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# **Ethical considerations cited in child health research published in leading nursing journals: 2015-2019**

## **ABSTRACT**

**Background:** Child health research comprises complex ethical considerations. Understanding the extent to which the ethical process is reported in child health research is needed to improve reporting.

**Aims:** To identify reportage of ethical considerations in child health research in leading nursing and paediatric journals.

**Methods:** All child health research published between 2015 and 2019 in ten leading nursing journals and two paediatric journals were retrieved and critically appraised for the reportage of informed consent and ethical approval.

**Results:** Eight hundred and fifty-one child health research papers were included. Whilst 544 (79.9%) of the prospective studies mentioned informed consent, only 300 (55.2%) reported that written informed consent was obtained from the participants. Overall, 748 (87.9%) of child health research papers noted obtaining research ethics committee approval. Articles that mentioned financial support were significantly more likely to report informed consent and ethical approval than unfunded studies (all  $P < 0.001$ ). Prospective studies showed higher rates of reportage of ethical approval compared to retrospective studies ( $P = 0.027$ ). Rates of child consent (assent) obtained in different age groups of children ranged from 29.6% to 66.3%.

**Conclusion:** Despite improvements in the reportage of ethical review and approval processes in child health research, consistent and transparent reports are still lacking.

**KEYWORDS:** child, informed consent, ethical approval, publication ethics, research ethics

## **SUMMARY STATEMENT:**

### **What is already known about this topic?**

- Research related to child health has highlighted concerns about ethical and methodological considerations.

- Little work has systematically assessed the reportage of ethical considerations in child health research.

**What this paper adds:**

- To our knowledge, this is the first study to investigate the ethical considerations in child health research published in recent years.
- The research explored how ethical protections are performed and reported in child health research and identified that efforts from publishers and researchers still needed.

**The implications of this paper:**

- Strategies are still required to ensure the rights of children are upheld in medical research
- The significant ethical issues that attend engaging children in research and protecting their rights is, and must remain, priorities of medical researchers.

## **1 INTRODUCTION**

Given the rapid development of clinical research, the protection of human subjects has become one of the highest priorities of medicine (Bauchner and Sharfstein, 2001). Medical journals act as gatekeepers and play an essential role in the process to assure ethical considerations in publications involving human subjects. This duty is supported by international ethics standards such as the Declaration of Helsinki and the International Committee of Medical Journal Editors (ICMJE), which stipulate that publishers are obliged to uphold ethical principles and any reports involving human subjects that are not in accordance with the principles should not be considered for publication (International Committee of Medical Journal Editors, 2019). One major purpose of ethical review in publications is to make sure that informed consent and ethical approval has been obtained and reported in the research when possible (Yank and Rennie, 2002; Bauchner and Sharfstein, 2001). Despite the clear ethical reporting obligations, growing evidence has indicated that medical journals do not always meet these ethical reporting requirements (Fitzgerald, 2012; Lawrence, 2011; Murphy et al., 2015; Wu et al., 2017; Block et al., 2006).

Recent years have seen increasing clinical research related to child health conducted to improve healthcare for children (Helseth and Slettebø, 2004). Although the principles

of research are similar between adults and children, the ways to obtain parental informed consent, collect data, protect the confidentiality, and guarantee the rights of children are distinctive (Huang et al., 2016; Helseth and Slettebø, 2004; Kirk, 2007). For example, children are considered a vulnerable population, hence research that involves minors has aroused greater concerns about ethical and methodological considerations (Yank and Rennie, 2002; Huang et al., 2016). The Declaration of Helsinki stated that “*All vulnerable groups and individuals should receive specifically considered protection.....For a participant who is incapable to give informed consent, assent must obtain from the legally authorised representative*” (World Medical Association, 2013). These considerations have influenced investigations into the ethical challenges of child health research; for example, Bauncher and Sharfstein (2001) studied the child health research published in 1999 in five American journals and found that 40% of papers did not report ethical approval. Equally, Yank and Rennie (2002) reported that only 5% of studies involving vulnerable populations published after 1997 in five leading medical journals reported ethical considerations. More recently, similar findings were found by Dingemann et al (2011) who reported that only 16% and 54% of articles published in 2010 in three paediatric surgical journals mentioned informed consent and ethical approval, respectively. In conclusion, mounting evidence suggests that the reportage of ethical considerations in child health research still needs to be improved and reinforced by publishers and researchers.

