## **Policy Document**

# **Research and Reportage**

## **Position Statement**

AMSA believes that:

- Medical students and doctors should engage in evidence-based medicine (EBM) to ensure safe and high-quality patient care, whilst acknowledging and addressing its limitations in practice;
- 2. EBM is an integral part of medical education across all stages of a doctor's training and should be taught comprehensively;
- 3. In order to ensure a sufficiently wide evidence base for clinical practice, research should be conducted on the unique health challenges faced by underrepresented groups, including, but not limited to, women, people from culturally and linguistically diverse backgrounds and Aboriginal and Torres Strait Islander people;
- 4. There should be greater diversity of participants in clinical trials to increase the applicability of findings to all population subgroups;
- 5. Research should be conducted to the highest standards of integrity and rigour, including:
  - The minimisation of publication bias, especially for industry-funded studies, through advance publication of protocols for clinical trials to enable the detection of selective publication of results;
  - b. Adherence to high standards of self-regulation by researchers to prevent research misconduct;
- 6. All publicly and privately-funded scientific and scholarly output from research should be made Open Access (OA), and;
  - a. Where possible and where appropriate consent should be obtained from human participants for associated datasets to be freely available alongside scientific and scholarly articles to ensure that any secondary research carried out is ethical;
- 7. The Government and other funding agencies should play a role in promoting research transparency, integrity, and accessibility;
- 8. The increasing research expectations for medical students place undue pressure on students and research should instead be undertaken for its benefits to medical education;
- 9. Participation in research can benefit medical students during their studies and future practice, and as such:
  - a. Extra-curricular involvement in research should be accessible to medical students should they wish to pursue it;
  - b. The provision of good mentorship and support systems is key to students' research experiences;
  - c. Medical schools should play a role in defining relationships and setting expectations between researchers and students so as to create transparency and prevent exploitation;
  - d. More feedback is necessary to understand the experiences of Australian medical students undertaking research and allow improvements to be implemented accordingly.

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### Policy

AMSA calls upon:

- 1. The Australian government to:
  - a. Mandate the OA publication of results pertaining to projects, whether publicly or privately funded;
  - Devise and enforce guidelines detailing diversity of research participation and the recruitment of representative subgroups to which the research pertains;
  - c. Allocate more resources and funding for research involving participants who are currently under-represented in clinical trials;
  - d. Encourage the release of raw data from research where appropriate and ethical.
- 2. Australian higher education institutions and other bodies conducting research to:
  - a. Encourage an environment of self-regulation for research misconduct and of scientific rigour;
  - b. Implement systems to support and monitor institution-wide compliance to OA policy;
  - c. Provide staff and students with the appropriate education and training necessary to uphold OA policy standards in their research outputs;
  - d. Offer sufficient extra-curricular research opportunities to medical students;
  - e. Develop policies to help researchers and medical students understand their respective roles and expectations in research endeavors;
  - f. Collect feedback from medical students about their experiences in research and act on it accordingly;
  - g. Provide detailed ethical guidelines on participant recruitment in clinical trials, with particular focus on participant rights and representation;
  - h. Assess the quality of EBM teaching at their institution and adjust their curriculum accordingly;
  - i. Expose students to research environments that teach them the importance of research integrity, whilst reiterating the need to critically appraise research.
- 3. Researchers and/or Academics to:
  - a. Continue conducting research with high scientific rigour and validity, including the advanced publication of protocols for clinical trials to ensure transparency of post-trial publications where appropriate;
  - b. Be aware of any OA policy of their institution and its associates;
  - c. Where the above does not currently exist, initiate and support action to implement policies supportive of OA at their institution and its associates;
  - d. Publish in OA journals, deposit manuscripts in OA repositories, and ensure underlying data is openly available where appropriate, and where prior consent has been obtained from research participants;
  - e. Advocate for the publication of all clinical trials in their respective capacities;
  - f. Ensure participant information contains simplified English with minimal jargon, and that information is translated when necessary;

