

1 **Reporting of Ethical Approval and Informed Consent in Clinical Trials in Twelve**
2 **Nursing Journals in China between 2013 and 2016**

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1 **Abstract**

2 **Background:** It is acknowledged that publishers now require all primary research
3 papers to demonstrate that they have obtained ethical approval for their research.

4 **Objectives:** To assess the rate of reporting of ethical approval in clinical trials in core
5 nursing journals in mainland China.

6 **Research design:** A retrospective observational study.

7 **Participants:** All clinical trials published in all of the twelve core nursing periodicals
8 from 2016 edition China Science and Technology Journal Citation Report (core version)
9 between 2013 and 2016 were retrieved by hand to explicate rate of reporting ethical
10 approval and informed consent.

11 **Ethical considerations:** The study did not require approval from the research ethics
12 committee as it did not involve human subjects or records.

13 **Results:** In total, 40278 papers were published in twelve nursing periodicals between
14 2013 and 2016. Out of these, 9488 (23.6%) focused on clinical trials. Informed consent
15 obtained from patients or the legally authorised representative was reported in 51.8%
16 of clinical trials. Notably, only 27.4% of clinical trials reported that they had obtained
17 written consent. Furthermore, 25.9% of clinical trials described ethical approval;
18 however, the rate of reporting informed consent and ethical approval in these twelve
19 nursing journals in China during four years from 2013 to 2016 improved markedly, with
20 38.1%, 44.0%, 59.0%, and 66.6%, respectively ($P<.001$), and 17.6%, 21.9%, 28.6%,
21 and 35.8%, respectively ($P<.001$). In addition, both reporting informed consent and
22 reporting written informed consent had a positive significant correlation with the

1 reporting ethical approval ($P < .05$ or $< .01$).

2 **Conclusion:** Chinese scientific nursing journals have improved the rate of reporting
3 informed consent and ethical approval in clinical trials during the last four years.
4 However, it should be noted that nearly half of clinical trials still did not report either
5 ethical approval or whether informed consent was obtained. Efforts from editors,
6 researchers, sponsors, and authors are needed to ensure the transparency of ethical
7 scrutiny and adherence to ethical guidelines in publishing clinical trials in Chinese
8 nursing journals.

10 **Keywords**

11 China, nursing journal, clinical trials, research ethics, informed consent

13 **Introduction**

14 The Declaration of Helsinki, which was first formulated in 1964 by The World Medical
15 Association, is considered to be at the vanguard of policy that has informed the ethical
16 principles of researchers¹. Central to the principles of non-maleficence and beneficence,
17 the Declaration of Helsinki placed a duty of responsibility on all researchers in all
18 human experimentation to protect the right of participants. It specifically identified two
19 key processes be included: ethical approval from research ethics committee and the
20 individuals' right to be informed². Since 1964, it is recognised that publishers also have
21 an ethical obligation to ensure that human experimentation which is not compliant with
22 the principles in the Declaration of Helsinki should not be published². A range of

1 documents, principles, and organizations including The Nuremberg Code ³, the NHS
2 Research Ethics Committee ⁴, as well as Academic Research Ethics Committee in
3 colleges & Universities also formulated principles to manage and protect human rights
4 for research participants. The requirement of ethical review for clinical trials has
5 received more attention, because the unethical experiments may not only lead human
6 participants being exposed to risks and burdens, but may also mislead clinical practice
7 ⁵. As a result, guidelines have been formulated to ensure that confirmation of ethical
8 approval is provided when research has been published ⁶. However, whilst the ethical
9 standards of research have significantly been improved through the regulation of
10 research ethics committees in recent years, a number of experiments misconduct have
11 been reported ⁷. For instance, Fang, Steen ⁸ stated that 67.4% of 2047 biomedical and
12 life-science retraction articles indexed by PubMed between the years of 1977 and 2011
13 were due to misconduct, and the experiment known as “Golden rice event” which
14 conducted by research groups from Tufts University and other Chinese scientific
15 research institutions have prompted significant discussion in China because of the non-
16 transparent informed consent ⁹.

