AUSTRALIAN
MEDICAL STUDENTS'
ASSOCIATION

Policy Document

Research (Trial Registration and Reporting) Policy

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Background

The Australian Medical Students' Association (AMSA) is the peak representative body for Australia's 17,000 medical students. AMSA believes that best medical practice and decision-making is necessarily supported by evidence-based medicine. Accordingly, AMSA actively seeks to advocate on issues that may compromise the completeness and validity of the evidence base for clinical decision making, in the interests of the broader community.

The most updated review on the dissemination and publication of clinical trials provides strong evidence to suggest that more than half of all clinical trials go unpublished and further, that trials yielding negative results regarding particular treatments are far less likely to be published. A major 2010 systematic review on publication related biases concluded that "dissemination of research findings is likely to be a biased process"[1]. These estimates are made possible by the advent of clinical trial registration.

This kind of publication bias not only limits medical knowledge and understanding of treatment and disease, but has extensive ethical implications for patient safety and exposure to avoidable risk. Above all, the current situation greatly impairs the ability of doctors and other medical professionals to deliver truly informed patient care, perpetuating the somewhat false reassurance of "evidence-based medicine".

Article 30 of the Declaration of Helsinki, the cornerstone of human research ethics, states that "authors have a duty to make publicly available the results of their research on human subjects …negative and inconclusive as well as positive results should be published or otherwise made publicly available"[2]. In January 2013, the British Medical Journal underscored these sentiments, stating "the responsibilities of authors are clear. The Helsinki Declaration leaves no room for ambiguity", and that "there is clear and consistent evidence of under-reporting and manipulation of the scientific literature"[3].

A driving force behind the issue of research dissemination is the lack of incentive for companies and researchers to comply with existing mandatory reporting guidelines. In 2007, the United States Food and Drug Administration (FDA) introduced regulations under the US government FDA Amendment Act which mandates compulsory publication of a results summary on the ClinicalTrials.gov database for most FDA-approved trials. A 2012 cross-sectional study published in the British Medical Journal found a compliance rate of only 22% after four years, with no punitive ramifications for the researchers who failed to comply with the law[4]. This follows the failure of previous efforts by the International Committee of Medical Journal Editors to uphold a 2005 promise to publish only registered clinical trials[5].

Position Statement

The publication of all clinical trials is crucial to the expansion of the scientific knowledge upon which evidence-based medicine and sound clinical decision-making is based. As such, AMSA believes that all clinical trial results should be published.

Policy

1. AMSA believes that:
    a. Current rates of publication of registered clinical trials are inadequate and undermine the ability of medical practitioners to make sound clinical decisions grounded in evidence-based medicine.
    b. All clinical trials should be published, regardless of whether they are positive, negative, conclusive or inconclusive.
    c. Health professionals, medical and health sciences students, university researchers and academic staff are in a favourable position to support campaigns which seek to strengthen health science research and the practice of evidence-based medicine.

2. AMSA supports
    a. Appropriate campaigns which advocate for the full and transparent publication of all clinical trials regardless of the completeness or nature of the results.
    b. The mission of the WHO International Clinical trials Registry Platform (ICTRP)to facilitate the registration and public accessibility of all clinical trial data.

3. AMSA calls upon:
    a. All Australian medical students and health professionals to advocate for the publication of all clinical trials in their respective capacities.
    b. All those that sponsor or conduct research such as pharmaceutical companies, universities, laboratories, health professionals and medical students to uphold their ethical responsibilities as researchers by registering all clinical trials and providing full and easy access to the publication of the results and associated data sets of these trials.
    c. Publishers of medical journals to enforce stringent requirements for registration of all clinical trials seeking publication and open access to all results.
    d. Human Research Ethics Committees to require compulsory registration of clinical trials for approval.
    e. The Australian Government to legislate for:
        i. The compulsory registration of all clinical trials with a publicly accessible registry.
        ii. The compulsory publication of all completed and registered clinical trials, whether conclusive or inconclusive.

References

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[2] WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (2008) World Medical Association http://www.wma.net/en/30publications/10policies/b3/

[3] Chalmers, I., Glasziou, P., & Godlee, F. (2013). All trials must be registered and the results published. BMJ, 346. doi: 10.1136/bmj.f105

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[5] Mathieu S, Boutron I, Moher D, Altman DG, Ravaud P. Comparison of Registered and Published Primary Outcomes in Randomized Controlled Trials. JAMA. 2009 Sep 2;302(9):977–84. http://jama.jamanetwork.com/article.aspx?articleid=184503

Policy Details

Name: Research (Trial Registration and Reporting) Policy

Category: F – Medicine in Australia

History: Adopted, Second Council, 2013