Reporting Ethical Protections in Physical Therapy Research

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Background and Purpose. Efforts to make physical therapy more evidence based have increased demand for human participants, raising concerns for their safety and welfare. This study examined how often research articles in physical therapy journals report basic ethical protections. Methods. We carried out a retrospective audit of research articles in 6 physical therapy journals between 1996 and 2001. Results. Of 806 articles reviewed, 48% documented both research ethics committee approval and informed consent. Articles reporting clinical interventions had the highest reported rate (64%) of both protections. Articles reporting qualitative methods, chart reviews, and case reports had the lowest rates of documentation of both requirements: 30%, 17%, and 11%, respectively. Reported rates of both requirements in vulnerable populations were 55% for children, 48% for students, and 33% for employees. Twenty-six percent of articles included confidentiality assurances. Case reports were most likely and chart reviews were least likely to mention confidentiality: 88% and 8%, respectively. Discussion and Conclusion. There is no uniform editorial policy among physical therapy journals for reporting basic ethical requirements. Physical therapy journals should standardize ethical protections and make documentation of compliance a prerequisite of publication. [Henley LD, Frank DM. Reporting ethical protections in physical therapy research. Phys Ther. 2006;86:499-509.]

Key Words: Physical therapy, Publication ethics, Research ethics.

Although the rewards of biomedical research, such as advances in treatment and prevention of disease, are enormous, in some cases research can seriously harm participants, as illustrated by the Nazi atrocities committed on prisoners of war in the name of science and a series of well-publicized scandals in the United States. These include the Tuskegee Syphilis Study, involving 399 poor African-American men who, without their knowledge, were denied treatment so that the natural history of their condition could be investigated and experimentation on institutionalized children with mental retardation who were intentionally infected with hepatitis to determine the effects of a vaccine. More recent examples include the death of an 18-year-old subject in a gene therapy trial and the death of a 24-year-old volunteer who was healthy in an asthma study.

Although instances of flagrant abuse are exceptional, human research nonetheless puts some participants at risk or inconvenience in the hope of benefiting others. Consequently, human research is regulated by research ethics codes requiring that participants' rights and welfare are elevated above scientific and societal goals. International guidelines are located in the Nuremberg Code, the World Medical Association Declaration of Helsinki (1964, last revised in 2000), and the Council for International Organizations of Medical Sciences guidelines (1993, revised 2002). The United States also has enacted federal regulations, known as the Common Rule, to protect human participants in federally funded studies. Additionally, the Belmont Report identified 3 ethical principles relevant to human research: respect for participants, beneficence, and justice. Respect for participants entails the moral conviction that participants should be treated as autonomous agents and that those with diminished autonomy need protection. Beneficence requires investigators to promote participants' well-being through maximizing benefits and minimizing risks, and justice demands that the benefits and burdens of research be fairly distributed. Drawing on these codes, guidelines, and regulations, Emanuel and
colleagues9,10 offered 8 ethical requirements to guide the conduct and evaluation of human research (Tab. 1).

Advances in medicine depend not only on the generation of information through research but also on its dissemination, and journals have a responsibility to ensure that the research published therein meets current ethical standards. To this end, the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, drafted by the International Committee of Medical Journal Editors,11 instruct researchers to indicate in their manuscripts whether a study was conducted in accordance with the Helsinki Declaration of 2000. Practically speaking, this means that researchers who want to publish in journals subscribing to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals must supply information relating to research ethics committee (REC) approval, procedures used to obtain informed consent, confidentiality protections, and possible conflicts of interest. It is crucial that manuscripts not in accordance with the principles of the Helsinki Declaration should not be accepted for publication. Recently, the United Kingdom-based Committee on Publication Ethics12 produced a similar set of guidelines for reporting ethical practices.