17
18 Demographic changes concurrent with the rapid development of medical technology
19 present new challenges to nursing research. For example, during the last three decades,
20 nursing research has experienced significant growth designed to guide clinical practice
21 and improve the health care of patients ¹⁰. The ethical awareness and activity of nursing
22 research has highlighted concerns resulting with the International Council of Nurses

1 formulating ethical codes of practice to guide the nursing profession ¹¹. However,
2 Mohajjel-Aghdam, Hassankhani ¹² highlighted that knowledge and attitudes about
3 ethical issues in nurses is lacking. This limitation was also reported by Negarandeh and
4 Gobady ¹³ who argued that 70.8% of nurses and midwives required education on ethical
5 issues. In addition, Fernandez ¹⁴ described that numerous published examples of
6 ethically suspect research, with examples such as lack of written informed consent
7 which are still present in the literature. It is also suggested that ethical problems in
8 qualitative research involving children, for example, the evaluation of potential risks
9 and benefits, also need more attention ¹⁵. Therefore, it is essential that ethical scrutiny
10 is needed to strengthen and monitor ethics in nursing research to protect the health and
11 rights of human subjects.

12

13 China has the largest number of scientific researchers in the world and the publication
14 rate has increased sharply over the past two decades ¹⁶, but ethical challenges remain
15 commonplace within experimental research in China ¹⁶. Whilst it is recognised that
16 ethical accountability resides with the researcher, more recently, there has been a
17 growing expectation that the editorial team are viewed as “gate-keepers” and “rule-
18 makers” of papers submitted for publication and hence, are an essential factor to
19 improve the ethical situation ¹⁷. This additional responsibility mirrors the requirement
20 of American Medical Association who first initiated the requirement for editors of
21 biomedical journals to scrutinize the ethics of clinical research submitted for
22 publication. Furthermore, the Declaration of Helsinki, the Committee on Publication

1 Ethics (COPE), the International Commission of Medical Journal Editors (ICMJE), as
2 well as the World Association of Medical Editors (WAME) recommended that editors
3 were obliged to ensure ethical scrutiny in all publications ^{2, 18-22}. Moreover, it is
4 recommended that journals should publish author guidance about the need to describe
5 informed consent and ethical approval, and state the reason in articles if informed
6 consent was waived ²³.

7
8 Following Yank and Rennie ²⁴ who stated the importance of reporting ethical approval
9 and informed consent in clinical trials, we chose to perform a similar search of Chinese
10 scientific journals, to map, for the first time, how ethical scrutiny is recorded and
11 performed in clinical trials in scientific nursing journals in China.

12

13 **Literature Review**

14 The following databases were systematically searched from 1964 to May 2017 to
15 identify relevant studies: Medline (Ovid), The Cochrane Library, CINAHL (EBSCO),
16 Web of Science, PsycINFO as well as Google Scholar. A variety of search terms and
17 combinations were used, which included journals, periodicals, ethical approval, ethics
18 committee approval, ethical research committee approval, IRB approval, institutional
19 review board approval, informed consent, subjects' consent, research ethics committee
20 approval, REC approval, clinical trial, human research, and the research designs
21 described in the papers. The searching start date was limited after the year 1964 to
22 reflect the publication of The Declaration of Helsinki was formulated ¹. In addition,

