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Round Table: The Ethics of Sponsorship



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Divestment or management? Organisational ethics and commercial sponsorship.

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This edition of the Australasian Epidemiologists' roundtable asks the question whether the AEA should accept sponsorship for conferences and events from commercial organisations. There has been concern expressed in the academic literature, by the public, and by some individuals and professions about the extent to which the activities of professional associations are or can be influenced by corporate funding. These concerns raise important questions about the ethics of organisations recognising that 'moral demands exist not only on the individual but also on organizations, systems and institutions.' The field of organisational ethics provides a framework to enable organisations to evaluate whether the organisation's practices are consistent with its professed values. A professional association represents the values of its members and is the public face of a profession. Accordingly, this raises a question for an organisation about how it can model best practices for its members and how it can maintain the trust of the public in the profession. As Brody notes "Trust is a delicate matter that often depends as much on appearance as on reality." The AEA states that one of its aims is to develop "strategic alliances with related organisations to maintain high standards of public health practice, teaching and research in Australasia". If the 'maintenance of high standards of public health practice' is a central organisational value for the AEA then it is important to examine whether the receipt of sponsorship from commercial organisations has any potential to give rise to a perception that the organisation might put aside its primary interest to further its sponsor's interests and in so doing compromise the trust vested in the organisation and the profession by society. It is not a given that both parties to a sponsorship transaction are motivated by the public good; a commercial organisation's primary motivation is generally to sell a product or a service to further the private good of its shareholders and a professional association's is to make recommendations on public health-related issues based on evidence.

As Brody notes, there are essentially two possible approaches to the question of whether to accept industry sponsorship. The first is a divestment strategy where no sponsorship is accepted from commercial organisations, generally so as to maintain the public's perception that the association is a trustworthy source of information. The second is a management strategy where sponsorship may be accepted under certain conditions; conditions designed to limit the degree of influence the commercial organisation has on the professional association's

functions and to maintain the integrity of the organisation. There are a variety of strategies suggested as to how best to do this, but many focus on disclosure. The challenge is that some evidence suggests that, as Kirkland notes, "neither awareness nor disclosure is adequate to negate the potential influences of relationships between individuals with conflicting interests".

Parkin and Paul start off the discussion by arguing for a divestment strategy – that the AEA should not under any circumstances accept pharmaceutical industry sponsorship for scientific meetings and other events. Parkin and Paul focus on the risks to the AEA's integrity from receiving industry sponsorship. They argue that the refusal of sponsorship from pharmaceutical and vaccine companies is critical to maintaining and enhancing the reputation of the AEA as an advocate for robust scientific practices and for beneficial public health policies and argue that accepting funding may compromise AEA's independence. Drawing on his experience as President of the International Society for Behavioral Nutrition and Physical Activity, Crawford argues that professional associations should carefully consider the benefits and costs of accepting industry sponsorship, highlighting the important of perceptions of independence when professional associations advocate for particular issues.

The remaining authors argue for a management strategy: that the AEA should continue to accept conference-related sponsorship from commercial companies if certain conditions are met and certain rules abided by. Accordingly, in the third Roundtable paper Raynes-Greenow suggests that there is an important difference between industry funding of research and industry funding of conferences. The former creates conflicts of interest shown to distort the results of such research. The latter, she argues, creates potential conflicts of interest that are manageable by conference organisers through the usual structures of conferences and the institution of certain practices, including disclosure, not accepting sponsorship from certain types of sponsors, seeking multiple sponsors, and maintaining standards for the organisation of conferences. Le Jian also argues that sponsorship can be accepted as long as the AEA considers whether the products or services that the company produces broadly align with the AEA's public health-related mission. Naggan suggests that the reality is that commercial sponsorship funds much research. Such research must be disseminated and this may be supported by commercial organisations as long as

independence is preserved. Diug advocates the development of guidelines in respect of the relationship between professional organisation's and commercial sponsors.

This roundtable discussion has illustrated some of the issues that arise in the context of determining whether the AEA should accept any form of sponsorship from commercial organisations. It has also illustrated a variety of opinions on whether the AEA should adopt a divestment strategy (i.e. accept no sponsorship) or whether it should adopt a management strategy, and what the components of that strategy should be. An organisational ethics perspective would suggest that it is important that the AEA clarify how its values, mission and objectives may be affected by commercial sponsorship and develop a policy to address this issue to provide clarity and certainly to its members, to the public and other interested stakeholders, and to potential sponsors.

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Round Table

Should the AEA accept pharmaceutical industry sponsorship for annual scientific meetings and other AEA related events: the argument against

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Sponsorship reduces the cost of scientific meetings to participants. Few people who attend AEA meetings or other events prescribe medicines, so there is little risk that industry influence will compromise clinical decision making. Further, pharmaceutical manufacturers are not 'dangerous consumption industries' like the tobacco, alcohol, and gambling industries. As well as valuable medicines, pharmaceutical companies produce vaccines which contribute greatly to improving public health. And maybe the potential for bias in research is ubiquitous, in which case it would be wrong to single out the influence of the pharmaceutical industry.

There are arguments of this sort in favour of pharmaceutical industry sponsorship that deserve to be taken seriously. We address these in arguing the case against, below. We draw on principles that have been developed by professional medical associations and by researchers contending with the effects of dangerous consumption industries,^{1,2} while focussing on the core values and activities of the AEA.

We focus on the AEA as a collective body of epidemiologists and the risks to the perceived integrity of our professional association. Individual AEA members may receive funding from the pharmaceutical industry for research, but that is a separate matter not dealt with here, and there is no implication that our conclusions relate to individuals. Concerns about scientific independence can arise in relation to industry-funded research, but the issue is complex and the extent of these concerns depends on the nature and directness of the link between the funder and the researchers.

We also focus on pharmaceutical industry sponsorship because our work in the field of post-marketing surveillance of medicine safety has inevitably made us more familiar with the potential problems this source of funding might bring. AEA members working in other fields will be more acquainted with threats to perceived integrity that might arise from sponsorship by other commercial entities such as manufacturers of unhealthy foods or beverages than we are. However, we suspect that many members would argue that sponsorship of AEA events by fast food manufacturers would be inappropriate. We suggest that acceptance of pharmaceutical industry sponsorship might similarly be a 'bad look'.