Despite well-established ethical guidelines for research and stringent publication requirements, evidence suggests major shortcomings in the quality of the requirements for13,14 and reports of15-30 ethical protections in journal articles. In a landmark study of English-language biomedical journals, Amdur and Biddle13 found that many editors did not communicate basic ethical requirements to potential researchers and authors. Their review of journals' instructions to authors showed that slightly less than one half specified REC approval as a prerequisite for publication and that about one quarter did not provide or refer authors to any information related to research ethics. Fifteen percent of journals referred authors to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, and 3% referred authors to the Declaration of Helsinki. Disturbed by these variable guidelines relating to ethical protections in biomedical journals, Amdur and Biddle recommended that journal editors standardize their requirements and that instructions to authors contain a clear and detailed description of ethical standards needed for the publication of human research. Moreover, they believe that documentation of REC approval should be a condition of publication and that, when a study is exempt from review, the reasons for the exemption must be stated. Furthermore, a growing body of research, including research on vulnerable or captive populations such as children,17-21 medical students,22 older people,23 nursing home residents,24 and people needing cardiopulmonary resuscitation25 and areas such as critical care,26 emergency services,27 psychopathology,28 Alzheimer disease,29 and genetics,80 reveals considerable variation in the reporting of ethical practices (Tab. 2).

Table 1.

Requirements for Ethical Research(a)

In physical therapy, pressure to become more evidence based31,32 has accelerated the output of empirical research, raising concerns about the protection of participants' rights and welfare.33-35 However, a recent literature review, spanning 30 years (1970-2000), of advances in ethics knowledge in physical therapy identified only 9 articles in research ethics.39 Given this dearth of literature on research ethics in physical therapy and low reported rates of documentation of ethical protections in the medical and psychological literature, we sought to examine equivalent protections in published physical therapy research. This study addressed 2 questions: (1) Do instructions to authors in physical therapy journals contain explicit ethical guidance regarding REC approval, informed consent, and confidentiality? and (2) Do authors report these ethical protections in physical therapy research and, if so, is documentation associated with journals' instructions to authors, study design, or study population? Ultimately, with this study, the first to examine compliance with ethical protections in physical therapy publication, we hope to increase awareness among physical therapists of the need for high ethical standards when conducting and reporting human research.
This study was a descriptive audit of investigators' compliance with international and journal-specific requirements for documentation of ethical safeguards in physical therapy journals. The Australian Journal of Physiotherapy, Physical Therapy, Physiotherapy, Physiotherapy Canada, Physiotherapy Research International, and South African Journal of Physiotherapy were chosen because they represent a spectrum of official physical therapy societies, with many enjoying a high circulation. Furthermore, on the basis of the quality of published clinical trials, the Australian Journal of Physiotherapy, Physical Therapy, Physiotherapy, and Physiotherapy Canada are among the highest-ranked exclusively physical therapy journals and, according to a citation analysis, are considered core physical therapy journals. Additionally, the Australian Journal of Physiotherapy and Physical Therapy are indexed in the prestigious MEDLINE database. Physiotherapy Research International was selected because of its empirical and international focus. The South African Journal of Physiotherapy reflects practice in a developing country. All of the journals are peer reviewed and listed in the Cumulative Index to Nursing and Allied Health Literature. Although relevant articles are published in other journals, these 6 distinctively physical therapy journals were judged to reasonably represent current scientific and ethical practices in physical therapy research. A key practical criterion circumscribing the choice of journals was availability in a printed format in the medical library of the University of Cape Town.

All research articles available to the authors and published between 1996 and 2001 were reviewed. Letters to the editor, editorials, abstracts, meta-analyses, systematic reviews, presidential addresses, and technical articles were excluded from the study.

Information relating to selected ethical protections (REC approval, informed consent, and confidentiality) was extracted from journals' instructions to authors and research articles by use of 2 sets of structured data collection and coding forms. Research ethics committee approval, informed consent, and confidentiality were the ethical protections of choice because of their prominence in research ethics guidance and regulation. Informed consent and confidentiality form the basis of the principle of respect for participants. In addition, REC approval and informed consent are both necessary because of shortcomings in the consent process, such as the therapeutic misconception, which may cause participants to underestimate a study's risks.