- g. Ensure that research involving diverse and vulnerable populations is of benefit to the populations being studied, and is conducted in a fair, respectful and appropriate manner;
- Recognise that research with Aboriginal and Torres Strait Islander people should be based on mutual trust, respect and shared values and complies with the Ethical Conduct in Research with Aboriginal and Torres Strait Islander Communities Guidelines;
  - i. Advocate for community-led Indigenous research via roles such as chief researcher or research team members;
- i. Investigate barriers to the implementation of EBM in clinical practice and conduct research to guide evidence-based solutions;
- j. Commit to best-practice mentorship of students undertaking research.
- 4. Companies and organisations that fund and/or sponsor research to:
  - a. Ensure the the advanced publication of protocols for clinical trials to ensure transparency of post-trial publications where appropriate;
  - b. Advocate for the inclusion of negative result studies and to encourage the release of raw data from research where appropriate and ethical;
  - c. Secure an undertaking from researchers that they will publish in OA;
  - d. Invest in programs that support the transition to OA;
  - e. Base research funding to include priority areas as identified by clinicians, such as women's health, mental health, migrant health, Aboriginal and Torres Strait Islander health, as well as rural outcomes.
- 5. Medical Students to:
  - a. Engage with existing and forthcoming research;
  - b. Appreciate the importance of research undertaken with integrity and rigour;
  - c. Engage with research vigilantly and critically;
  - d. Engage in informed and judicious use of the evidence when practising EBM.
- 6. Specialty training programs to:
  - a. Reduce the pressure on medical students to produce research during their medical degrees.
- 7. The AMSA Executive to:
  - Advocate to their peers and the wider community on the necessity of OA;
  - b. Educate their peers and the wider community on the feasibility of transitioning to a predominantly OA system;
  - c. Encourage more feedback to better understand the experience of Australian medical students involved in research;
  - d. Advocate for appropriate support and mentorship of students undertaking research;
  - e. Advocate for flexibility for students furthering their professional development through research in an extra-curricular capacity, including access to conference leave.

## Background

The Australian Medical Students' Association (AMSA) is the peak representative body of Australia's 17,000 medical students. AMSA believes that best medical practice and decision-making is supported by evidence-based medicine (EBM). With the recognition

that the quality of research that doctors can access directly influences the quality of care they can provide, AMSA actively seeks to advocate on issues that may compromise the validity and accessibility of the evidence base for clinical decisionmaking, as well as the ability of doctors to critically appraise and apply this evidence. Additionally, AMSA recognises the benefits of research experience for medical students, both intra- and extra-curricular, and seeks to advocate for a positive and fruitful experience that is transparent, non-exploitative and bestows appropriate acknowledgement upon medical students.

#### What is good research?

The National Health and Medical Research Council (NHMRC) defines high-quality research as research that is [1]:

- Rigorous uses robust scientific methods and avoids or acknowledges biases
- Transparent research findings and methodologies and supporting data are made openly accessible, and shared responsibly and accurately
- Conducted with accountability in accordance with relevant legislation, policy and guidelines
- Innovative the need for both novel research and replication studies is balanced
- Efficient there is timely reporting and synthesis of research

#### Research integrity and academic misconduct

According to the NHMRC Research integrity and misconduct policy, the primary responsibility of researchers is to conduct research with integrity [2]. However, the prevalence of research misconduct was estimated to be 0.3% to 4.9% in 2017 [3]. A 2009 study by Fanelli found that around 2% of scientists admitted to fabrication, falsification or plagiarism in their work, whilst one third of scientists admitted to committing "questionable research practices" [4].

The Australian Code for the Responsible Conduct of Research calls on research institutions to provide ongoing training that supports responsible research conduct [5]. In fact, the NHMRC defines it as misconduct if institutions do not engage in this responsibility [2].

Enforcing higher standards of self-regulation could be an effective method of preventing research fraud that allows for more research freedom compared to increasing legislation [6]. Scientists should therefore hold themselves to higher standards of accountability.

#### Participant diversity in clinical trials

Increased participant diversity in clinical trials would produce more effective therapies and enable equal access to such treatment, upholding the medical principles of justice, advocacy and advancing knowledge [7].

In Australia, minority groups including Aboriginal and Torres Strait Islander people, people from culturally and linguistically diverse (CALD) backgrounds, the elderly, and women, tend to have less participation in clinical trials [8,9]. Approximately 15% of the Australian population is over the age of 65, with 20% of them identifying as CALD [10,11]. Furthermore, Aboriginal and Torres Strait Islander people make-up 3% of the population and need to be accounted for in research settings [8]. Collectively, the outcomes of clinical trials lack the ability to be generalised due to under-representation of these groups resulting in a lower standard of care and inequity [9]. This prompts the questioning of the overall translation efficacy of clinical trial outcomes to medical practice.

It is important to recognise that there has been a history of ill assumptions surrounding Aboriginal and Torres Strait Islander culture and values following colonisation of Australia. These errors in judgement have continued to have long lasting effects, and it is therefore critical that the diversity within Aboriginal and Torres Strait Islander communities be appreciated [12]. Certain guidelines such as the Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities have been put in place to ensure that research involving such participants is meaningful and ethically sound [13].

Current guidelines from the National Statement of Ethical Conduct in Human Research state that research should be "just" and that the "process of recruiting participants is fair" [14]. However, there is no description of what constitutes "fair recruitment", which threatens the effectiveness of these guidelines. For example, 20% of clinical trials in Australia continue to exclude participants based on English literacy and proficiency, despite 19% of the population identifying as having a first language other than English [15,16,17]. Therefore, guidelines about the diversity of participants in clinical trials need to be reinforced and facilitators to language barriers need to be explored. These include translated participant information and the use of simplified English language [9].