The vision of the AEA is 'excellence in epidemiology' and the mission is to be a member-focussed organisation of professionals dedicated to excellence in epidemiological research, capacity building, and advocacy in the Australia, New Zealand, and south Pacific region.

The environment in which epidemiological research is undertaken affects the moral risks related to this endeavour. The environment nowadays is one in which epidemiologists are potentially powerful arbiters of the truth in relation to establishing the efficacy and safety of medicines. To maintain that role we need most of all to be independent and to be seen to be independent.

The environment is also one in which notable departures from good research practice have been engaged in by the pharmaceutical industry. These are well-documented and include the use of inappropriate comparators, deviations from clinical trial protocols, ghost writing and guest authorship of clinical trial manuscripts and scientific review papers, multiple publication of favourable results, failures to publish unfavourable results, overstating benefits and understating harms, misrepresenting epidemiological evidence (in information provided to regulators, journals, and prescribers), organised campaigns to discredit unfavourable results, and marketing framed as science.³⁻⁵ There are documented instances of industry-funded clinical trials being more likely to favour the sponsor's product than non-industry funded studies,⁶⁻⁷ as well as examples of head-to-head clinical trials which have compared the efficacy of the same medicines and have found contradictory results depending on which company sponsored the trial.⁸⁻⁹ Similar concerns have emerged in relation to post-marketing investigations of suspected adverse events. For example, in a meta-analysis stratified by funding source, an excess risk of venous thromboembolism in users of so-called third generation oral contraceptives relative to older preparations was found for studies undertaken without industry funding, but not for studies sponsored by manufacturers of the newer pills.¹⁰

The pharmaceutical industry is now exceedingly powerful. Undeniably it has produced many useful therapies that have transformed people's lives. But an important aim of the industry is to make a profit for shareholders and this is in potential conflict with its aim to produce effective and safe therapies. The combination of great financial power, inbuilt competing interests, and documented examples of poor research practice, all point to the importance of the AEA maintaining independence from this industry in order to avoid real and perceived conflicts of interest.

A conflict of interest can arise when organisations "enter into a set of arrangements which under usual circumstances would lead to a reasonable presumption that they will be tempted to put aside their primary interests (such as advocacy for their patients

and the public health) in favor of a secondary set of interests (the financial well-being of some commercial entity, or their own financial profit).¹¹ The danger for the AEA is that we might be perceived as having a conflict of interest if we accept pharmaceutical industry funding to offset the costs of our meetings. It is clear from the above definition that conflict of interest is different from the ubiquitous risk of investigator bias.¹¹ It also has different solutions.

For other health-related professional associations, especially medical associations, for which pharmaceutical industry funding has been the norm, there is movement to change the situation. The pervasive influence of the industry and the evidence for the effects of gifts on individual physicians has finally led to a re-evaluation of the relationship with industry. For instance, in the US a proposal to move towards zero funding of annual scientific meetings of medical associations (except for exhibit hall fees) was published in JAMA in 2009.¹

Zero funding is a so-called 'divestment' strategy. The alternative is a 'management' strategy in which conflicts of interest are disclosed and rules are adopted to limit their effect.¹¹ This latter strategy is widely applied in medical journal publications. It is, though, not appropriate for funding of conferences where publication of the sponsor's name is akin to advertising by the industry sponsor.

Maintaining and enhancing the reputation of the AEA as an advocate for good research practice and for independent judgment should entail a commitment to zero funding of scientific meetings. This should include funding from vaccine manufacturers as well as medicine manufacturers. Vaccination is a powerful preventive measure, but because epidemiologists may be involved in recommending to government how vaccines should be used it is important that such advice is independent of any real or perceived conflicts of interest. Moreover, though we are not aware of any examples of research malpractice by industry in relation to vaccines, often these are made by the same companies for which there are documented departures from good practice in research on medicines.¹²⁻²⁵

If we do not adopt a zero funding policy, several specific dangers follow. First, the AEA may appear to endorse products or activities of the sponsoring company and in this way our independence is compromised. Second, there is a danger to the reputation of the AEA in the eyes of the public, as well as in the eyes of agencies the AEA might work with (e.g. government agencies) and other professional groups. As one commentator has noted, "Trust is a delicate matter that often depends as much on appearance as on reality. The appearance created by an arrangement that could interfere with physician or organisational allegiance to their duty to promote the public health may be as corrosive of public trust as actual unethical behavior."¹¹ Some of the questionable research (and marketing) activities discussed earlier received extensive media coverage, thereby making any sponsorship arrangements with the pharmaceutical industry a potentially perilous alliance in terms of public trust. Thirdly, there are dangers for governance, with the possibility of restraints being instituted to avoid being perceived as critical of a funder. For instance, a conference speaker might be reluctant to discuss a particular instance of poor research practice on the part of a pharmaceutical company, if that same company was sponsoring the meeting. Conversely, conference organisers might be

suspected of having imposed restraints even when they had not (for example, if they rejected a poor-quality abstract which was critical of the sponsoring pharmaceutical company). Fourthly, there are dangers to internal relations among members. Some are more acutely aware, through their own work experiences, of the potential for conflict of interest, and may cease to attend annual meetings or even leave the organisation.

Past experience has shown that successful AEA scientific meetings can be held without financial assistance from the pharmaceutical industry. And with so much at stake, why would we accept such sponsorship in the future?

Acknowledgements

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Round Table

Should AEA receive sponsorship from a commercial company or organisation?

Professor David Crawford

Director, Centre for Physical Activity and Nutrition Research, Deakin University

Professional societies require significant resources – human and financial – in order to function and be effective for their members. So having money is necessary and important. At some point during their maturation most societies have a debate about sponsorship – whether to accept it, from who and under what conditions. As a founding member of the Executive of the International Society for Behavioral Nutrition and Physical Activity (ISBNPA), its current President, and organiser of ISBNPA's 10th Annual Conference held in Melbourne this year, I have been involved in many debates over sponsorship and so provide a view based on this experience.

In ISBNPA's case, we have received offers of sponsorship from the food industry, including an offer of significant funds from a major soft drink manufacturer. One of our sister societies has had funding from such a source to support its conferences, and there were/are a range of views within ISBNPA about whether soft drink industry sponsorship was/is appropriate. I see four main issues to consider when contemplating whether or not to accept commercial sponsorship.