1 manual searching including the reference lists of retrieved articles and citation tracking
2 has been done to be a supplement of database searches to improve comprehensiveness.
3
4 After screening full text articles, the literature search resulted in 15 articles that were
5 considered for inclusion. Several study outcomes showed that the publication of
6 ethically suspect research has previously been reported in international and national
7 journals. For example, Yank and Rennie²⁴ studied the clinical trials in *JAMA*, *BMJ*, *The*
8 *Lancet*, *Annals of Internal Medicine*, and *The New England Journals of Medicine*, and
9 found that 26% and 31% articles published before 1997 did not report informed consent
10 and ethical approval, respectively. Moreover, 18% of papers after 1997 did not report
11 whether consent or ethical approval was obtained. More recently, Schroter et al²⁵
12 reported similar findings in 2006 and revealed that 31% and 47% of articles in five
13 general medical journals did not mention ethical approval and informed consent.
14 Equally, Myles and Tan²⁶ reported that 29% of publications in six leading anaesthesia
15 journals from 2001 did not report institutional review board (IRB) approval, and 31.5%
16 did not report informed consent, respectively. Similar findings were reported by Henley
17 and Frank²⁷ in 2006 who found that only 48% physical therapy articles mentioned both
18 informed consent and ethical approval. Moreover, Block et al²⁸ reviewed three thoracic
19 surgery journals and the results showed that only 41% of human research mentioned
20 ethical process. A common trend emerged in other professional journals, for example,
21 oral and maxillofacial surgery research indicate that only 22% reported ethical approval
22 and 25% described whether informed consent had been obtained²⁹. The reporting of

1 ethical approval and informed consent in human resuscitation research ³⁰ and child
2 research ³¹ is also highlighted as a significant issue where between 26% and 51% of
3 ethical approval is reported. Furthermore, the lack of reporting of ethical approval in
4 other national journals remains inconsistent, for example, Bavdekar et al ³² reviewed
5 biomedical research in two Indian journals in 2006 and identified that only 29.53%
6 articles reported ethical approval, and 46.94% reported informed consent. Finally,
7 Sumathipala et al ³³ found only one-third of the biomedical articles from Sri Lanka
8 reported Ethical Research Committee approval as well as informed consent.

9
10 It is acknowledged that some progress with regards to the reporting of ethical approval
11 has made progress in the last five years. It is understood that the improved reporting is
12 due to the increasing concern about the participants' protection, for instance, Bridoux
13 et al ³⁴ reviewed ethical progress in phase III surgical trials and the results revealed that
14 87.7% of publications documented ethical approval and 92.2% stated that informed
15 consent had been requested. However, most of published articles showed that the
16 document of ethical process remains inadequate. Fitzgerald ³⁵ reviewed four major
17 orthodontic journals in 2012 and the results showed that only 48.6% of Randomized
18 Controlled Trials (RCTs) had reported both informed consent and ethical approval and
19 27.1% had neither, and the data in Controlled Clinical Trials (CCTs) is 36%, 39.3%,
20 respectively. Similar findings were reported by Murphy et al ³⁶ in 2015 who identified
21 that 49.9% of clinical research published in three leading European
22 Otolaryngology periodicals lacked a statement of ethical approval and 42.9% lacked

1 reported informed consent, and the data in three chiropractic journals is 88% and 56%,
2 respectively that conducted by Lawrence ³⁷ in 2011. Finally, 54% and only 16% of
3 publications in three paediatric surgical journals ³⁸ documented ethical approval and
4 informed consent, respectively. In conclusion, the report of ethical scrutiny in
5 publications still need to be improved, and evidence of these is lacking in scientific
6 nursing journals in China.

7

8 **Methods**

9 *Study design and inclusion criteria*

10 This is a retrospective observational study ³⁹. All clinical trials published in all of the
11 twelve core nursing periodicals from 2016 edition China Science and Technology
12 Journal Citation Report (CJCR) (core version) ⁴⁰ between 2013 and 2016 were retrieved
13 to examine for evidence of ethical review. CJCR was formulated by The Institute of
14 Scientific and Technical Information of China (ISTIC) annually and has become
15 characterised as an authoritative and popular tool to manage and evaluate periodicals
16 in China. In 2016, 1985 periodicals including twelve nursing journals were collected in
17 CJCR and have been identified as statistic source (core) journal in China ⁴⁰. Clinical
18 trials were studied as the use of interventions on human subjects makes the reporting
19 of safeguards extremely important ²⁴. The studies that met the following criteria were
20 retrieved by hand: (1) Clinical trials. It was defined as a research with interventions
21 performed on human subjects ^{24,41}; and (2) Full-text published. Supplement published
22 articles, news, and letters were excluded. All of the twelve core nursing periodicals were

1 published in Chinese.