Additionally, research must be conducted in areas of clinical importance and relevance. Currently, in Australia, clinicians have argued that there is not enough government funding for research in key neglected areas such as women's health, mental health and rural health [18,19]. By directing funding, governments can guide research priorities by involving underrepresented stakeholders, and can reduce selection bias by requiring funded researchers to represent the demographics of the population [20, 21, 22]

#### Industry funding in medical research and bias

Industry funding plays a key role in medical research and innovation and is undoubtedly playing a key role in improving healthcare practices and technologies. Nonetheless, it is critical to view industry-funded research with caution. It has been illustrated that studies sponsored by industry are poorly designed and report more favorable results relating to efficacy than studies funded from other sources, whilst unfavorable data is not published for the purpose of bolstering the financial interests of the for-profit organisation [23,24,25].

Publication bias results in the availability of data to not be representative of all the collected data [26]. This distorts the results of meta-analyses and systematic reviews which EBM is reliant upon [27]. There are a variety of factors that influence the decision to publish, such as [28]:

- Acquiring insignificant results from small studies
- The researcher(s) deciding not to publish due to negative results
- Journals rejecting articles with negative results
- Researchers not publishing due to study results going against the sponsors' expectations

One method to improve research quality and transparency is the advanced publication of study design for clinical trials prior to commencement. Although current agencies require publication of protocols to registries (including ClinicalTrials.gov), it is not peer reviewed, and generally lacks extensive detail. Advanced publication in peer-reviewed journals would facilitate the improvement of study design, ensure transparency in study protocol and reporting which leads to increased quality of results [29].

#### **Open Access (OA) research**

Research and the dissemination of knowledge are central to the progression of every field of academia, yet traditional methods of publishing restrict access to those who can afford to pay subscription. This is the status quo, even for most research conducted

through private, public, or other public interest sources such as charitable organisations [30].

Open Access (OA) refers to "the removal of major obstacles to accessing, sharing and re-using the outputs of scholarly research" [31]. The OA movement offers numerous advantages. Researchers benefit from having the widest possible audience whilst preserving the author's right to proper acknowledgement [30]. Hoarding research in subscription journals serves only to hinder EBM, and neglects our moral duty to make research freely accessible to the public.

Reflecting this ambition, there are currently over 700 OA mandates and policies recorded worldwide from a range of funding bodies and research institutes [32]. Within Australia, institutions such as the National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC) have contributed significantly to our current OA repositories. The NHMRC mandates OA sharing of publications funded by their financial scheme [33]. Likewise, the ARC specifies a 12-month period in which funded research must be made openly accessible [34]. Privately funded research is following similar trends. The proportion of OA papers published by twenty three large drug companies have almost doubled between 2009 and 2016 [35]. They have "overtaken the proportion of freely available papers published generally in medicine-related fields" [36]. Despite these well-defined policies, compliance remains an ongoing issue.

Furthermore, one of the main criticisms of OA is its financial viability. However, research indicates this transformation could be a cost-neutral process where funds currently invested in the subscription system could be successfully and sustainably re-purposed for OA publishing [30,35].

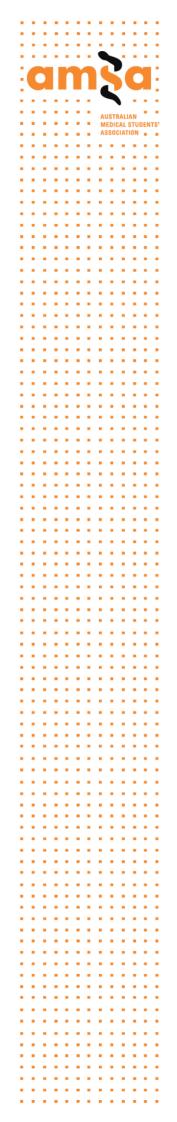
#### Importance of evidence-based medicine

With medical knowledge constantly evolving, clinicians must keep up-to-date with the latest developments to provide their patients with the best possible care in accordance with the principles of EBM [37]. EBM involves the integration of clinical expertise, patient values and best available evidence within the broader healthcare context. The five-step process of EBM is [38]:

- Translation of uncertainty to an answerable question
- Systematic retrieval of best evidence available
- Critical appraisal of evidence for validity, clinical relevance and applicability
- Application of results in practice
- Evaluation of performance

EBM is essential for the provision of quality patient care. For example, 'low-value care' occurs when interventions with evidence for very little to no benefit, a risk of harm that exceeds the likely benefit or costs that are disproportionate to its benefits are delivered to patients, such as stent placement for stable coronary disease and arthroscopy for knee osteoarthritis [39]. These have a negative impact on both patient outcomes and healthcare system efficiency. As such, medical students and doctors have a moral obligation to practise in accordance with the principles of EBM to uphold their duty to provide safe and high-quality care to their patients.