1. There is empirical evidence that suggests industry support may bias scientific conclusions

For example, Lesser et al (PLoS Medicine, Jan 2007) reviewed papers examining relations between soft drink, juices and milk consumption with health or disease. They examined 206 papers published between January 1999 and December 2003, of which 111 reported their financial sponsorship. Among intervention studies, those with all industry vs no industry funding were less likely to have an unfavorable conclusion (0% vs 37%, $p=0.009$). The odds ratio for a favorable or neutral vs unfavorable result, comparing all industry to no industry support was 6.2 (95% CI = 1.2-31.9).

2. Perceptions matter

Perceptions are important and accepting industry sponsorship may affect credibility. This could occur at multiple levels: among professional colleagues; those reviewing your papers and grants; key stakeholders like government and non-government agencies; and the broader community. It may well be more difficult for a professional society to advocate on a particular issue if it is seen to be too closely linked to an industry that has a vested interest in that issue.

3. Can we influence industry to play a role in promoting health?

In our debates within ISBNPA, some members have argued that we could not expect the food industry to produce more healthy foods if we didn't speak with them. In other words, if we want to influence industry we need to be prepared to have them at our conferences and to talk with them. However, my view is that scientists can interact usefully with industry without accepting their sponsorship. For example, scientists can sit on advisory committees in honorary capacity, they can participate in industry organised meetings without accepting speaker fees, and industry representatives can participate in meetings of professional societies as registrants to hear the latest evidence. We don't need to accept their sponsorship money to influence them!

4. Weighing the costs and benefits of sponsorship

In the end, whether to accept or decline commercial sponsorship comes down to a decisional balance equation.

In the current economic environment, where funding is tight, commercial sponsorship may appear to be attractive for professional societies. However, it is important that professional societies carefully consider the costs of accepting industry money.

| Potential benefits of commercial sponsorship | Potential costs of commercial sponsorship |
|--|--|
| Ability to fund more keynote and invited speakers, and support student travel awards | Government and non-government health agencies may not wish to support us or listen to us |
| Would provide delegates with cheaper registration | Some members may chose not to attend at all in protest |
| Opportunity to interact with the industry and influence them | Negative impact on credibility – too close to industry |
| Would generate additional income for the society | Loss of income as members withdraw from Society |

Round Table

The ethics of accepting industry money for conference sponsorship: more is less.

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Much of the discussion and general disapproval surrounding commercial sponsorship is directed at drug company gifts for medical practitioners,¹ where the sponsorship provided is intended to leave practitioners with a feeling of obligation that will impact upon their prescribing practice. In Australia there has been mandatory reporting of this type of sponsorship since 2007¹. Research into the influence of pharmaceutical company sponsorship of clinicians suggests that regardless of the size of the gift there is influence on prescribing practices². More pertinent to epidemiologists, as researchers, is the potential influence of commercial sponsorship on results from pharmaceutical company funded research. Most agree that there is an inherent conflict between the commercial aims of the industry sponsor and the scientific objectives of research. To this end there have been at least two systematic reviews of industry funded research and the impact of commercial funding on research findings^{3,4}.

Overall these reviews have found that commercial sponsorship is positively related to the research findings, and that although the rigor of the scientific methodology is not necessarily affected the outcomes are typically in favour of the sponsor's product^{3,4}. The potential conflict of interest in this type of commercial relationship is clear and researchers should pursue ethical standards while conducting industry sponsored research. However, I argue industry sponsored research and industry sponsorship or donation to a scientific conference is quite different. The inherent conflict of interest in industry sponsored research is not necessarily transferable to an industry donation for a scientific conference.

The most obvious difference here between industry sponsored research and an industry sponsorship for a conference is the lack of influence between the industry representative and the researchers presenting at a conference. Researchers submitting abstracts several months before a conference are unlikely to know what sponsorships the organising committee has secured, and abstract submissions are independent of the conference committee quest for sponsorship. Local conference committees search far and wide for sponsors: this is to reduce fees to members; provide prizes (such as book donations); or sponsor satchels. For the most part sponsors are not secured until quite close to the conference, and sponsors are not aware of what

research is being considered for presentation. Further, the time lines between conference organising committees and research abstract preparations are independent of each other. The lead time for most research is considerably longer than the time it takes to secure conference sponsorship. For all of these simple reasons there are limited opportunities for any influence to occur and therefore it is unnecessary to consider that industry sponsorship for our meetings are inherently conflicted. There are also a number of practices that we can institute to ensure that our principles withstand the scrutiny of commercial funding and reduce the chance of any bias entering our conferences.

- Disclosure of any commercial sponsorship for the conference/meeting, abstracts, committee members or researchers. We could also ask all researchers to disclose industry sponsorship on abstracts submitted for conference proceedings.
- Document and disclose all sponsorship deals. As industry funding is usually advertised this will be easy to enforce, and this will ensure that there is less chance of commercial influence. The convenor of the local organising committee reports to our association's council. These reports could include industry sponsorship and thus could be assessed by Council for any conflicts of interest.
- Not accept sponsorship from industry whose commercial interests are known to be harmful to health (i.e. Phillip-Morris). Maintain continued peer review of abstracts for conference presentation. This has been shown to reduce industry influence on research results⁵. Our conference abstracts are peer-reviewed and if we continue to maintain this practice we can reduce the risk of this conflict arising.
- Encourage multiple sponsors of events. Some research has found that studies presented at non-peer reviewed meetings tended to favour the sponsors product, and that symposia with a single sponsor were most at risk of presenting exaggerated drug findings⁵. This suggests that to avert the influence of a single sponsor we should gain multiple sponsors thus diluting the effect of a single sponsor. This will also decrease the cost of our conferences and thus is a win-win for all.

During the conference committee preparation for the Sydney 2010 conference we were concerned about the cost of the conference. If we had been unable to accept industry sponsorship conference fees would have increased and potentially more delegates, especially students, may not have been able to afford the fees.