2

3 *Data extraction*

4 Data was collected between October 2016 and January 2017. To ensure the credibility
5 and accuracy of data extraction, two authors (YNW and JXO) independently screened
6 the included nursing journals on databases or the official website of each journal and
7 extracted clinical trials in keeping with the eligibility criteria. China National
8 Knowledge Infrastructure (CNKI) and WANFANG DATA which are the two main
9 databases in China have been used in this research. Following this, data were extracted
10 independently using a standardized data extraction form after careful reading the full-
11 text of each extracted article and recorded it on a table. The primary outcome measures
12 of the study were the rates of reporting ethical approval and informed consent. The
13 definitions were fulfilled by the following descriptions: (1) ethical approval—the study
14 has got ethical approval from the Research Ethics Committee in hospital or other
15 institutions before the research can be undertaken. Whether reported the Research
16 Ethics Committee reference number has been recorded; and (2) informed consent—
17 written informed consent got from participants or the legally authorised representative,
18 and the implied description that human subjects agreed to join in the research. The
19 secondary outcome measures of the study were the rates of reporting some further
20 details about informed consent and ethical approval: (1) ethical declaration (the author
21 declared the research conformed to the Declaration of Helsinki, or stated the research
22 met the principle of research ethics, but not described whether the research obtained

1 ethical approval or not); (2) confirmation that the confidentiality of individual
2 information of human subjects was maintained; and (3) whether the research
3 participants had been informed that they had the right to withdraw from the research at
4 any point without reprisal. For instance, the number of written informed consent was
5 counted if it had been reported in the article.

6

7 The Chinese character “正” which consists of five strokes was used as tally marks to
8 count the data by hand to represent the digits one to five. A table was used by two
9 authors to calculate the data independently for each variable in the research. It has been
10 advocated that tally marks, usually clustered in groups of five, have the advantage in
11 counting, decimal conversion as well as avoiding error as it is far more easily for human
12 beings correctly identify a cluster of five than one of ten ^{42, 43}. Disagreement was
13 resolved by consensus or a third person (CLZ).

14

15 *Ethical considerations*

16 The study did not require approval from the research ethics committee as it did not
17 involve human subjects or records.

18

19 *Data analysis*

20 Data from the included papers were analysed using SPSS 20.0 software (IBM, USA)
21 and Microsoft Excel 2016 (Microsoft, Redmond, Wash). Categorical data were
22 presented as a number ²⁶ and Chi-square was used to test the differences between the

1 rates of reporting. Correlation analysis was used to test the relationship among the
2 variables (reporting of informed consent, reporting of written informed consent, and
3 reporting of ethical approval). If the data did not in accordance with bivariate normal
4 and homoscedastic, a Spearman correlation was used ⁴⁴. All *P* values were two-sided,
5 and significance was indicated when a *P* value was reported as less than .05.

6

7 **Results**

8 The study located 40278 papers that were published between 2013 and 2016, in all of
9 the twelve Chinese scientific nursing journals. Of these, 9488 (23.6%) focused on
10 clinical trials (Table 1).

11

12 *Informed consent*

13 A total of 4916 (51.8%) from the 9488 clinical trials reported that informed consent had
14 been obtained from patients or the legally authorised representative. Notably, only 2604
15 (27.4%) of clinical trials reported that written consent was obtained, which suggests
16 that nearly half of the papers only described that participants agreed to join in their
17 research, rather than consented as it is not clear whether the researcher asked
18 participants to sign a consent form. The reporting of informed consent was different
19 between the 12 Chinese scientific journals and ranged from 31.2% to 79.1% (Table 1).
20 Furthermore, a growing trend in the reporting of informed consent was observed of the
21 rate between 2013 and 2016, with 38.1%, 44.0%, 59.0%, and 66.6%, respectively
22 ($X^2=480.603, P<.001$) (Table 2 and Figure 1). Six papers reported that human subjects

1 had been informed that they had the right to withdraw from the research at any time
2 without reprisal, and twelve articles confirmed that confidentiality of research subjects
3 was maintained.