Recent international efforts to encourage adherence to ethical standards in human research were published by the Committee of Publication Ethics (COPE) (2011) and the World Association of Medical Editors (WAME) (2011). Both COPE and WAME established ethical reporting standards and stated that medical journals should bear the social responsibility to promote routine reporting of ethical considerations in studies involving human subjects. However, evidence is lacking of investigations of ethical considerations published in contemporary child health research and it is unclear whether the recent efforts of international ethical institutions and editorial boards have achieved the desired results. Furthermore, in the context of nursing research, which has progressed rapidly in recent decades, numerous challenges have been highlighted especially for the regular conduct of soundly ethically-based research (Polit and Beck, 2004; Clark and Thompson, 2018; Chan, 2010). This may be due to inadequate education compared to other medical professionals, perhaps compounded with lack of ability and

ethical awareness in clinical research (Mohajjel-Aghdam et al., 2013; Freda and Kearney, 2005). Therefore, the ethical considerations of work in nursing publications may require particular scrutiny.

To address these gaps, following the work of Bauncher and Sharfstein (2001), we undertook this current study to review how ethical protections are performed and reported for child health research published within the last five years in leading nursing and paediatric journals. We aimed to identify reportage of ethical considerations in child health research in ten nursing and two paediatric leading journals.

## **2 METHODS**

### **2.1 Study design and data sources**

This was a bibliometric analysis. Child health research was included if it involved patients < 18 years old, clinicians who take care of children or pregnant women, based on the work of Bauchner (2001). Studies were published between 2015 and 2019 in ten nursing and two paediatric leading journals, identified in relation to their 2016 *SCI Journal Citation Reports'* impact factors. These twelve leading journals and their impact factors have been set out in Table 1. The two paediatric journals were chosen because these two journals are the top paediatric journals in the field of nursing, according to the 2016 *SCI Journal Citation Reports'*.

We excluded supplement published studies, conference abstracts, protocols, reviews, laboratory studies, letters, editorials, erratum/corrigendum, discussion papers, commentaries, and news. Studies were reviewed to identify the reportage of ethical considerations.

### **2.2 Data extraction**

Data were collected between August 2017 and May 2020. All publications in the 12 journals between 2015 and 2019 were browsed issue by issue for the five-year period. Each publication was reviewed independently by two research assistants (W.L.C and M.Y.H) according to the eligibility criteria and the results were recorded in a standardized data collection form, including the journal, publication date, first author, study type, participant type, and the items identified as ethical considerations. Papers that were recorded as not reporting ethical considerations were reviewed again by the third investigator (Y.N.W). Consensus was reached between the three reviewers for the

final results. Inter-rater reliability of data extraction was checked, with excellent agreement on the reportage of informed consent and ethical approval between the two reviewers (W.L.C and M.Y.H) ( $k > 0.95$  for all).

Following the work of Yank and Rennie (2002), where a paper stated that more details about the process of the research was described in an earlier, cited, paper, the earlier publication was also reviewed. It was acknowledged that previously reported and cited ethical considerations could be a plausible reason for omitting mention of ethical considerations in a later paper.