To promote our association and encourage growth into the future we need to accept industry sponsorship and continue to act in a responsible manner with such sponsorship. Ethics and ethical standards are very much subject to personal perception, by disclosing the details of all industry sponsorship we reduce the risk of potential conflict of interest and at the same time benefit financially. Accepting commercial sponsorship for a conference is different to accepting sponsorship for research. Conference sponsorship is not inherently conflicted and can be done without compromising our standards. Sponsorship reduces conference fees which allow more delegates to attend future meetings. Rather than rejecting industry sponsorship we should encourage more thus diluting the effect of a single sponsor.

I declare that I have no conflicts of interest to disclose. My area of research has limited industry sponsored research, and I have received none. I was on the local organising committee for the Sydney 2010 conference, which gratefully accepted industry sponsorship.

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Round Table

Ethics concern in implementing health professional events

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On 21 September, the Australasian Epidemiological Association (AEA) Annual Conference 2011 – Combining Tradition and Innovation – was successfully closed on the banks of the beautiful Swan River in Perth, Australia. The annual AEA meeting provides a professional platform for policy makers, researchers, lecturers, and university students to present and share research activities relating to current and future epidemiological, biostatistical, and public health issues. As a member of the Perth Organising Committee, I was involved in approaching a number of organisations for sponsorship of this national event. While it is common sense that obtaining sufficient funding is one of the key elements of organising a successful conference, some members raised concerns that, as a professional association, it is inappropriate to accept sponsorship from commercial companies. Obviously, whether or not to accept commercial sponsorship is not a question that has a simple yes or no answer.

Let's first ask the question: do we need any sponsorship for professional events? My answer is "Yes". We live in a contemporary society, and when organising AEA conferences and other professional events we have to pay to rent venues and equipment, and provide catering and other services. Given that AEA is a non-profit professional association, the association has limited financial resources. Unless we increase the rate for conference registration, which may reduce the ability of members and students to attend the conference, registration fees are unlikely to cover the total conference budget without sponsorship from other organisations. Thus it is a realistic approach to seek additional financial sponsorship from other organisations to ensure the running of a quality professional conference.

The next question is: what type of organisation should we approach for sponsorship? My answer is: carefully select sponsorships based on the health merit of the proposed sponsors and ethical considerations.

Epidemiology is a research discipline underpinning public health, providing evidence to prevent diseases and promote public health through state-of-the-art epidemiological methodologies. AEA members and non-member epidemiologists work in a wide variety of government departments, universities, research institutes, hospitals and other health care organisations thus the discipline aligns strategically with relevant organisations

for the maintenance of high standards of public health practice. AEA is dedicated to excellence in evidence-based epidemiological research, education, training and advocacy in Australia and New Zealand¹. Thus the research discipline has a strong focus on population and practice and strong interactions between researchers and research subjects and consumers. To exclude other professional and commercial organisations to keep the 'purity' of the AEA, to me, is a type of French paradox^{2,3}.

Research participants and the general population use or consume a variety of commercial products on a daily basis. Although people are free to make their own choice about purchasing products, in order to reduce disease burden and related economic burdens, health professionals and professional associations have a responsibility to provide evidence-based data and recommendations on healthy lifestyle and behaviour choices for different targeted populations. I argue that, for the purposes of deciding whether a professional association should accept sponsorship, commercial companies can be divided into three categories, green, orange and red, based on health merit and ethical considerations surrounding their products:

- **Green** (Yes) category products have direct or indirect impact on disease prevention and treatment, rehabilitation, health promotion, or health related education, research and training. Some examples of these types of companies include medical and pharmaceutical companies, healthy supplements manufacturers, gym equipment manufacturers and retailers, providers of fresh vegetables and fruits, safety and protective equipment, research equipment, and computer and statistic software providers. These companies that produce products that support the public health should be encouraged and approached for sponsorship to promote their products as well as to support our professional events.
- **Orange** (Conditional) category products, under certain conditions, can provide beneficial health outcomes. These companies (e.g. McDonald's and other fast food producers) should be carefully selected to provide sponsorship when advertising their products positively supports the theme of the event. For example, consuming foods with a high density of energy increases risks of obesity and associated co-morbidities⁴⁻⁶ thus fast food producers should not be considered as a sponsor when the event has a theme like reducing obesity. However, these foods could provide health benefits to children with

Marasmus, a type of malnutrition with energy deficiency^{7,8}, if theoretically these high energy food could ever reach the starving children. Therefore, these food companies may be suitable for a conference related to reducing malnutrition.

- **Red (No)** category products will only cause harm to health. Companies such as cigarette manufacturers are not suitable sponsors, as so far no evidence of beneficial effects of cigarette smoking have been reported but reports on smoking related adverse health effects are abundant⁹⁻¹⁵. These companies should be permanently removed from the sponsorship list of AEA events.

In conclusion, I cannot agree that having commercial sponsorship makes a professional conference less professional. While we need financial support to run professional events, we also need to select sponsorship carefully. It must be clear that potential commercial sponsors' products must be aligned with the goals of the association in terms of health benefits before sponsorship should be accepted. A Sponsorship Policy should be proposed by AEA Council members and the Fundraising committee for future use. Once sponsors have been accepted some management issues may also arise and some principles of sponsorship management developed by government departments can be adopted and modified¹⁶⁻¹⁸ to address these issues.

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Round Table

Organisational and health professionals ethics

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The main objective of most medical conferences is to enable scientists to present and discuss their most recent research results, usually before these were to be published in the appropriate professional journals. Other objectives include round table discussions of topics of interest or controversy, and the invitation of expert guest speakers to present a lecture, often in plenary sessions and/or to chair one or more of the various sessions of the conference. These objectives have to be kept in mind when we discuss the above theme in general and specifically the issue of the conference sponsorship by commercial organisations.

Research

Medical research is quite often sponsored and funded by the many pharmacological companies, as well as by the medical equipment industry (from medical and surgical equipment to imaging machinery etc.). In fact randomised clinical trials of new drugs and novel instrument technologies are almost always sponsored and funded by the private companies who intend to sell these products. The pharmacological industry, for example, is expected to present primary results of stage I and II trials (toxicity and efficacy) before applying for license for production (e.g. to the FDA in the US), or to academic institutions' IRBs (Institutional Review Boards) to obtain permission to collaborate in large scale randomised clinical trials (often multi-center). Researchers in the various medical professions almost never turn down research grants simply because a commercial company sponsors it. They do have to make sure that the research contract between their employer institution and the sponsor protects them from any bias or pressure to deviate from the research protocol, or to intervene in the conduct of the research and/or publication of the results, whether positive, negative or equivocal.