4

5 *Ethical approval*

6 The results showed that 2459 (25.9%) of 9488 clinical trials reported in the twelve
7 scientific journals, stated that they obtained ethical approval from Research Ethics
8 Committees in hospital or other institutions before the research was undertaken. It is
9 interesting that only 90 (1.0%) of these papers reported the Research Ethics Committee
10 reference number. Moreover, out of 25.9% of the articles who secured ethical approval,
11 only seventeen (0.2%) of clinical trials included ethical statement, three of which
12 declared that the research conformed to the Declaration of Helsinki ¹ and fourteen of
13 which stated that the research met the principles of research ethics but did not mention
14 which principle. In addition, there was a significant difference between these twelve
15 nursing journals that reported whether ethical approval was granted ranging from 2.9%
16 in *Modern Clinical Nursing* to 43.3% in *Chinese Journal of Practical Nursing* (Table
17 1). The rate of ethical approval of clinical trials in Chinese nursing journals shows a
18 growing tendency between 2013 and 2016, with 17.6%, 21.9%, 28.6%, and 35.8%,
19 respectively ($X^2=225.866$, $P<.001$) (Table 2 and Figure 1).

20

21 *Correlations among variables*

22 As can be seen in Table 3, both reporting informed consent and reporting written
23 informed consent had a positive significant correlation with the reporting ethical

1 approval ($P<.05$ or $<.01$).

2

3 **Discussion**

4 This study identified that 51.8% of clinical trials published across twelve Chinese
5 scientific nursing periodicals reported that informed consent had been obtained, and
6 25.9% described whether the study had received ethical approval. Notably, only 27.4%
7 of clinical trials reported that written consent had been obtained, and only 1.0% of
8 clinical trials included the Ethics Committee reference number. Despite the rate of
9 ethical approval reporting improved sharply between 2013 and 2016 (all $P<.001$) which
10 may be induced by various kinds of efforts like the “Joint Statement of Establishing a
11 Chinese Clinical Trial Registration and Publishing System”⁴⁵, the regulation of ethics
12 committee, as well as the effectiveness of many ethics workshops⁴⁶; this data
13 symbolizes that the publication of ethically uncertain research occurs commonly in
14 nursing journals in China. Most of nursing periodicals in China did not meet their
15 commitment to the Declaration of Helsinki which stated: “Publishers have ethical
16 obligations”, significantly, the Declaration of Helsinki clearly stated that “reports of
17 experimentation not in accordance with the principles laid down in this Declaration
18 should not be accepted for publication.” Although a waiver of informed consent could
19 be allowed in some special circumstances by the ethical guideline of the IRB or Council
20 of Europe and Council for International Organizations of Medical Sciences (CIOMS),
21 there were no descriptions of impediments to obtaining written informed consent in
22 these retrieved clinical trials in the studies included in this review⁴⁷. Alternatively, the
23 data also indicates that the reporting of informed consent and ethical approval in clinical

1 trials needed to be more standardized and accurate to ensure that the implementation of
2 ethics was transparent as possible.

3

4 Apart from this study explored the ethical situation of human research in nursing
5 journals in China, there have been 15 articles available currently which identified the
6 reporting of ethical process in clinical trials in national ^{32, 33} and international
7 periodicals ^{24-31, 34-38}. Most of the results showed that ethical transgressions in clinical
8 research remains less than ideal and the public confidence in medical research has been
9 undermined as a result. However, whether to publish ethically suspect work remains
10 controversial. For instance, Smith ⁴⁸ and Levine ⁴⁹ argued that ethically uncertain
11 research could be published with an accompanying editorial for its potentially valuable.
12 Although it is not intrinsically immoral, some data may have its unique contributions
13 ⁵⁰. Furthermore, Fernandez ¹⁴ stated that the fact of some ethically uncertain researches
14 has been conducted will be hidden if the publication of the work is rejected, and
15 research may need to be repeated to get the results which could make the human
16 subjects exposed to such potentially risks again. The ICMJE recommends human
17 experimentation adhere to the Declaration of Helsinki, but may not explicitly refuse to
18 publish the research if it does not adequately meet the Declaration ¹⁴. Alternatively, a
19 number of people support withholding of publishing these kinds of articles because it
20 could potentially influence the researcher to misinterpret the Declaration. However, the
21 rejection of papers based on lack of ethical reporting transparency could have a negative
22 impact on the academic advancement of researcher ⁵¹ and could prevent the