The primary outcomes of our research were whether or not ethical review/ approval and a process of informed consent were reported in each publication. First, it was accepted as adequate reportage of a process of human research ethical review and approval if it was overtly stated that the study was approved by an Institutional Review Board (IRB) or other ethics committee. We recorded whether the name of the IRB and the reference number of the approval was reported. Second, with regard to the informed consent process, only prospective studies were reviewed for this, in line with the work of Murphy (2015). Where the paper stated that consent was obtained from participants or the legally authorized representative, the study was categorised as having informed consent. The consent types reported (written, oral, other consent type, or waiver from an IRB) in each article were also recorded. Furthermore, the reporting rate of child consent/assent (where able) and parental or legally authorized representative consent were recorded and categorised into different age groups of children: including a) patients 0 ~ 7 years old, b) patients >7 ~ 12 years old, and c) patients >12 ~ <18 years old. The categories of these age groups were based on the World Health Organisation Ethics Review Committee (WHO ERC) guidelines which stated that “*while the age at which this informed assent should be taken varies, researchers should consider asking for assent from children over the age of seven years with assent taken from all children over the age of twelve years*”. For research involving children whose ages spanned more than one group, the ethical considerations of this research were collected in more than one group. For example, if a study enrolled children/ adolescents between the ages of 10 and 18, the reportage of informed consent/assent for this study was counted in both the >7 ~ 12 years old group and the >12 ~ <18 years old group.

Additional information was also identified including: (1) ethical statement – if it was stated that the research was carried out in accordance with the Declaration of Helsinki or other ethical guidelines; (2) whether the requirement to report ethical considerations for studies involving human subjects was explicitly stated in each journal’s instructions for authors; (3) the funding of each study; and (4) the research was categorised by type as either prospective or retrospective, following the work of Block (2006). Prospective studies involved randomized controlled trials, non-randomized trials, observational studies, single-arm, qualitative and mixed methods studies. Retrospective studies included chart reviews and database studies.

Differences were sought in the rates of reportage of informed consent and ethical approval by year, study types, and whether or not financial support for the research was mentioned.

### **2.3 Data analysis**

Data analysis was performed using SPSS 20.0 software (IBM, USA). Chi-square tests or Fisher’s exact tests (where cell size was less than 5) were used to test for differences in the rates of reportage of informed consent and ethical approval. All *P* values were two-sided, and  $P < 0.05$  was considered significant.

## **3 RESULTS**

### **3.1 Included studies**

A total of 7,054 records were identified from the 12 journals between 2015 and 2019. Of these, 6,203 records were excluded, including 3,629 human studies not related to child health, 12 studies not including humans, 1,056 reviews, eight research protocols, and 1,498 records of other types such as letters to the editor, editorials, discussion papers, errata/corrigenda, commentaries, news, and position statements. Overall, 851 child health research papers were included, of which 681 were prospective and 170 retrospective studies (the PRISMA diagram see Figure 1).

### **3.2 Reportage of ethical review and approval in child health research**

A total of 748 (87.9%) child health research articles published in the 12 journals referred to a process of ethical approval. Of those articles, 702 (93.9%) stated the ethical approval was obtained from an IRB and 46 (6.1%) mentioned the ethical approval was

waived or not required after assessment by a research ethics committee or according to the policy of the government. Notably, for the 702 articles that reported having ethical approval, 643 (91.6%) reported the name of research ethics committee and 284 (40.5%) provided the ethical approval reference number. A small number, 54 (6.3%), of these child health articles stated that the research was conducted in line with the requirements of the Declaration of Helsinki (Table 2).

The rates of ethical approval reported showed no significant difference across the publication years ( $X^2=0.751$ ,  $P=0.945$ ). However, the rates of ethical approval reported in studies that mentioned financial support were significantly higher than for unfunded studies ( $X^2=40.668$ ,  $P<0.001$ ). Prospective studies also showed significantly higher rates of reportage of ethical approval compared to retrospective studies ( $X^2=4.872$ ,  $P=0.027$ ) (Table 4).

### **3.3 Reportage of informed consent in child health research**

A total of 681 prospective studies were reviewed to examine the frequency with which informed consent was reported. Overall, 544 (79.9%) of the included studies mentioned informed consent. The rates of reportage in the 12 individual journals ranged from 55.0% to 100%. However, of these 544 articles, only 300 (55.2%) reported written consent and 27 (5.0%) reported oral consent obtained from the participants, respectively. Twenty papers (3.7%) reported use of other ways to indicate informed consent, such as ‘assent’ through returning questionnaires, attending for the research, or clicking informed consent blocks electronically. Notably, 190 (34.9%) of these studies only provided a generic statement such as “consent was obtained from all the participants” but did not report how consent was obtained. Seven (1.2%) articles stated that informed consent was waived, or not required, by an IRB or according to the policy of the government (Table 2).