Publication of research results

The guiding rules of most respected, peer-reviewed medical journals is never to turn down a good research paper only because the sponsor is a commercial company. Most journals request information about the funding source which must appear in the paper, usually in the last section of the paper – 'acknowledgements', which often includes the authors' statements of conflict of interest as well as details of their employers. One recent example of a study funded by Pfizer Pharmaceuticals was published by the BMJ (December 6, 2010).

The acknowledgement section states that Pfizer scientists participated in the design, conduct, and data analysis of the results, as well as in the writing of the paper. It also states that approval of the research design was received by all participating institutions¹.

There are hundreds of similar studies published every year. Such papers are usually reviewed very carefully before being accepted for publication. There is, however, an ongoing debate on the issue of the role of commercial companies with obvious vested interests, in research and publications. I collected two examples (from PubMed) of such commentaries (out of many); their content is obvious from their titles^{2,3}. An interesting example of how fair, yet careful medical journals can be is seen in the International Journal of Epidemiology's approach to a 2007 literature review paper by Lee PN⁴. Dr. Shah Ibrahim, chief editor of the journal, included a paragraph on Lee's paper in his editorial comments, of which I quote just two sentences: "Peter N Lee will be well known to many as a tobacco researcher funded by Phillip Morris International, and some may wonder why we accept publications funded by the tobacco industry. We take the view that censorship is unacceptable and debate is essential"⁵. This example shows (in my opinion) a fair and correct academic approach to scientific publications.

Sponsorship of medical conferences by commercial companies

I have been involved in four conferences as either chair or co-chair of the organising or scientific committees⁶, and attended dozens of national and international conferences in all continents (except Australia), mostly in the field of epidemiology and public health. From my personal experience, as well as from discussion with many colleagues, I know that most, if not all, organisers of scientific conferences, actively seek funding support from their professional association, but also from commercial companies, where the pharmaceutical companies play a major role. To organise a successful and high level conference one needs funding to invite prominent guest speakers (and pay their expenses), as well as to provide fellowships to participants from developing countries. One needs to rent an appropriate venue, audiovisual equipment and a professional company that provides all the administrative services for the conference. The income derived from registration fees is very rarely sufficient to provide all the above mentioned necessities, unless registration fees

become prohibitively expensive, which may then deter many potential participants. Obviously, it is imperative to clarify to the sponsors that their contributions may not influence how the funds are used. However, some sponsors may wish to focus their contribution e.g. towards inviting speakers or providing fellowships to needy participants, which is acceptable as long as the sponsors have no say in who to invite and who gets a fellowship. Other forms of support in many conferences is provided through rental of booths, displayed at the conference's exhibition hall. These booths are often rented by academic institutions, government agencies and commercial companies interested in PR or product display (e.g. new drugs). This is an acceptable practice.

Conclusion

It is my opinion that since research and scientific dissemination of research results are invariably using sponsorship and funding of commercial companies, it is inconceivable that medical conferences, being an important forum for the dissemination of this important knowledge, should exclude themselves from receiving funding from these sources.

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Round Table

Would you attend a professional event organised by AEA had you known that the event is sponsored by a commercial organisation?

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Conferences play an important role in educating and keeping us up to date in our specialty. Delegates do this through attending lectures, plenary sessions, seminars and presentations. We go to conferences in order to present our work and obtain feedback but also to network by meeting our colleagues, collaborators and/or competitors. Therefore, education is the primary goal for most conference attendees, particularly as most meetings have a focus on the exchange of scientific knowledge and contributions to medical education.

Sponsorship of an event by a commercial organisation can be beneficial. Increased funding allows for the organiser to use better facilities, invite prominent speakers, can reduce registration conference fees and broadens access to the event by distributing travel subsidies and awards. This in turn increases the number of delegates which increases the dissemination of research data shown at the conference. Hospital-based events have similar outcomes. Sponsorship allows for provision of refreshments which allows doctors with busy schedules to attend during their lunch periods.

The quality of a professional event, such as a conference, is primarily based on the quality of the speakers and the data presented. Dissemination of research results from the researchers approached by the conference committee differs markedly from that of presenters who are paid a fee to speak during the conference. Presenters who are paid a fee to address the audience are likely to be less objective and are doing their best to re-coup their investment without really giving away any expertise or insight. Furthermore, even though most research that is conducted by the industry is both well conducted and rigorous there is the possibility that the commercial interests can bias the presentation and interpretation of results¹. Commercial organisations should not help shape the conference by controlling which scientists present and which papers are presented. The sponsor's agenda should not override the meeting's message.

Difficulties arise when commercially funded speakers are not identified. It is difficult to ascertain bias or a suppression of unfavorable findings without this knowledge. This has the potential to mislead delegates about research findings. Time for questions at the end of each session becomes even more important as it allows for an open discussion of ideas regarding the research and allows delegates to delve deeper into areas

regarding protocol and methods. However, it is all too common for presentations to be too lengthy and therefore for the sake of the timelines questions are kept to a minimum. To avoid this it is vital that there is a level of transparency between sponsors, conference organisers and delegates. Commercially funded research should be acknowledged and their relationship with the research should be well known. In areas where sponsors do present industry results the conference would benefit from officials monitoring the proceedings for signs of bias or marketing. In addition, multiple perspectives on the same issue would give the delegate a holistic understanding of the topic. A conference with dozens of speakers should have dozens of opinions, not just one.

The starting point must be to develop clear guidelines for the relationship between conference organisers and commercial organisations. This has been achieved by various professional associations including the Royal Australian College of General Practitioners², the Royal Australasian College of Physicians³ and Pharmaceutical Society of Australia⁴. Clearly identified sponsor speaker sessions allow for a more objective assessment by the delegate. In addition, highlighting how the funds are utilised with an assessment of the benefits would allow for more transparency.

It is important for organisations such as the AEA to remain independent. Dependence on industry sponsoring, where the revenue raised from conferences does represent a large percentage of all annual funding, may increase marketing of products and detract from the exchange of scientific knowledge. Furthermore, commercial organisations who are serial sponsors should be assessed. By running many conferences on totally different subjects the question arises if they really understand the meeting's message and provide the delegate with insightful commentary.

