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ORIGINAL ARTICLE

Reporting of consent rates in critical care studies: room for improvement

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Abstract

Objectives: Reporting of consent rates in published articles is important to determine potential sources of bias and validity and generalizability of results. Our objective was to determine the percentage of critical care studies for which the consent rate was reported.

Study Design and Setting: We reviewed all articles published in eight medical journals in 2013. Studies meeting the following inclusion criteria were selected: (1) randomized controlled trial (RCT) or observational clinical study, (2) study population involving critically ill patients, and (3) part of the study occurring in an intensive care unit.

Results: A total of 1,871 articles were screened of which 156 were included. The consent rate was discernable in 30.8% of articles (48/156, 95% confidence interval: 24.1, 38.4) with a median consent rate of 86.9% (interquartile range, 71.6, 94.1). A statement on Research Ethics Board approval was included in 96.8% of studies. There was a significant difference in reporting of consent rates between RCTs and non-RCTs (58.70% vs. 19.09%, $P < 0.0001$).

Conclusion: Consent rates are reported in less than one-third of critical care studies. We encourage journals to require reporting of consent rates to improve interpretation, validity, and generalizability of critical care study results.

Keywords: Consent; Medical ethics; Critical care; Intensive care unit; Consent rate; Bias

1. Introduction

Hundreds of thousands of patients are admitted each year to critical care units worldwide [1]. These patients represent a vulnerable patient population in whom research is necessary to improve care. The performance of research studies involving all human subjects requires the procurement of informed consent from patients or their delegates [2]. This requirement is mandated by the Declaration of Helsinki [2] and is enforced by local Research Ethics Boards (REBs) and related legislation [3,4]. Most medical journals require authors to include statements on whether REB approval and written informed consent were obtained in their submitted manuscripts but do not require them to report the actual consent rate obtained in their study.

Obtaining informed consent from critically ill patients in intensive care units (ICUs) involves unique challenges specific to the ICU environment including the need for surrogate decision makers [5], time sensitive protocols [6,7], highly stressed families [5,8], and high mortality rates [9]. These difficulties result in variable consent rates [10,11] and potential selection biases of participants enrolled into critical care studies [12–14]. Variable or unknown consent rates make it difficult for researchers to determine sample sizes, budgets, and timelines for future studies. In addition, selection biases that may occur in studies with low consent rates lead to difficulties with interpretation and extrapolation of study results [12,13]. Therefore, to correctly interpret the results of a given study, it is important for researchers to explicitly report their obtained consent rates in their published manuscripts. We found two studies examining the reporting of ethics documentation in critical care publications; however, neither study documented the actual consent rates reported in the manuscripts reviewed [15,16].

Therefore, our objective was to determine the frequency of consent rate reporting in a sample of critical care studies published in 2013 in eight specific medical journals.

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What is New?

Key findings

- Reporting of consent rates in critical care studies occurs in only 30% of high-impact publications.
- Consent rate reporting in critical care studies is higher in North America than Europe and higher in randomized controlled trials (RCTs) than in non-RCTs.

What this adds to the literature?

- Documentation of consent reporting in critical care studies.

What is the implication and what should change now?

- The low rate of consent reporting in critical care studies raises questions about the validity and generalizability of their results
- Journals should implement policies to ensure that consent rates are reported in all publications.

2. Methods

We extracted data from all critical care studies published in 2013 from eight high impact medical journals to determine what percentage of studies reported their actual consent rates.

2.1. Journal selection

Given the large number of potential publication routes for critical care studies, the first step was to identify those publications seen as most relevant to physicians working in critical care. A computer-generated random sample of physicians was selected from the Canadian Critical Care Trials Group (CCCTG) out of a total of 112 eligible adult critical care physicians. Selected physicians were asked to list the 10 journals they used to keep up to date on critical care research. The CCCTG is a network of adult and pediatric critical care researchers in Canada dedicated to the advancement of critical care through research. We selected a consolidated list of the eight journals chosen by all 10 physicians from an initial list of 12 journals for our study. Given the concordance of these eight journals among the selected individuals, we elected not to sample a larger group of physicians. We a priori divided these journals into two categories: (1) general medicine journals which publish manuscripts from all fields of medicine and (2) critical care medicine journals which only publish manuscripts relating to the care of critically ill patients. The eight selected journals along with their impact factors are shown in Table 1. The impact factor of a journal is a measure published annually by Thompson Reuters Scientific's ISI Web of Knowledge which reflects the average number of citations to recent articles published in the journal and is used as an estimate of the relative importance of a journal within its field.

2.2. Study screening and selection

Given the potential for a large number of publications and for varying standards of reporting practice over time, we selected the most recent complete year of publication (2013) as our sample frame. All studies published in the above listed journals from January 1 to December 31, 2013, were reviewed for eligibility. Studies meeting the following inclusion criteria were selected for extraction: (1) randomized controlled trial (RCT) or observational clinical study, (2) a primary study population of critically ill patients, and (3) the intervention, main observation, and/or data collection occurred in an ICU. ICUs included general medical, general surgical, combined, neurosurgical, and high dependency units. We excluded manuscripts that: (1) were editorials, case reports, expert opinions, reviews, and retrospective or database studies not requiring patient consent or (2) included animals, neonatal patients, or primarily cardiac surgery patients. We excluded neonatal patients as evidence suggests that the neonatal intensive care environment is significantly different than other critical care environments [17] and because most neonatal research is published in distinct journals which were not the focus of this study. Studies on primarily cardiac surgery patients were excluded as they occur in homogeneous populations cared for in separate cardiac ICUs thus making them difficult to compare to the general medical/surgical ICU population.

The title of the article (and the abstract where necessary) was screened by two individuals (A.G. and K.M.) (kappa = 0.876), and disagreements were resolved by discussion. Full-text articles were obtained for records that had not been excluded during the initial screening and were reviewed by one reviewer (A.G.) to determine final eligibility. Thirty percent of all articles were randomly screened by one of two independent reviewers (K.O. or K.M.) to ensure accuracy of inclusion of articles (kappa = 0.982), and disagreements were resolved with discussion.

2.3. Data extraction

All eligible journal articles and supplementary appendices (where applicable) were reviewed by one of three reviewers (K.M., K.O., and A.G.), and data on the consent rate, consent type, and continent of origin were verified by a second reviewer (K.M.) for 119 articles. The following data were recorded from all articles: journal name, volume and issue of publication, title of study, first author, study design, continent of origin of first author (continents