The rates of reportage of child consent (assent) was 29.6% in studies which recruited children aged 0 ~ 7 years; 65.1% in studies recruiting children aged >7 ~ 12 years; and 66.3% in studies recruiting adolescents aged >12 ~ <18 years. The rates of reportage of parental or legally authorized representative consent were 63.7% in studies including children aged 0 ~ 7 years; 73.7% in studies including children aged >7 ~ 12 years; and 68.3% in studies including adolescents aged >12 ~ <18 years. The rates of reportage of



informed consent was 73.5% in studies involving clinicians who take care of children and 91.0% in studies involving pregnant women (Table 3).

The rates of reportage of informed consent showed no differences between different publication years ( $X^2=2.590$ ,  $P=0.629$ ). However, articles that mentioned financial support were significantly more likely to report informed consent than unfunded studies, at 88.7% vs. 69.8%, respectively ( $P<0.001$ ) (Table 4).

#### **4 DISCUSSION**

Our findings indicate that the reporting of ethical considerations in contemporary child health research published in leading nursing journals has improved from the results of prior studies which focused on similar populations (Bauchner and Sharfstein, 2001; Yank and Rennie, 2002; Dingemann et al., 2011). We found that 79.9% and 87.9% of child health research reported informed consent and ethical approval, respectively. However, whilst papers reported whether ethical approval had been obtained, they did not always adhere to the publishers' standards for reporting.

Despite the overall increase in rates of reportage of ethical protections of children in research, some findings were unexpected. Numerous international ethical guidelines have clearly stated that sufficient detail is required on patient consent and ethical approvals in research reports (World Medical Association, 2013; Merz, 2018; Robinson et al., 2007; The Committee on Publication Ethics, 2011; The World Association of Medical Editors, 2011). For example, the Committee of Publication Ethics (COPE) has stated that editors should question authors about how the participants' informed consent was obtained and make sure that the research has been approved by an appropriate body (The Committee on Publication Ethics, 2011). Furthermore, the Declaration of Helsinki has advised that consent is preferable in writing, and non-written informed consent has to be formally witnessed and documented, where written consent cannot be obtained (World Medical Association, 2013). However, our study found that 34.9% of child health research did not describe the ways in which consent was obtained; only 40.5% of studies which reported having obtained ethical approval provided the reference number, and nearly 10% of studies did not include the name of the research ethics committee. However, some journals may regard naming the committee as potentially risking breach of confidentiality for vulnerable populations. However, in summary,

although the rates of reportage have improved in recent years, there is still a need for more standardized and transparent reporting of ethical considerations in articles.

Further, the results of our study also illustrated the rapid development of network techniques, with the internet having become a new popular tool to engage participants and obtain consent. Use of the internet is an effective method to recruit participants from diverse backgrounds and improve the efficiency of research (Bonevski et al., 2014). However, it has been argued that engaging children and families online and obtaining informed consent through the internet is complex and could pose additional ethical risks, such as the inability to either conceal or validate responses (Hokke et al., 2018; Livingstone and Locatelli, 2012; Mychasiuk and Benzies, 2012; Grady et al., 2017; Haigh and Jones, 2005). Therefore, ethical guidelines are needed, particularly for research online that engages children and families, to address these issues and inform internet-based research.