There also needs to be a balance between academic goals and the receipt of hospitality. Does receiving a token gift, may it be a pen, notepad or cup, change the researchers and health professionals health care approach and/or conclusions? The monetary value of these gifts is small and does not breach any guidelines and therefore they may be perceived as inconsequential and exert no influence⁵. However, this does build a relationship with social obligations which may lead to people reciprocating. The receipt of these small gift tokens has

given rise to negative public perceptions. These gifts may introduce the idea of bias or a conflict of interest when actually there was no influence on the therapeutic decision. The influence of such small gifts is not clear but is all too common at many conferences as these factors have been shown to increase delegate attendance and conference satisfaction⁶.

The advancing health of all Australians should be the goal for both sponsors and delegates. By upholding values of professional autonomy, independence and commitment there is a possibility that a balance can be achieved. Sponsorship of professional events has many benefits to all parties involved but needs to be founded on a transparent relationship with ethical guidelines. Ultimately, it is the responsibility of researchers and physicians to evaluate what they hear for scientific accuracy and signs of bias.

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The reliability of patient recall of hospital readmission following orthopaedic trauma

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Aim

Accuracy of patient recall of information is integral to the success of clinical registries, trials and doctor-patient interaction. Inaccurate or unreliable patient reporting of information has the potential to impact on the validity of research and clinical findings. The objective was to determine the level of agreement between patient recall of readmission to hospital in a population of orthopaedic trauma patients.

Methods

Patient recall of hospital readmission in the six-months following the index admission was compared to medical record documentation for a random sample of 200 orthopaedic trauma patients. Kappa statistics were used to quantify the level of agreement between patient-report and medical record documentation.

Results

Thirty eight patients had a recorded readmission, with only 18 (47.7%) of those agreeing with their hospital medical record. A total of 87% of patients accurately recalled their readmission status at six months corresponding to a moderate agreement ($\kappa = 0.51$, 95% CI: 0.347-0.670, $P < 0.001$). No significant differences were reported for demographic, outcome and recall data between patients who agreed with their hospital medical record and those that did not.

Conclusions

There were no personal, physical, pain or disability characteristics that influenced the ability of a patient to accurately recall information over a six month period, although this warrants further investigation. The poor recall of readmission information after six months indicates that the reliability of this information should not be assumed when used in clinical registries, trials, quality improvement projects or doctor patient interactions.

Introduction

Clinical registries, trials and public health research projects are often reliant on accurate recall of information from patients. Participants are frequently asked to report information related to specific diseases, injuries or events over various time periods, with the potential for inaccurate or unreliable recall, often resulting in an underestimation of rates, particularly for recall periods greater than two months.¹ Factors such as time-dependent memory decay,¹ telescoping,² personality characteristics and emotional state³ have all been purported to contribute to recall bias.

Studies investigating the reliability of patient recollection of a specific illness, disease or injury diagnosis have reported levels of agreement ranging from slight to excellent,^{2,4-7} false positives ranging from 0-75%^{6,8-10} and false negatives from 7-48%^{10,11} when compared to their medical record. Age, sex, socioeconomic status, education, length of hospital stay, number of health care visits, chronicity of condition, mental status, physical status, pain, number of injuries, presence of a head injury, return to previous activities and work, and level of disability have all been investigated as potential influences on recall with varying results.^{2,5,6,8,9,11,12} To ensure improved quality of care and research validity, accurate information must be passed between patients, health care providers and researchers.

In the context of injury or trauma, collecting information about readmissions following an index admission is important for establishing the burden of injury, the course of management, the impact of readmission on patient outcomes, and the prevalence of post-discharge complications requiring further hospitalisation. Not all subsequent admissions are to the index admission hospital, complicating the collection of readmission information. Without a unique identifier for the health system, data linkage becomes difficult and there are ethical implications for these types of data collection procedures. For cohort studies and clinical registries, where direct contact with patients occurs, readmission information could be collected directly from the

patient, negating the need for complex data linkages and ethics approval process. However, the potential for data inaccuracy, especially when recall periods are substantive, remains.¹³ The purpose of this investigation was to quantify the level of agreement between patient self-reporting of readmissions and hospital medical record documentation of admissions, to establish if patients can accurately report readmission information.

Methods

Setting and Participants

The Victorian Orthopaedic Trauma Outcomes Registry (VOTOR) captured information about all patients, admitted to the two adult major trauma services in Victoria, Australia for management of orthopaedic and/or spinal injuries. Victoria operates a regionalised trauma system where seriously injured patients are triaged to specialist major trauma centres designated by the Victorian State Trauma Service – triage guidelines and pre-hospital criteria.¹⁴ Patients were excluded from the registry if they presented with a pathological fracture related to a metastatic disease or their orthopaedic injury was managed by another unit. The methods used to collect data for VOTOR are described elsewhere with a summary provided here.¹⁴ Demographic, injury event, diagnosis, management and in-hospital outcomes were collected from the patient's medical record or hospital information systems. In addition, longer term outcomes, such as pain,¹⁵ function and health-related quality of life (SF-12),¹⁶ were collected by telephone interview at six and 12-months after injury. The telephone interview also collected information about admissions to hospital following the index VOTOR admission. A readmission was classified as any subsequent admission to hospital for day case procedures or admission to a ward bed. Outpatient appointments or emergency department presentations were excluded. Each patient was asked "Since your discharge from the <name of the hospital> in <date/month> have you been readmitted to this hospital or any other hospital?" Telephone interviewers used prompting and questioning techniques to clarify and verify each reported readmission. Examples were given by the interviewers to clarify the differences between an outpatient visit, an emergency department visit and an admission to hospital. The registry used an opt-off method of consent to prospectively enrol patients and ethics approval was received from the participating institutions and Monash University.