To facilitate the process of EBM, pre-searched, pre-appraised resources such as Cochrane systematic reviews and evidence summaries have been developed for use by time-poor healthcare professionals [38]. However, the practicality of EBM, and other concerns surrounding its use in everyday medical practice, have been raised [40]. For example, the assumption by clinicians and evidence-based guideline creators that statistical significance automatically translates to clinical significance; the overemphasis on following algorithmic rules and technology-driven prompts that may detract from patient-centred care and substitute expert judgement; and the difficulty in



applying guidelines about a single condition to patients with multiple comorbidities. These concerns should be acknowledged and addressed in turn by clinicians and researchers.

#### Application of EBM in practice

Despite the importance of EBM being widely recognised, it has been shown not to be consistently applied at the point of patient contact [41].

EBM is widely considered a core competency for health professionals of every kind, and has been increasingly integrated into undergraduate, postgraduate and continuing professional education healthcare curricula in recent decades [42]. For example, the Australian Medical Council requires that medical school programs "equip graduates for evidence-based practice and the scholarly development of medical knowledge" to meet their accreditation standards [43]. Despite this, insufficient knowledge and skills in EBM remains one of the most significant barriers to its implementation, potentially due to inconsistency in the quality and content of teaching. For example, courses often only focus on one of the five steps in the five-step process of EBM, such as critical appraisal, whereas all should be taught and evaluated in trainee healthcare professionals [38].

Whilst multiple resources on teaching EBM have been developed to guide healthcare educators and hundreds of articles published on the topic, recent reviews evaluating EBM education point to poor uptake of the existing resources [41]. Further investigation into the quality of EBM education across medical schools and beyond and reasons for the inconsistent uptake of EBM is required.

#### Medical student involvement in research

There has been significant concern around the increasing requirement of research for progression along the medical training pathway. Creed et al. report increased stringency of requirements for entry into medical specialties that are viewed as more 'prestigious' [44]. Specialty training programs have an expectation that their applicants can demonstrate a long-held commitment to research [45].

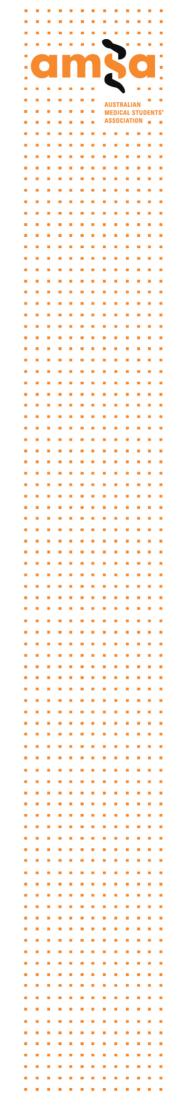
Whilst this credential inflation is unfavourable, research experiences can present benefits for students if completed under the appropriate circumstances and without undue career pressure.

The involvement of medical students in research strengthens the medical field by consolidating students' appreciation of EBM and their role as not only consumers, but contributors to the evidence base [46]. It also teaches valuable skills – such as research literacy and teamwork – to complement a theoretical education [47].

However, a barrier to medical students' involvement in research is the lack of established expectations surrounding research opportunities [48,49,50]. Students can lack clarity as to how to seize research opportunities earlier, and then as to what is expected of them [49]. In turn, it is often ambiguous as to what students might expect in return for their research. This pertains to: credit received, authorship attributed, hours demanded, support provided, learning opportunities offered and more [50].

In order for medical students to thrive in research they need support from relevant stakeholders. However, current infrastructure does not adequately provide this support; students report uncertainties around how to get involved, the lack of time, difficulty organising projects and finding mentors, inadequate skills or training, as obstacles to research involvement [48,49].

Provision of good mentorship is another key feature of the students' support system. Students require attention and investment from their supervisors in order to achieve best outcomes, and so increasing the quality and quantity of mentors is integral to fostering healthy and impactful research experiences [51].



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#### **Policy Details**

Category: H – Ethics

**History:** 

Reviewed, Council 1, 2020 <u>Mary Malek</u>, <u>Eeleen Tey</u>, Akhilesh Ayalasomayajula, Wilhelm Christen Fernando, Shahmza Merani, Terra Sudarmana, Melissa Maysa Younes, Travis Lines (National Policy Officer) ASSOCIATION

Adopted, Council 3, 2016 as an amalgamation of *Research* (*Open Access*) 2013 and *Research* (*Trial Registration and Reporting*) 2013

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