1 dissemination of significant research.

2

3 The study also identified a positive significant correlation between reporting of
4 informed consent, written informed consent, and ethical approval. This is familiar with
5 other research findings, for instance, in the research conducted by Myles et al ²⁶,
6 journals who had a high rates of reporting informed consent are more likely to get a
7 similar rates of reporting ethical approval. There are two possible explanations for the
8 correlations between these variables, one is in relation to the journals author instructions.

9 In this research, only three of the twelve core nursing periodicals had a statement
10 regarding reporting of ethical approval and informed consent in their instructions to
11 authors. These included, the Chinese Journal of Practical Nursing, the Chinese Journal
12 of Modern Nursing, and the Nursing Journal of Chinese People's Liberation Army. The
13 rates of reporting informed consent and ethical approval in these three journals were
14 63.9% vs 43.4%, 64.3% vs 71.6%, and 68.5% vs 36.2%, respectively which is much
15 higher than other nine journals (from 2.9% to 17.0% in ethical approval) (Table 1). The
16 effectiveness of instructions to authors in improving the reported rates of ethical process
17 have been identified in previous research ²⁶. It is acknowledged that author guidelines
18 are an effective method to use to remind investigators to obtain and report ethical
19 approval and informed consent during a research, because they provide a clear guidance
20 about the format of the publication ³¹. Investigators were more likely to document
21 ethical approval, informed consent, or both when periodicals mentioned the
22 requirement in instructions ³⁰. However, author guidelines lack consistency, and some

1 international journals do not provide authors with relevant guidance. For example, a
2 literature review included 102 English-language biomedical journals identified that
3 only approximately 50% of periodicals mentioned ethical approval and only 10%
4 mentioned informed consent should be obtained in their instructions to authors ⁵².

5

6 In summary, adherence to ethical guidelines is expected and encouraged, but effort is
7 needed to ensure that ethical scrutiny is transparent. We recommended that authors
8 should provide detailed information in relation to the implementation of ethical
9 guidelines in paper. Furthermore, the in-house practices of periodicals also should be
10 assessed to ensure more robust methods are used to improve the reporting. Hence,
11 editors, researchers, publishers, sponsors, and authors all have an obligation to ensure
12 that ethics approval process are reported in the publication.

13

14 **Limitations**

15 The rate of reporting informed consent and ethical approval of this research relied on
16 self-reported data. Therefore, the process of consent and ethical assessment cannot be
17 collected explicitly. The potential bias that some clinical trials in accordance with the
18 ethical principle but did not report in articles, and anecdotally, ethical adherence may
19 be described but not necessarily approved as well as someone just mentioned it but did
20 not conduct in practice may exist. It was challenged to analyse the data in-depth, due to
21 the limitation of self-reported data in articles. However, the results from this study
22 clearly present the ethical situation of scientific nursing journals in China.

23

1 **Conflict of interest**

2 The authors have declared that no conflicts and competing interests exist.

4 **Author contributions**

5 Yanni Wu was responsible for all aspects of the research, including protocol design,
6 data collection and analysis, drafting, and revision of the article. Chunlan Zhou was
7 responsible for the protocol design of the research and Michelle Howarth helped with
8 the revisions of the article. Xue Ji, Jiexia Ou, and Xiaojin Li were assisted with the data
9 collection and analysis.

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