For the current study, a simple random sample of 200 patients, enrolled between August 2003 and July 2006, was extracted from the registry. A simple random case number generation with a block restriction of 100 cases from each hospital site was used. Patients with six-month outcome data provided by a proxy were excluded from the sample. The sample size was based on a standard error (SE) of between 0.05 and 0.1 to detect a kappa score of 0.4.^{17, 18}

Procedure

Data on readmission, patient demographics and six-month outcomes were retrieved from the registry for the randomly selected patients. Patient follow-up occurred at six months after the initial date of injury. Hospital medical records were requested from the participating hospitals and readmission details recorded. Only readmissions to the VOTOR participating hospitals were used for validation purposes and patients were excluded from analysis if incomplete or missing hospital medical records were identified. Data recorded from each hospital for comparison with patient-report included information on the number of readmissions, hospital of readmission, date of readmission, length of stay, reason for each readmission, and procedures undertaken during the readmission. Precise data for all the readmission categories was used in determining accuracy of recall. Readmission reasons and procedures were collated and categorised according to procedures undertaken related to the patient's index admission (e.g. delayed fixation surgery, removal of implants or revision for implant failure or non-union), orthopaedic procedures not related to their index admission (e.g. hip replacement for a fall subsequent to their initial injury presentation), and other procedures related to their index admission (e.g. removal of inferior vena cava filter, post-operative infection tissue debridement and antibiotic treatment).

Data Analysis

Summary statistics were used to describe the patient profile and outcomes. Kappa (κ) statistics and 95% confidence intervals (CI) were used to assess the agreement between patient-reported and medical record data.¹⁷ The kappa statistic was interpreted using the guidelines reported by Landis and Koch.¹⁹ Kappa coefficients of less than 0 were considered poor, between 0.01 and 0.2 slight, 0.21 and 0.4 fair, 0.41 and 0.6 moderate, 0.61 and 0.8 substantial, and 0.81 and 1 almost perfect agreement. Comparison between patients who agreed and disagreed with their medical record for demographic, outcome and recall data was determined by chi-square test for nominal data and Mann Whitney U-test for continuous data. Analysis was performed using the Stata software package version 9.2 (StataCorp, College Station, Tx, USA).

Results

Using hospital medical record information, the readmission rate to the participating hospitals was 19%. The percentage of cases where there was agreement between patient self-report and the medical record was 87% (n=174) (Table 1). Agreement between self-report and medical record determined readmission was moderate ($\kappa = 0.51$, 95% CI: 0.35-0.67, $P < 0.001$), although the prevalence index was high (0.69). The percentage agreement between patient self-reported readmissions and hospital medical record data varied as more detailed information was required, from readmission status (87%) to date of readmission (82%). Table 2 shows the profile of patients, outcomes and readmission agreement status. There was no association between self-report and medical record agreement, according to demographic or six-month outcomes, for the whole group or patients with hospital readmissions.

Table 1. Agreement between patient recall and hospital medical records

| | | Hospital Medical Records | | Total |
|----------------|--------------|--------------------------|-----------|-------|
| | | No admission | Admission | |
| Patient recall | No admission | 156 | 20 | 176 |
| | Admission | 6 | 18 | 24 |
| Total | | 162 | 38 | 200 |

The examination of patient hospital medical records, for the selected sample, revealed 38 patients had 44 readmissions over the six-month post injury period. The sensitivity and specificity

of patient report of readmission was 47%, and 96%, respectively. Six patients reported readmission to the participating hospitals that was not substantiated by medical record documentation, giving a false positive rate of 3.7%. Twenty patients failed to report readmission to the participating hospitals despite hospital medical record documentation that readmission had occurred, giving a false negative rate of 53% (Table 3). For patients with a hospital medical record readmission the number of readmissions ($\kappa_{21}=2.17$, $P=0.34$), length of stay ($\kappa_{21}=1.43$, $P=0.23$), days to readmission since injury ($z = -1.33$, $P = 0.18$) or reason for readmission ($\kappa_{21}=2.97$, $P=0.23$) showed no association with their accuracy of recall.

Table 2. Demographic characteristics of patients, overall and by recall status[†]

| | All cases (n=200) | Agree (n=174) | Disagree (n=26) |
|-----------------------------|-------------------|---------------|-----------------|
| Age (yrs): Median (IQR) | 43 (28-59.5) | 42.5 (28-60) | 45.5 (27-59) |
| Gender: | | | |
| Male: n (%) | 119 (59.5) | 101 (58.1) | 18 (69.2) |
| Marital Status: n (%) ‡ | | | |
| Married | 85 (42.5) | 72 (41.4) | 13 (50.0) |
| Single | 68 (34.0) | 60 (34.5) | 8 (30.8) |
| Divorced/separated | 14 (7.0) | 12 (6.9) | 2 (7.7) |
| De Facto | 13 (6.5) | 13 (7.5) | 0 (0) |
| Other | 14 (7.0) | 13 (7.5) | 1 (3.9) |
| Education: n (%) § | | | |
| Tertiary | 53 (26.5) | 46 (26.4) | 7 (26.9) |
| Secondary | 114 (57.0) | 101 (58.1) | 13 (50.0) |
| Primary and other | 19 (9.5) | 15 (8.6) | 4 (15.4) |
| Return to Work: n (%) ¶ | | | |
| Yes | 91 (45.5) | 79 (45.4) | 12 (46.2) |
| No | 35 (17.5) | 31 (17.8) | 4 (15.4) |
| Not Applicable | 65 (32.5) | 56 (32.2) | 9 (34.6) |
| Head Injured? n (%) □ | | | |
| Yes | 40 (20.0) | 33 (19.0) | 7 (26.9) |
| Multiple Injuries? n (%) ^ | | | |
| Yes | 124 (62.0) | 106 (60.9) | 18 (69.2) |
| PCS-12: Median (IQR) × | 38.5 (31-50) | 38.5 (31-50) | 38.5 (28-48) |
| MCS-12: Median (IQR) × | 54.5 (43.5-59) | 55 (45-59) | 52.5 (38-59) |
| Pain Score: Median (IQR) ×× | 2 (0-5) | 2 (0-5) | 2 (0-4) |

†All data presented as n (%) unless otherwise described; ‡ Data missing for 6 cases; § Data missing for 14 cases; ¶ Data missing for 9 cases and not applicable refers to patients who were not working prior injury; □ Head injury defined using ICD-10 AM diagnoses; ^ Multiple Injuries defined as ≥ 2 ICD-10 AM coded diagnoses; × Physical (PCS-12) and mental (MCS-12) component scores of the SF-12 (data missing for 2 cases); ×× Data missing for 1 case; IQR – Inter quartile range

