⁸

More than 500 journals around the world have responded and adopted the requirements of the ICMJE.⁹ As a result the number of articles reporting informed consent in clinical trials increased from 64% to 82%, and the number reporting ethics committee approval increased from 59% to 82%.¹⁰

All Sudanese scientific medical journals require authors to declare informed consent and ethical approval by an ERC in their published reports. Authors should therefore provide sufficient information for readers to know how the study was performed with regard to ethical issues. We investigated documentation of ethical considerations in articles published in Sudanese scientific and medical journals from 2003 to 2008 and assessed to what extent they fulfilled the set requirements.

Similar studies have been published in North American and European journals. Most examined the reporting of ethical approval and/or informed consent in scientific publications.¹¹⁻¹³ One study was conducted in Sri Lanka.¹⁴ To our knowledge no similar studies have been conducted in Africa, and little is known about research published in Sudanese peer-reviewed medical and scientific journals. Our study provides unique information on the re-

porting of ethical approval and informed consent in a developing country where research and scientific publications are increasing. In Sudan there are currently more than five quarterly scientific peer-reviewed journals.

We investigated research studies, including clinical trials, because interventions involving human subjects make the reporting of safeguards particularly important.

Material and methods

We reviewed original research articles published in five Sudanese peer-reviewed medical and health journals, *Sudan Medical Journal*, *Sudanese Journal of Public Health*, *Sudan Medical Monitor*, *Gezira Journal of Health Sciences* and *Sudan Journal of Medical Sciences*, covering the period from September 2003 to September 2008, and examined the extent to which ethical considerations such as ethics review committee approval, informed consent, privacy, confidentiality, risk to participants, inducement to study participants and conflict of interest were reported. Scrutiny of the articles was extended to include study design, study population, study sites and tools for data collection. We examined these issues to determine the degree to which human subjects were involved in these studies.

The two authors reviewed every article independently and then jointly assessed the comments made. We used a check-list to obtain the desired data. For data analysis, a manual master sheet was prepared in accordance with study variables and then computed and analysed using Microsoft Excel 2007.

This study did not involve human participants or records. Therefore, review and approval by the Alzaiem Alazhari University ethics committee was not required. To maintain confidentiality, the research assistant removed authors' names and all identifiers from all articles before we reviewed them.

Results

We assessed 114 articles that originated from research involving human subjects published in five scientific and medical journals. A check-list tested the predetermined study variables. Ninety-two research studies (80.7%) involved adults, and 24 (21.0%) involved only women; in 17 (70.8%) of these the women were pregnant. Children were included in 22 studies (19.3%), 86 (75.4%) were done in health facilities, 24 (21.0%) were community-based and 8 (7.0%) explored the effect of work on workers and were done at the workplace. Four of the studies were done in more than one place. Ninety-nine studies (86.8%) used an observational design, 11 (9.6%) were randomised clinical trials, and 4 (3.5%) used a quasi-experimental design. Researchers reported using a wide variety of tools for data collection (Table I).

Of the reviewed articles, 5 (4.4%) had a subtitle indicating 'ethical considerations'. Issues covered in this section were protecting the privacy of study participants and maintenance of confidentiality. Concerns such as risk posed to participants by involvement in the study, inducement to participants and conflict of interest were not documented in any of the articles reviewed. Thirteen articles (11.4%) recorded that the study had been approved by an independent ERC, but only 5 of these named the ERC concerned. Thirty-five (30.7%) of the reviewed articles documented that informed consent had been obtained from the study participants – in 6 studies consent had been obtained in written form and in 8 it had been verbally obtained, while 21 studies (60.0%) did not specify

Table I. Methods of data collection described in the articles reviewed

Tool of data collection	Frequency	%
Questionnaire	75	65.7
Medical (physical) examination	57	50
Blood collection	53	46.4
Procedures	19	16.6
Imaging	18	15.7
Review of records	16	14
Urine analysis	12	10.5
Tissue biopsy	10	8.7
In-depth interview	5	4.3
Skin test	5	4.3
Sputum analysis	4	3.5
Stool analysis	4	3.5
Not stated	3	2.6

the means by which consent was obtained. Only 4 (36.4%) of the 11 randomised clinical trials reported obtaining informed consent and only 2 (18.1%) reported ERC approval. Seventy-nine studies (69.2%) failed to report either approval or informed consent.

