

Nurse Author & Editor

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Moths to a Flame: How We Can Improve the Quality of Clinical Trial Reporting in Nursing Journals

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Patients consent to take part in clinical trials because they believe they are contributing to the advancement of medical and nursing knowledge that ultimately will lead to better patient care and treatment. They are almost certainly unaware that the results of only 50% of trials are ever published (Jones, 2013). The failure to publish has the potential to distort the evidence base, with potentially profound consequences; clinicians make decisions based on a partial understanding of the science with potentially tragic outcomes.

The All Trials (www.alltrials.net) movement was set up to campaign for all past and present trials to be registered and for their methods and results to be reported: all trials registered, all trials reported. To date 88,712 individuals and 682 organisations (including Wiley) have signed up to the campaign. In this paper I want to share some thoughts with fellow nurse authors and editors about how we can ensure that clinical trials done by nurses are reported to the highest possible standards.

HOW IS NURSING DOING?

With colleagues I recently published an audit of trial reporting in the *Journal of Advanced Nursing (JAN)* (Gray, Badnapurkar, & Thomas, 2016). Of the 44 trials published in *JAN* over the last 5 years, 70% were not registered. *JAN* is not unique; we have also audited the *Journal of Psychiatric and Mental Health Nursing (JPM)* (of which I am one of the editors) and the *International Journal of Nursing Studies (IJNS)*; currently the nursing journal with the highest impact factor). And the pattern is fairly consistent—only around a third of trials are registered, a handful prospectively (i.e. before the study started). Registration matters. It might be tempting, would it not, to reorder primary and secondary outcomes if results showed that intervention X did not, as expected, improve outcome Y but did enhance outcome Z. This practice is sometimes referred to as “hypothesising after the results are known,” abbreviated to HARKing. Trial registration helps minimise HARKing, publication bias, and selective reporting; it also helps increase awareness of similar studies and therefore reduces the chance of unnecessary replication. Why then are so few nursing trials registered? The most likely explanation is that investigators are not aware of the need to register their trial. In 2005, the International Committee of Medical Journal Editors (ICMJE) announced that their journals would not publish reports of trials unless they had been registered. This intervention has probably had more impact on trials registration

than any other. Nursing journal editors have yet to speak with the same collective voice.

DO WE RECOGNISE WE HAVE A PROBLEM?

Having recently reviewed well over 200 clinical trials published in leading nursing journals—in my opinion—the nursing scientific community of researchers, reviewers, and editors needs to make a concerted effort to improve the quality of trial reporting. Beyond issues with trial registration our audits revealed multiple cases of salami slicing (reporting a single trial in multiple papers) and serious issues with the quality of safety reporting. *JAN* needs to be commended for reflecting on the quality of trials it has published and for taking active steps to improve the quality of reporting.

WHAT IS THE GOAL?

As a community of nurse researchers we need to work together towards a shared goal of open and transparent reporting of all clinical trials. The question is, how do we get there?

1. Publish your protocol.

The trial protocol provides the foundation for the planning, conduct, reporting, and appraisal of a clinical trial. A well-written protocol enables a review of scientific, ethical, and safety issues before a trial starts. At the end of the trial it also allows the conduct of the study to be checked. Trial protocols should be easily accessible. A number of specialist (such as [Trials](#)) and more general (such as *JAN*) journals support protocol publication. Publication of protocols confers a number of important advantages; it is a permanent, locked record of what was planned that can be easily accessed and checked. There are guidelines, such as Standard Protocol Items: Recommendations for Interventional Trials ([SPIRIT](#)),

that can help researchers draft their protocols and ensure that minimum content of a clinical trial protocol are included (Chan et al., 2013).

2. Register your trial.

A clinical trials registry is a catalog for registering a [clinical trial](#). The first and largest is [clinicaltrials.gov](#); other widely used registries include the [EU Clinical Trials Register](#) and [ISRCTN](#). There is some variation as to what information is included in different registries. Typically registries will require details of the intervention, study hypothesis, outcome measures, eligibility criteria, key trial dates, recruitment targets, funding, and contact information for the principal investigator. The World Health Organization is working towards developing a consensus as to the minimal and the optimal operating standards for registration. It is hard to think of a justifiable reason why a researcher would submit a trial to a journal that has not been registered (even retrospectively). It is perhaps harder still to explain why so many unregistered trials have been published in nursing journals.

3. Explain amendments.

In our audits of nursing trials we found a number of discrepancies between trial registry entries and the published manuscript; for example primary outcomes had been changed or additional measures added. During the conduct of a trial amendments may need to be made—this is perfectly acceptable and happens during most projects (in my experience). In the spirit of transparent reporting, researchers need to provide justification as to why amendments were made. When amendments are made the trial registration should be updated. The details of amendments should be included in the manuscript reporting the trial findings.

4. Follow reporting guidelines (and ensure you report adverse events).

Many journals now require that authors follow CONSORT (consolidated standards for reporting randomised controlled trials; Schulz, Altman, & Moher, 2010). Even so there is evidence that authors are only partially compliant with all of the 30 items of CONSORT (Ghimire, Kyung, Kang, & Kim, 2012). Safety reporting is an important part of reporting and is an area where greater diligence is required. Safety reporting is the process of gathering information about adverse events so that it can be determined if an intervention under investigation may be causing unexpected harm. Adverse events do not seem to be reported in sufficient detail in nursing trials (Gray et al., 2016). Perhaps investigators do not consider that the interventions they are testing could potentially do harm. This is not their judgment to make. Researchers need to comply with Good Clinical Practice (GCP) guidelines which clearly state that investigators have a responsibility to record and report safety concerns (World Health Organisation, 2010).

5. Treat positive and negative trials equally.

This point applies equally to researchers, journal editors, and reviewers. Like moths to a flame, we are drawn to shiny new trials reporting groundbreaking findings. Prizes are not given to researchers for reporting (and journal impact factors are not boosted by publishing) negative trials. We cannot be like our insect cousins flitting from one bright light to the next. Researchers who do and editors who publish research have an absolute duty to ensure that all clinical trials are published. Some, particularly open access, journals (such as [PLOS](#)) have an editorial policy to publish based on the execution of the science not the novelty of the observation. It is—at least morally—hard to argue against this position that is perhaps one that nursing editors should choose to follow.

COMMENTS

All trials registered, all trials reported. We have a task ahead to encourage open and transparent reporting in nursing science. As nursing develops as a discipline we can expect to see an increase in the number of trials published in our journals. Editors, reviewers, and authors need to have a much greater awareness of the reporting requirements for clinical trials. Trials that have not been registered (noting registration can be retrospective) should not be published. This is something that journal editors can audit and is a metric that could easily be published (for example on the journal website). Patients take part in clinical trials because they are committed to advancing knowledge and helping others. Researchers do trials for much the same reasons. All trials—positive and negative—contribute to knowledge and clinical decision-making. We need to constantly remind ourselves of our duty to ensure the findings of our work are freely available for the benefit of the patients and communities we serve.

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