As yet, there are no universally accepted measures of ethical requirements, such as social value; in addition, consensus on controversial ethical issues, such as inclusion of vulnerable participants in research, remains elusive. However, prospective REC approval is a useful proxy measure of several ethical requirements, all of which need a favorable review before a study can proceed. Furthermore, REC approval, informed consent, and confidentiality are necessary, if not sufficient, requirements for submission to journals subscribing to international publication guidelines. The inclusion of these protections also allowed comparison with similar findings in published medical and psychological literature.

Table 2.

Documentation of Research Ethics Committee (REC) Approval and Informed Consent in Published Research*

Ethical Protections in Instructions to Authors

Information was extracted on journals' reporting policies regarding informed consent, REC approval, and confidentiality, as described in instructions to authors. Informed consent was coded as an ethical requirement if the instructions to authors included a statement indicating that informed consent should be obtained when conducting human research. Also noted was whether written confirmation of informed consent was needed. The requirement for REC approval was
documented as present if the instructions to authors contained statements such as "REC approval of studies involving human research is required for publication." Phrases such as "institutional review board," "responsible committee on human experimentation," and "institutional approval" were used interchangeably with "REC approval." A statement in the instructions to authors requiring that a study was conducted in compliance with the Helsinki Declaration was interpreted to include the following combination of ethical requirements: REC approval, informed consent, assent, proxy consent, and confidentiality protections (articles 13, 22, 24, 25, and 21, respectively, in the Helsinki Declaration). Confidentiality referred to specific instructions to maintain participants' privacy and confidentiality.

Ethical Protections in Research Articles

Information was extracted from research articles on methodology (study design and population) and ethical protections (REC approval, informed consent, and measures to protect confidentiality). Specific methodological information related to the setting of the study and the inclusion of vulnerable populations, such as children (<18 years of age), students (people receiving tertiary education), employees, subjects with impairments in decision making (those with mental illness, those who are unconscious, or those with severe dementia), and subjects in intensive care or emergency settings. Furthermore, each study was categorized as clinical (e.g., clinical trials or studies involving interventions such as blood draws, chest radiographs, massage, and walk-run tests), behavioral (interviews, questionnaires, or both), a combination of both (clinical interventions plus questionnaires), chart review or clinical audit (use of medical records or pre-existing databases), or case report (in which the term "case report" appeared in the title, abstract, or key words of an article). Also noted was whether qualitative methods (defined as such) were used in an investigation. These categorizations were selected to reflect specific ethical concerns, such as capacity to consent, susceptibility to harm, voluntariness, and difficulties in defining human research. Research ethics committee approval for a study was assumed when statements indicated that an REC approved the protocol, the study adhered to the Helsinki Declaration, or the study was exempt. The presence of informed consent was inferred from statements such as "patients gave informed consent to participate in the study," "all subjects gave written or oral consent," "parents agreed to take part," "there were no refusals," and "consent was waived." Assurances of confidentiality were inferred from statements such as "participants' confidentiality and privacy were respected," "data were collected anonymously," and "identifying information was removed." Confidentiality was inferred if participants' eyes were covered in published photographs in case reports.

To establish the reliability of data extraction and coding, we independently completed and coded the first 20 data collection forms. Discrepancies or disagreement in the interpretation of the coding rules were settled by consensus. For example, a phrase such as "parents had the opportunity to decline to participate" was consistently interpreted as showing that oral consent was obtained in a study. One researcher (DMF) extracted and coded all remaining data according to criteria in the data collection forms. Although interrater agreement was not statistically determined, wherever ambiguities arose during data extraction, these were resolved by verbal agreement between the authors.

Analysis

Specific ethical protections were analyzed according to study design and study population. Because of the small numbers, analyses of vulnerable groups were limited to children, employees, and students. Frequency distributions and cross-tabulations, including chi-square tests of statistical significance, were calculated with Epi Info Version 6.* Percentages were rounded to the nearest whole number.