Furthermore, although there is a broad consensus that assent should be sought from children to enrol in research in addition to gaining consent from parents, the current guidelines avoid reducing the age of consent. For example, the UK Royal College of Paediatrics and Child Health (2000) guidelines suggest that researchers should consider seeking assent from school age children who take part in research; the American Academy of Paediatrics guidelines suggest that assent should be sought from children from the age of seven, and that all children over 12 years need to assent in research (Shaddy and Denne, 2010). Our research categorized children into three age groups and found that rates of reported child consent (assent) were only 65.1% and 66.3% for the >7 ~ 12 years old and >12 ~ <18 years old groups, respectively. In 29.6% of studies where children aged 0 ~ 7 years were recruited, child consent (assent) was described as obtained where able. Furthermore, the rates of reportage of consent from parents or legally authorized representatives were similar among the three age groups of children, ranging from 63.7% to 73.7%. Taken together, these rates indicate that the current situation of child consent (assent) or parental consent in research involving children is not ideal.

Our results identified that articles which mentioned financial support were significantly more likely to report informed consent and ethical approval than unfunded studies. There are several possible explanations for these findings. Research that

receives funding is usually required to demonstrate to the funding body that it has received ethical approval, which could influence the standardisation of research processes to facilitate funded studies (Goldfarb, 2008). Conversely, the cost of obtaining ethical approval could deter researchers in seeking ethical review if funds were not available for this (Crooks et al., 1996). In our study, we did not differentiate between funding types, and simply identified studies that “mentioned financial support”, regardless of the source of funding. Prior work by Yank and Rennie (2002) analysed the rates reported according to different sources of funding, showing no statistically significant differences between different types of funding.

Instructions for authors are typically published by journals to guide authors when submitting a paper and also serve to influence the effectiveness of improvements to the reportage of ethical processes (Myles and Tan, 2003). Our study assessed whether each journal’s guidelines for authors stated the requirement that authors report studies’ ethical considerations. The results showed that all but two of the journals (the *Journal of Nursing Scholarship* and *Journal of Cardiovascular Nursing*) explicitly require authors to report their consent processes and ethical approval. However, only four of these ten journals specified the detail of consent and ethical approval required, such as requiring that the name of ethics committee, the approval number, and the consent type is reported in the methods section for research involving human subjects. Seven of the journals stipulated that authors should act in accordance with the Declaration of Helsinki when reporting human research, and most journal guidelines referred readers to the Committee of Publication Ethics (COPE) and the International Committee of Medical Journal Editors (ICMJE) research ethics guidelines. These results highlighted increasing concerns expressed by editorial boards of medical journals compared to earlier years (Amdur and Biddle, 1997; Wu et al., 2017). Despite these increasing concerns our study identified that, still not all journals state ethical reporting requirements in their author guidelines and most do not stipulate the detail required for publication. This may be one of the reasons why we found a predilection for nonstandard and often inadequate reporting of ethical considerations in included journals.

#### **4.1 Limitations**

There are some limitations to the present study. Firstly, we relied on reportage of ethical considerations in child health research publications. Therefore, it was not possible to be clear whether the ethical considerations that were reported in the article were actually addressed in practice, or vice versa. Ethical approval and informed consent processes may not have been mentioned yet been carried out. Secondly, the ages of children across the studies varied, which created challenges collecting the process of consent (assent) obtained from children or their parents, particularly where participants were children of different age groups. Finally, given the restrictions of time and resources, we only collected data from the last five years in 12 nursing and paediatric journals. However, the results of our study clearly indicate the reportage of ethical considerations of child health research in these areas.

## **5 CONCLUSION**

Despite study findings showing improvements in reportage of ethical processes in child health research compared to earlier work, efforts are still needed to promote the standardised and consistent reportage of ethical considerations in child health research publications, to promote and ensure the rights of children who are involved in research. Due to the many and complex ethical issues of engaging children in research, protecting their rights is, and must remain, one of the priorities of health research. Nursing and paediatric journals could and should play a greater role in promoting the adoption of ethical standards. They should assess their in-house practices and publish in their author guidelines detailed requirements of what they want to see as ‘best practice’ in reporting ethical processes. Journals should follow through, by prompting reviewers to seek this and ensuring it is provided in the material they publish. Researchers could and should pay more attention to ethical considerations in their child health research and authorship, to address the gaps shown in this study and the paucity of reportage of ethical process issues.

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