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# Clinical Practice Guidelines in Australia – the need for transparency, evidence-based data, and currency

## Health Consumers' Council submission to Australian Commission on Safety and Quality in Health Care

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## Introduction

Clinical practice guidelines are an important tool for health practitioners and consumers which bring together the best available evidence to support recommendations relating to appropriate treatment for specific conditions. In theory, guidelines should be 'of high quality, free from commercial and intellectual bias and fit for purpose.'[1] This is definitely not the case in Australia as reported recently by the National Health and Medical Research Council (NHMRC). In their *2014 Annual Report on Australian Clinical Practice Guidelines,* the NHMRC found that there were 'ongoing serious and systemic problems in the way guidelines are funded and developed'.[2] Before criteria for assessing Australian guideline topic priorities is considered, we need to ensure that any clinical practice guidelines are standardised by being transparent, based on the best available evidence, up-to-date and developed by a multidisciplinary team. These issues need to be addressed before prioritising clinical areas for guidelines.

## Who funds and develops guidelines?

Federal, State and territory governments are responsible for around 27% of guideline development, with national condition groups and specialty societies developing around 25%.[3] The NHMRC report found that despite government involvement in the development of clinical guidelines, and the associated funding remaining consistent, this has not resulted in high level evidence-based health advice, nor in a uniform approach to clinical guidelines development.[4] A recent US study which looked at the evidence used to develop clinical guidelines for managing cardiovascular disease found that almost 50 percent of the recommendations were 'derived from the lowest level of acceptable evidence'.[5] In other words, there was little or no objective empirical evidence to support the recommendations. This is also the case in Australia, where the NHMRC found that 'only 22% of guidelines funded or developed by government have been "evidence documented"' and only 11% of guidelines include a full systematic review.[6] This deficiency of evidence impacts directly on the quality of the clinical practice guidelines and brings into question the validity of many of the recommendations.

Another issue related to the funding of clinical practice guidelines is that government agencies and professional associations are vulnerable to interest-group influence, political preferences by governments, or by individuals with an agenda. One way to address this particular issue is covered by the 2011 NHMRC Standard which is required for guidelines seeking NHMRC approval. The Standard states that 'a multidisciplinary group that includes end users, relevant disciplines and clinical experts' is required in the group structure overseeing the development of guidelines. Currently, only 30% of all relevant disciplines make up guideline development groups.[7] This does not necessarily mean that some of the

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1 National Health and Medical Research Council, *2014 Annual Report on Australian Clinical Practice Guidelines,* Canberra, National Health and Medical Research Council, 2014: p. 4

2 NHMRC, *2014 Annual Report,* p. 4

3 NHMRC, *2014 Annual Report,* p. 10

4 NHMRC, *2014 Annual Report,* p. 25

5 Ronen Avraham, 'Clinical Practical Guidelines: the warped incentives in the US healthcare system', *American Journal of Law & Medicine,* 37.1 (Spring 2011): p29

6 NHMRC, *2014 Annual Report,* p. 21

7 NHMRC, *2014 Annual Report,* p. 22

other 70% were not made up of multidisciplinary personnel, but 50% of guideline groups could not be categorised because of the absence of author or personnel information, another shortcoming with many of the current guidelines. For rigorous clinical guidelines, development group members must be drawn from all relevant professional groups and this needs to be documented.

Possibly the biggest issue that needs addressing, however, is conflict of interest. In the dataset that the NHMRC used to compile its report, which excluded guidelines developed by pharmaceutical companies, it was found that in 2013 only 21 of 79 guidelines studied had full disclosure either in the guidelines or that were readily available from another source.[8] Whilst there has been a slight improvement in published conflicts on interests in the past decade,[9] the base figure is still low. People need to have confidence in the guidelines development group because if their objectivity is compromised, the guidelines by default will be biased. One American physician, Dr. Marcia Angell, in a 2009 article 'Drug Companies & Doctors: A Story of Corruption' argues that 'It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgement of trusted physicians or authoritative medical guidelines.'[10] Without full disclosure of ties to industry of guideline development group members, the soundness of clinical guidelines can always be questioned.

An example of conflicts of interest concerning the development of clinical guidelines can be seen when the 1997 NHMRC guidelines for the treatment of ADHD were rescinded in 2005. These guidelines were rescinded because they were considered not sufficiently evidence based, and had not addressed the issue of co-morbidity. The NHMRC outsourced the guidelines development to the Royal Australasian College of Physicians (RACP) but this action was dogged by controversy. One major reason was the allegations of bias amongst the guidelines reference group members. For example, the chairperson had been on the advisory boards of ADHD drug manufacturers Novartis and Eli Lilly, and when this was made public he resigned from the chairperson position, but remained on the reference group. He argued that pharmaceutical company ties were irrelevant, stating 'the important thing is we declare our potential conflicts of interest'.[11] However, the names of the reference group members and their ties to drug companies were not made public until Freedom of Information processes revealed that at least seven, but possibly eight of the original reference group members declared receiving funding and gifts from ADHD drug manufacturers.[12]

These guidelines were completed with the 'majority of the identified studies on ADHD medications being sponsored, at least in part, by the manufacturers of the medications.'[13] In addition, two thirds of the 2009 draft recommendations were made without any supporting scientific evidence. They were based entirely on reference group consensus and justified as