Authors used various wording to report ethical approval, such as 'ethical clearance was obtained', 'the study protocol was approved by ethical committee', and 'ethical clearance was sought'. In declaring informed consent authors used wording such as 'informed consent was obtained', 'patients gave verbal consent', and 'each patient gave written informed consent'.

Discussion

We found that shortcomings in the documentation of ethical considerations are common in scientific and medical publications in Sudan. Despite global concern about the protection of research participants, only 4.4% of articles provided some information about ethical considerations. Although all five journals explicitly ask authors to document ethical approval and informed consent, 88.6% and 69.3% of the articles we examined failed to document ethical approval and informed consent, respectively. Our figures are the lowest reported. Sumathipala *et al.*¹⁴ found that one-third of the articles published in Sri-Lanka from 1999 to 2005 recorded approval by an ethics committee and 61% documented obtaining informed consent. Yank and Rennie¹⁵ found that reporting ethical approval and informed consent increased from 175 of 300 articles (58%) before 1997 to 221 of 300 (74%) after 1997.

There are three possible explanations for the high proportion of papers that did not report ethical approval and informed consent. Firstly, both approval and informed consent may have been obtained but not reported because the authors considered these procedures unimportant details. This situation is unlikely owing to low awareness of ethical issues among Sudanese researchers.^{16,17} Secondly, researchers may have failed to obtain approval and informed consent because of ignorance of the requirements

and consequently did not report them. Some investigators reported randomised clinical trials (9.6%), the design of which requires meticulous review by an ERC. Failure to obtain or report ethical approval by an ERC and informed consent from study participants may suggest that these studies were carried out without review or approval.¹⁸ Finally, some authors used the available records on patients to obtain the data in their studies. They may not realise that studies which use available records should be reviewed, that they must obtain approval by the ERC and that informed consent may be required. We are not certain to what extent identifiable private information was exposed to researchers, because no article described the methodology used to obtain such data.⁹

There was a similar rate of failure to report ethical approval or consent in all study designs used by researchers, i.e. reporting of ethical considerations did not differ according to study design. This contrasts with the findings of Schroter *et al.*¹⁹ that randomised clinical trials in American and British journals had better reporting than other study designs, and that reporting improved over the period studied.

Failure to document ethical considerations, ERC approval, and obtaining of informed consent in particular does not necessarily mean that they were ignored by the researchers. At the same time we cannot assume that these principles were respected. Even if they were respected, conducting ethically sound research is of paramount importance, but not enough on its own. It is equally important to document ethical considerations in every article based on research involving human subjects. We do not know whether failure to document ethical considerations resulted from ignorance or reflects intentional behaviour of the authors. Also, in the few articles that reported ethical considerations it is not clear whether the requirements were in fact met or were just reported to make the article acceptable to the journal editors and therefore publishable.

The language used by authors to declare ethical approval and informed consent was often unclear. While stating that the procedures had taken place during the study, they did not explain how they were performed. Also, it is not clear whether patients (study participants) gave fully informed consent or merely agreed to participate. Careful and accurate use of language will give the reader a better understanding of how these procedures were actually performed.¹⁹

Conclusion

Information about ethical considerations should be readily available for readers of biomedical research involving human subjects. It is important to explain how approval was obtained and to record which ERC reviewed and approved the study protocol. Informed consent must be clearly explained, as informed consent is a process rather than agreement to participate or just a paper signed by the participant.

Many Sudanese journals, including those that we reviewed, provide guidance and information on ethical approval and obtaining consent in their instructions for authors. However, it is obvious that the journals do not enforce these requirements effectively. Journal editors should be committed to the requirements and instructions for authors and establish effective mechanisms to ensure that full information on ethical considerations is reported for all research on human participants. Reviewers can also play a positive role in this regard by requiring the inclusion of a statement

on ethical considerations, including ethical approval and consent, in all publications based on research involving human subjects.

Limitations of the study

We reviewed only Sudanese journals and are not aware whether or not papers published by Sudanese authors in non-Sudanese journals reported ethical considerations more frequently than in local publications.

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