Table 3. Comparison of patients by recall status, documented readmission only†

| Variable | Agree (n=18) | Disagree (n=20) |
|---|------------------|------------------|
| Number of readmissions | | |
| One | 83.3 (58.6-96.4) | 90.0 (68.3-98.8) |
| Two or more | 16.7 (3.6-41.4) | 10.0 (1.2-31.7) |
| Readmission LOS (n=44) | | |
| Day Case | n=21 | n=23 |
| Overnight | 57.1 (34.0-78.2) | 39.1 (19.7-61.5) |
| Days to readmission (n=44) | | |
| Median (IQR) | 86 (21-130) | 21 (11-94) |
| Reason for readmission | | |
| Orthopaedic procedure related to their index injury | 66.7 (43.0-85.4) | 87.0 (66.4-97.2) |
| Unrelated orthopaedic procedure | 4.8 (0.1-23.8) | 4.3 (0.1-21.9) |
| Other procedure related to their index injury | 28.6 (11.3-52.2) | 8.7 (1.1-28.0) |

†All data presented as percentages (95% CI) unless otherwise described; LOS - Length of Stay; IQR – Inter quartile range.

Discussion

This study investigated the agreement between patient self-report of readmissions and hospital medical record documentation in a cohort of orthopaedic trauma patients to establish whether patients can reliably provide this information. Accurate provision of information by patients and research participants is integral to the success of clinical registries, quality improvement projects, clinical trials and public health research. Most patients sampled demonstrated an agreement between their self-report and hospital medical record. However, 20 out of 38 patients with a documented readmission were unable to accurately recall any details of their hospital admission, leading to marked under-reporting.

Overall, the level of agreement, using unadjusted kappa statistics, found in our study was similar to those reported for hospital outpatient clinic utilisation ($\kappa=0.51$)⁵ and primary care consultations for knee pain ($\kappa=0.46$).² Studies investigating the validity of self-reported musculoskeletal disease and injury diagnoses have reported kappa coefficients ranging from 0.316 for arthritis to 0.7120 for fracture, and percentage agreement from 60%²¹ to 100%²² depending on fracture type. The agreement coefficients obtained in the current study of hospital readmission reporting were similar to previous diagnosis-based reports^{8, 20, 22, 23} and indicate a good overall recall.

However, while the overall level of agreement was substantial in our study, the rate of false negatives was high. The proportion of patients that failed to report hospital medical recorded documented readmissions was similar to a New Zealand study which found that 55% of the sample with valid readmissions were unable to recall the event.¹² Further comparisons with the literature are difficult as most studies investigating the accuracy of self-report have compared patient self-report of specific diagnoses^{6, 7, 9, 10, 20, 21, 24}, or clinical consultations^{2, 5}, with medical record documentation. The false negative rates reported by diagnosis recall studies have ranged from 0%^{8, 9} to 24%¹⁰, considerably lower than the false negative rate of 53% found in

the current study of patient-reported hospital readmission. While our reported false negative rate is high, caution must be used in reviewing these results given that less than a quarter of the sample (n=38) recorded at least one re-admission.

The reason for the high false negative rate in the current study is unclear. Most hospital admissions were related to their index admission and comprised of delayed operations, revisions of open reductions, post-discharge infections related to their initial surgery, and surgical revisions for non-union. Colditz et al. have suggested that recall can only reliably be utilised for diseases or information with clearly defined characteristics.²² While readmission to hospital would meet this criterion, the use of a simple yes/no question with interviewer prompting, identified under-reporting in our cohort of orthopaedic trauma patients. Our results challenge the validity of using these methods, and any potential conclusions based on patient self-report of readmission information.

In comparison to the high false negative rate, the rate of false positives (i.e. reporting a readmission when none occurred) was low (4%), lower than the false positive rates reported previously by studies investigating the accuracy of self-reporting of fracture diagnoses (7-13%).⁸⁻¹¹ The false positive cases in the present study comprised of individuals who reported details consistent with their index admission, or described reasons or procedures consistent with presentation to an emergency department or outpatient clinic, which were unlikely to be recorded as an admission according to hospital protocols.

Previous studies of the validity of patient self-report have suggested that patient characteristics, including personality and state-dependent factors,³ can influence an individuals' ability to provide accurate clinical information. Studies have investigated the influence of gender,¹² age,^{5, 12} education,²⁴ admission information,¹² length of stay,¹² pain,² injury² and disability² on patient recall with varying results. Our data indicates that none of these factors were associated with the accuracy of self-report of readmission information. Telescoping² and time-dependent

memory decay¹ have also been reported as reasons for poor recall but, again, these are unsupported by the current study as the time to readmission was not related to the accuracy of patient recall of readmission occurrence.

While the findings of our study are clear, limitations must be acknowledged. Firstly, the number of patients readmitted to hospital over the six-month period was low, limiting the ability to definitively assess the association between patient characteristics and recall accuracy, including independent analysis of the false positives and false negatives in isolation. A second limitation was the inability to assess the validity of patient self-report of all hospital readmissions to hospitals not participating in VOTOR, limiting the number of cases in the readmitted group. Further ethics approvals would have been required to evaluate patient self-report of readmissions to hospitals not participating in VOTOR, a resource intensive process, particularly as only a single readmission was reported for many of the non-participating hospitals. A final limitation is the potential for a differential measurement bias between patients who had been readmitted in the preceding six months and those that did not. Although this occurred across the VOTOR sample, with the data collection processes implemented, the sample size derived and the arbitrary selection of cases the instances were infrequent.

Overall, this study has highlighted the importance of verifying patient-reported information with more than 50% of patients with a hospital readmission unable to recall that readmission over a six-month period. The findings suggest that patient self-reported readmission information should be used with caution, highlighting the need for accurate sources of readmission information. Potentially, innovative automated data linkages with hospital administrative data could provide this information for use in registries and quality improvement programs, assuming that complex privacy and data ownership issues can be overcome.

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The Australasian Epidemiological Association was founded in 1987.

Membership is open to anyone with an interest in epidemiology.

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As of 2006, AEA also appoints an Executive Officer one day per week.

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