Advanced Emergency Nursing Journal
Vol. 39, No. 1, pp. 1–2

FROM THE
EDITORS

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Integrity and Transparency in Reporting Clinical Trials

Evidence-based practice has become an expectation in health care. In recent years, the retraction of studies based on scientific fraud and outright fabrication of data has been highly publicized in both popular and scientific literature. Although the repudiation of research due to scientific misconduct represents an obvious and egregious breach of professional integrity, these examples may represent only a small portion of the difficulties surrounding the incorporation of valid evidence into practice. Clinicians and students in all disciplines of health care are taught the importance of integrating the best evidence into clinical care; however, many health care providers don't realize that the data found in published reports of clinical trials may account for only a fraction of the research actually conducted (Song et al., 2010). Studies with negative or nonsignificant results are twice as likely to remain *unreported* as those with positive results (AllTrials, n.d.-b). The difference in findings between nonreported studies and reported studies of the same phenomena can have important clinical implications. Bias in the dissemination of outcomes represents a significant issue for health care providers and patients and may result in the adoption of treatments for which evidence actually supports a lack of effect. As a result, the risks of treatment may outweigh the benefits, particularly if the patient suffers an adverse effect or forgoes other, truly effective treatments. How can practice be truly "evidence-based" if all the evidence isn't available?

Efforts to provide oversight and improve the transparency of clinical trials are underway. Launched in 2013, the AllTrials Initiative is designed to raise awareness and promote policy change with the succinct goal statement of "all trials registered, all results reported" (AllTrials, n.d.-a). AllTrials is supported by multiple organizations, journals, publishers, and almost 90,000 individuals from around the world (AllTrials, n.d.-a). Historically, compliance with requirements for registering and reporting clinical trial results has been poor in the United States, but progress is being made here and in several countries. In September 2016, the U.S. Department of Health and Human Services (DHHS) issued a rule specifying requirements for registering and reporting clinical trials (Clinical Trials Registration and Results Information Submission, 2016; Zarin, Tse, Williams, & Carr, 2016). The National Institutes of Health (NIH) issued a complementary policy for all NIH-funded studies (National Institutes of Health Policy on the Dissemination of NIH-Funded Clinical Trial Information, 2016). The NIH policy will use multiple strategies to clarify and expand requirements for registration of clinical trials

Disclosure: *The editors report no conflicts of interest.*
DOI: 10.1097/TME.0000000000000136

and reporting of results in the *ClinicalTrials.gov* database (Hudson, Lauer, & Collins, 2016). The *European Medicines Agency* has even more stringent rules that require pharmaceutical companies to provide detailed reports about study methodology and results (European Medicines Agency, 2014).

In their roles as researchers and consumers of research, nurses can play a valuable part in the origination, critical appraisal, and application of evidence in patient care. The first step is to visit www.AllTrials.net and sign the petition supporting the need for improvements in transparency of clinical trial registration and reporting. Encourage other individuals and organizations to also sign the petition. The International Academy of Nursing Editors (INANE) signed on as a supporter stating,

> It is likely that most nurses as well as most physicians are unaware of the depth and breadth of the gaps in the scientific literature with regards to clinical trial results. Only when we have all of the information can we make sound, informed decisions about patient care. (AllTrials, n.d.-a).

The *Advanced Emergency Nursing Journal* (*AENJ*) editors have signed on as individuals. The *AENJ*, the *Journal of Emergency Nursing*, the Emergency Nurses Association, and the American Academy of Emergency Nurse Practitioners have signed on. The petition is used as evidence of support when governments and organization make decisions about trial registration and reporting.

Researchers are integral both to the success of this initiative and to the integrity of the research process. If you are a participant in the design and implementation of clinical trials, familiarize yourself with the DHHS and NIH requirements. Educate other members of the research team and strive to comply with best practices as outlined by the NIH and other bodies. At a minimum, ensure the study is registered before participants are enrolled and that the results are reported within a year of trial completion.

As nurses, we are committed to the health and well-being of our patients. Decisions about practice must be based on *all* of the evidence, and integrity in the research process is an imperative. As editors of nursing journals, we recognize our role in research evaluation and dissemination. We are committed to implementing the requirements for trial registration and reporting in our respective journals.

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