Ethical Considerations
Because this study did not involve human subjects and the data were in the public domain, REC approval was not needed.

Results

Instructions to Authors

No ethical protections were stipulated in the instructions to authors of Physiotherapy Research International. The South African Journal of Physiotherapy requested only confidentiality protections, which were introduced in 1997. Physical Therapy provided the clearest and most detailed conditions, including written confirmation of both REC approval and informed consent and where in the manuscript this information must appear. Physiotherapy required a signed certificate from the REC as well as a written statement on informed consent. Physiotherapy Canada required written REC approval and written informed consent. The instructions to authors of the Australian Journal of Physiotherapy, accessible only on the journal's Web site, requested written REC approval. With the exception of Physiotherapy Research International, all journals published ethical requirements for confidentiality. However, the guidelines were limited mostly to issues relating to publication of photographs, for which the journals requested written permission from participants and, in the case of minors, the consent of parents or legal guardians. Physiotherapy Canada stipulated that subjects' eyes must be obscured with a black bar. Physiotherapy expected authors "to obscure facial features." Physical Therapy instructed authors to submit written permission, signed by participants, to publish photographs in which participants might be recognized. With respect to case reports, Physiotherapy suggested that authors use subjects' names ("but they should not be their real names") for clarity and humanity. With the exception of Physical Therapy, no instructions to authors referred to subjects' "rights" in research or to the Declaration of Helsinki. Physical Therapy required a statement that the rights of human and animal subjects had been protected in a study.

REC Approval, Informed Consent, and Confidentiality

Between 1996 and 2001, 806 articles meeting the inclusion criteria were extracted from 6 physical therapy journals (Tab. 3). Because the medical library's subscription to Physiotherapy Research International began in 1999, 12 issues for years 1996 to 1998 were missing from the final data set. Most (n=577, 72%) research took place in hospitals, with a further 14% (n = 115) taking place in a university setting. Ten percent (n = 85) of studies were conducted in private practices, ambulatory services, rehabilitation centers, residential care settings, and schools. One third (n = 270) of the studies included participants who were classified as vulnerable; most of them were children (n = 101, 37%), employees (n=91, 33%), and students (n = 63, 23%). Only 9 studies included participants who were either impaired in decision making or critically ill. A further 6 studies included pregnant women, survivors of sexual abuse, and army recruits.

Table 3.

Frequency Distribution of 806 Articles in Physical Therapy Journals Between 1996 and 2001

In general, journals were significantly more likely to report informed consent than REC approval (65% versus 54%; $\chi^2=21.75, P=.0000$). Whereas the overall rates of reporting of informed consent remained relatively constant between 1996 and 2001 (range=59%-73%), a trend analysis of rates of documentation of REC approval showed a statistically significant improvement over the 6-year period: 46% in 1996 to 64% in 2001 ($\chi^2=11.74, df=5, P=.034$).

Reporting practices for REC approval and consent are shown in Table 4. Less than half (48%) of the journals reported both REC approval and consent. Physical Therapy had the highest rate
(73%) of documentation of both REC approval and consent and the lowest rate (14%) of reporting of neither requirement. Over half of the articles in the Australian Journal of Physiotherapy reported both protections (54%). The South African Journal of Physiotherapy and Physiotherapy were the least likely to document both REC approval and consent (25% and 21%, respectively). Clinical studies were the most likely to have evidence of both REC approval and consent (64%), with chart reviews and case reports being the least likely to note both protections (17% and 11%, respectively). Most case reports and over two thirds of chart reviews had no documentation of either REC approval or consent (80% and 69%, respectively). Less than two fifths of articles involving behavioral and qualitative methods reported obtaining both REC approval and consent (39% and 30%, respectively). Approximately one half of studies involving children and students (55% and 48%, respectively) and one third of research involving employees (33%) included both REC approval and consent.