8 NHMRC, *2014 Annual Report,* p. 19
9 NHMRC, *2014 Annual Report,* p. 19
10 Marcia Angell, 'Drug Companies & Doctors: A Story of Corruption', *The New York Review of Books*, 15 January 2009.
11 Janet Fife-Yeomans, 'ADHD reviewer double-up', *The Daily Telegraph,* 30 April 2007.
12 Martin Whitely, 'Attention Deficit Hyperactivity Disorder Policy, Practice and Regulatory Capture in Australia 1992-2012, *PhD Thesis,* March 2014: p. 122. Available at http://speedupsitstill.com/wp-content/uploads/2014/06/Martin-Whitely-PhD-Thesis-Copy-ADHD-and-Regulatory-Capture-in-Australia-PDF.pdf
13 Royal Australasian College of Physicians, *'Draft Australian Guidelines on Attention Deficit Hyperactivity Disorder (ADHD)',* Melbourne (209), p. 82

*'best practice based on clinical experience and expert opinion.'*[14] Clearly there can be little confidence in guidelines developed in the absence of robust evidence.

Another major reason why these draft guidelines were contentious was because of the reliance on research by ADHD experts with undisclosed commercial ties to ADHD drug manufacturers. The most frequently cited author in the first draft, Harvard University Professor Dr Joseph Biederman, was under investigation for undisclosed pharmaceutical company payments. Dr Biederman was paid US$1.6 million in consulting fees from drug makers between 2000 and 2007 but did not disclose this income to his employer Harvard University.*[15]* Biederman received research funds from fifteen pharmaceutical companies and served as a paid speaker or adviser to at least seven drug companies.'*[16]* Other researchers cited in the draft guidelines were also under investigation for undisclosed drug company payments,[17] were members of pro-ADHD support groups, or were frequent paid speakers for ADHD drug manufacturers.[18] Ultimately the NHMRC did not approve these guidelines when they were completed in 2009, and a substitute process was began in 2011 to formulate Clinical Practice Points. The new reference group still had some members with commercial ties to pharmaceutical companies but not to ADHD drug manufacturers, and was balanced with other reference group members who had concerns with ADHD diagnosis and prescribing.[19]

A zero tolerance policy is sometimes advocated whereby members of guidelines development groups are unable to hold any stock or equity interests in pharmaceutical companies involved in research, or receive funding or gifts.[20] However, this action might limit the pool of researchers dramatically. What is required is to recognise and identify a conflict of interest, then being able to manage, reduce or eliminate the conflict, and ensure the research is overseen by an independent board.[21] This would ensure that the development of clinical guidelines were open and transparent and not captured by industry bodies. One recent move towards reporting conflicts of interest is that the publishers of journal articles are increasingly requiring that authors of articles list the companies that fund their research, another step towards more transparency.

## Conclusion

The NHMRC report found that it was unable to 'identify the specific impact of guidelines in the delivery of Australian health care, and this can be regarded as a major deficit in our understanding of guidelines.'[22] This is of concern considering the amount of money that has

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14 RACP, *Draft Australian Guidelines,* p.x – xxix.

15 Gardiner Harris and Benedict Carey, 'Researchers Fail to Reveal Full Drug Pay' *New York Times,* 8 June 2008.

16 Dr. Joseph Biederman , 'The Evolving Face of ADHD: From Adolescence to Adulthood—Clinical Implications' , 2006. Available at https://itunes.apple.com/us/podcast/evolving-face-adhd-from-adolescense/id210821748 (accessed 29 October 2012).

17 Gardiner Harris (2009), '3 Researchers at Harvard are named in subpoena', *The New York Times,* 27 March 2009.

18 Greg Birnbaum and Douglas Montaro (1999), 'Shrinks for Sale. Analyze This: Docs get Drug Co. $$', *New York Sunday Post*, 28 February 1999.

19 Whitely, 'Attention Deficit Hyperactivity Disorder Policy'

20 Columbia University, *Responsible Conduct of Research, Conflicts of Interest,* (2004). Available at http://ccnmtl.columbia.edu/projects/rcr/rcr_conflicts/foundation/index.html#top

21 Columbia University, *Responsible Conduct of Research*

22 NHMRC, *2014 Annual Report,* p. 25

been spent on developing clinical guidelines, with a figure of between $1 million and $1.6 million to develop and disseminate current national guidelines.[23] Until clinical guidelines are required to be more transparent, more evidence based, and the product of relevant professionals and not those with pharmaceutical industry ties, clinical guidelines in Australia will continue to generally be of low quality and often captured by those with a vested interest. To this end, the focus firstly needs to be on standardising all clinical guidelines development processes before priority criterion are established.

**Recommendations**

1. Before proposed criteria for assessing Australian guideline topic priorities are implemented, clinical practice guidelines development processes need to be standardised to ensure their integrity.

2. The development of guidelines must be transparent and conducted by a team with no conflicts of interest that would discredit the process.

3. Clinical practice guidelines must be based on independent robust evidence. The current deficiency of evidence in most guidelines impacts directly on the quality of the guidelines and this in turn brings into question their validity. If guidelines are not high level, evidence-based health advice, they will not improve the quality of clinical decisions and health outcomes.

[23] NHMRC, *2014 Annual Report,* p. 6