In addition, findings relating to specific vulnerable groups were examined according to study design. Children were 3 times more likely to take part in clinical investigations than in behavioral investigations (66% versus 19%). No children were included in research involving qualitative methods. Most research (87%) including employees involved behavioral methods. Similarly, students were more likely to take part in behavioral investigations than in clinical investigations (52% versus 40%).

In total, about one quarter of articles documented evidence of confidentiality (Tab. 5). Case reports were most likely and chart reviews were least likely to report confidentiality protections (88% and 8%, respectively). Approximately one third of behavioral studies and one fifth of studies involving qualitative methods mentioned confidentiality (31% and 22%, respectively). Confidentiality was reported in approximately one third and one quarter of studies involving employees and students (35% and 27%, respectively).

Discussion

Advances in physical therapy practice rely on a solid foundation of quantitative and qualitative research undertaken with a growing pool of participants, students, colleagues, and healthy volunteers. Ensuring participants' safety and welfare during experimentation requires continuing ethical vigilance. This statement is confirmed by a follow-up study of participants in physical therapy research. Shortcomings identified during the research included a consent process that left some participants ignorant of potential psychological risks, ill equipped in their role as participants, and with unfulfilled expectations regarding study outcomes.

Instructions to Authors

A powerful mechanism for encouraging ethical research is the requirement underwritten by international journal editors that authors include in their manuscripts written statements confirming that REC approval and consent were obtained and that confidentiality was protected. Significantly, analysis of instructions to authors revealed disparate editorial policies among physical therapy journals for reporting these ethical requirements. Moreover, journals' publication practices did not always coincide with their directives to authors. For example, of the 3 journals requesting written statements of both REC approval and informed consent, rates of nondocumentation ranged between 14% and 52%. Therefore, even when journals provided explicit guidance to authors, manuscripts not meeting these minimum ethical standards were published. Alternatively, authors may have submitted separate documentation of REC approval and consent, for instance, in a cover letter or in a standard checklist, instead of providing documentation in the actual manuscript. Additionally, lack of written evidence in an article of REC approval and consent does not mean that researchers failed in their ethical obligations or that participants were placed at risk. Indeed, an e-mail survey of authors of articles in major pediatric journals showed higher rates of actual compliance with REC approval and informed consent than were reported in their articles (92% versus 52% and 91% versus 43%, respectively).
Similarly, Sigmon and colleagues28 found large discrepancies between documented and actual practices. Whereas researchers obtained REC approval and informed consent in 88% and 80% of studies, these were reported in only 3% and 39% of psychopathology publications, respectively.

Table 4.

Documentation of Informed Consent (IC) and Research Ethics Committee (REC) Approval According to Journal, Design, and Vulnerable Groups

Table 5.

Documentation of Confidentiality According to Source, Design, and Vulnerable Groups

REC Approval, Informed Consent, and Confidentiality

In total, 48% of articles analyzed in physical therapy journals included information on both REC approval and consent, and 29% had no information on either protection. Strikingly, almost three quarters of research articles in Physical Therapy documented both ethical protections. Well-publicized research scandals in the United States, stringent federal regulations governing human research, and detailed guidance for authors may account for this finding.

When viewed against published findings (Tab. 2), the overall rate of documentation in physical therapy publications (54%) of REC approval compared favorably with those in fields of research as wide ranging as anesthesia,16 pediatric,18 critical care,26 and emergency medicine.25 Moreover, this rate improved noticeably (from 46% to 64%) between 1996 and 2001. Likewise, the overall rate of documentation of informed consent (65%) was similar to those in almost half of the studies (eg, in general and emergency medicine), whose rates ranged between 50% and 70%,14,16,17,26Z,27,29,30 and was vastly better than those in others, with rates of less than 30% (eg, in medical education) (Tab. 2).22,23,25 Encouragingly, studies with clinical interventions that carry potential physical risks for participants had the highest reported rates of both REC approval and consent (64%), with only 17% of studies reporting neither protection. These data compare fairly favorably with rates in clinical trials published in leading medical journals.42,43 In a review of clinical trials published in the British Medical Journal, Journal of the American Medical Association, Lancet, and New England Journal of Medicine between 1993 and 1995, Ruiz-Canela and colleagues found documentation of REC approval and informed consent in 71% and 80% of articles, respectively.42 Using data from a similar set of journals (Annals of Internal Medicine, British Medical Journal, Journal of the American Medical Association, Lancet, and New England Journal of Medicine), Yank and Rennie also noted improved rates of reporting of ethical protections when random samples of trials 18 months before and after 1997 were compared.43 Documentation of REC approval and informed consent rose from 69% to 82% and from 74% to 82%, respectively. Yank and Rennie contended that rates of compliance should be 100% to reassure participants of their safety.43

Considering that two thirds of physical therapy research involving children was clinical, it is disquieting that both REC approval and informed consent were reported in only 55% of articles, with almost one third reporting neither protection. Still, this disappointing finding is more or less in keeping with reported rates of REC approval and informed consent in the related fields of child health (61 %),18 general pediatrics (52% and 43%),20 and child psychology (41.5%).21 Research involving children presents an ongoing ethical challenge.44 On the one hand, society must protect individual child participants; on the other, the welfare of children as a class depends on research to ensure the safety and effectiveness of diagnostic and therapeutic interventions. Accordingly, journals ought only to publish research involving children that documents the highest ethical standards.
A minority (17%) of chart reviews or audits reported both REC approval and consent. These data reflect similarly low levels of REC approval (26%) and informed consent (7%) in published research with pre-existing data in general pediatric journals. Whether these protections are needed to gather pre-existing data is controversial. Some argue that REC approval is unnecessary because these activities represent routine clinical care and carry minimal risk of harm and because the findings will not affect subject management or outcomes. In contrast, it is argued that a variety of people, such as research assistants, gain access to personal subject information to which they would not normally be entitled outside the research situation. If investigators are undecided about ethical protections for certain research designs, they should seek an opinion from the REC as to best ethical practice and report the results of such consultations in their publications. Less than 1 in 10 chart reviews reported that confidentiality had been protected. If data are extracted anonymously, then breaches of confidentiality are unlikely. Even so, REC approval is desirable. Increasingly, physical therapist researchers will need to ensure that their studies comply with country-specific legislation to protect personal information. For example, in the United States, the Health Insurance Portability and Accountability Act governs the use and disclosure of personal health information and sets boundaries on the use and release of medical records. Covered entities, such as universities or hospitals, may not use or disclose private health information for research purposes unless a subject has given advance written authorization on a specified form.

Likewise, physical therapist researchers may not consider case reports a form of research. This consideration may account for the low reported rate of REC approval and consent (11%) in that study and an even lower rate (2%) in an analysis of case reports in anesthesia research. Although there is general agreement that single case reports do not constitute systematic data collection requiring REC approval, there are risks of disclosing personal information, and informed consent for publication from the subject or family is recommended to protect privacy and confidentiality. In accordance with most physical therapy journals' instructions to authors, a high proportion (88%) of case reports included some form of confidentiality assurance. This rate was far higher than the overall rate (26%) of documentation of this ethical safeguard.

In medical settings such as hospitals, in which most physical therapy research was undertaken, studies involving questionnaires and interviews can involve the collection of sensitive information that could be harmful if disclosed outside the research environment. Nevertheless, only 39% of articles involving these methods reported both REC approval and consent. Similarly, studies involving qualitative methods, which most likely overlapped behavioral interventions, had an even lower rate of documentation of both protections (30%). Debate about the role of RECs in evaluating qualitative research is intense. Critics contend that REC members lack expertise in qualitative methodologies. Although this view has merit and REC members should become better informed about qualitative approaches, it should not imply that REC review is best avoided. Arguably, there is scope for modifying these requirements because much qualitative research is an emergent process, making it difficult to establish in advance and with certainty the balance of risks and benefits. Therefore, it may be more appropriate to obtain consent throughout a qualitative study rather than as a one-time ethical obligation. It is preferable for researchers to describe and justify any adjustments to the informed consent process in their manuscripts.

Two distinctive ethical concerns in research involving students and employees are voluntariness of consent and breaches of confidentiality. In educational settings, students' relative powerlessness, dependence on faculty, limited financial resources, and overlapping roles as students and study subjects can make it difficult to decline participation, thereby threatening voluntary informed consent. Indeed, students may feel pressured to take part, fearing reprisals (such as low grades) should they refuse. Similarly, employees (e.g., junior physical therapists, physical therapist assistants) may be susceptible to subtle pressures, particularly from management, to take part in research to benefit their institutions. There is also a danger that investigators-managers may view research in the workplace as quality improvement not needing REC approval. "Paycheck vulnerability" experienced by employees-participants thus
is complicated by the ambiguity that characterizes definitions of research and legitimate managerial activity. Inadvertent disclosure of sensitive information, causing unintended psychosocial or economic harm, is a further concern. However, only a minority of studies with these groups documented REC approval, consent, and confidentiality. Inasmuch as most research (87%) including employees involved behavioral methods, it is of concern that approximately two thirds of these research studies made no mention of confidentiality. To protect vulnerable populations against subtle forms of inducement and possible psychological or social harm, investigators must pay special attention to informed consent and confidentiality, as well as acknowledge these ethical requirements in subsequent publications.

Limitations

This study could not corroborate whether investigators' failure to report ethical safeguards reflected actual failure to implement such protections or simply failure to document whether they were followed. Likewise, this study did not determine whether ethical dimensions were explicitly addressed in cover letters to editors when manuscripts were submitted, a practice consistent with recommendations of several physical therapy journals' instructions to authors. Thus, low rates of reporting may not imply that the research was unethical, merely that authors failed to adequately inform readers.

The generalizability of findings is limited to physical therapy journals included in this study. Fourteen issues, including 12 from Physiotherapy Research International, were excluded from analysis either because they were lost (n=2) or because they were unavailable in the medical library. The missing issues of Physiotherapy Research International were not available in South African libraries, and costs per copy of international library loans were prohibitive. However, because Physiotherapy Research International had no instructions to authors regarding specific ethical requirements, the missing information likely would have had minimal, if any, impact on the overall findings and conclusions.

Conclusion

Human research must meet international ethical standards, which include social value, scientific merit, a favorable risk-benefit ratio, fair subject selection, informed consent, confidentiality, and approval by an impartial REC.9 In addition, international committees of journal editors10,11 should require authors to document compliance with certain ethical standards in manuscripts submitted for publication.

The emphasis on evidence-based practice, by definition reliant on a firm research foundation, has highlighted the need to consider ethical issues in physical therapy research. Prompted by the dearth of literature on research ethics in physical therapy, we examined physical therapy journals' publication requirements relating to documentation of REC approval, informed consent, and confidentiality, along with evidence of authors' adherence to these instructions in published articles. Findings showed a wide variation in physical therapy journals' policies and in authors' documentation of ethical safeguards. Moreover, there were discrepancies between journals' directives to authors and publication practices, which meant that articles not strictly meeting journals' ethical requirements were published nonetheless.

However, the broad spectrum of physical therapy research in this study, which crossed quantitative and qualitative boundaries, often within vulnerable populations in hospital, educational, and work settings, indicates a need for clear and consistent publication guidelines between and within physical therapy journals concerning appropriate ethical protections. Arguably, journal editors should make documentation of these internationally recognized ethical standards a prerequisite for publication. Even if careful attention to the reporting of ethical issues in physical therapy research cannot guarantee that a study will be conducted ethically, it might at
least heighten investigators’ awareness of these protections in the planning, conduct, and dissemination phases of physical therapy research, as well as consolidate improvements in existing rates of documentation of REC approval.

* Centers for Disease Control and Prevention, Atlanta, Ga, 2001.

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Both authors provided concept/idea/research design, data analysis, and consultation (including review of manuscript before submission). Dr Henley provided writing. Ms Frank provided data collection.

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