Delays in adoption of statins on the Pharmaceutical Benefits Scheme: Reflections of a John Snow Scholar

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Michael came to medicine from a background of pharmacy. He was the Western Australian winner of the John Snow Scholarship for 2010. His research interests include endocrinology, preventive cardiovascular medicine, public health and clinical pharmacology. He hopes that some career can eventually be synthesised out of these!

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The evidence for using statins in diabetic patients with normal cholesterol levels to prevent myocardial infarction or stroke was firmly established in 2002 with the publication of the Heart Protection Study. This large, prospective controlled trial found a relative risk reduction attributable to statins of around 25% in this and other population groups. [1] Statins were not subsidised for this indication in Australia until 2006. [2] I conducted a research project that sought to quantify the effect of this delay in terms of the number of cardiovascular events that might otherwise have been prevented if the subsidy for statins had occurred in 2002, when the evidence for this indication became available.

Completion of the project provided me with a more complete understanding of the use of the breadth of data sources available to synthesise an answer to the research question: what was the impact of the delay in subsidising statin drugs for diabetics with normal cholesterol from 2002 to 2006, in terms of cardiovascular outcomes? It also gave me valuable insights into the public health implications of the decisions of Medicare Australia relating to the funding of drugs, such as those for lowering cholesterol for the primary or secondary prevention of cardiovascular disease.

As an unusual research question, for which I could find little precedent in the published literature, it posed a challenge in terms of designing some means of answering it and required a creative approach. I used baseline cardiovascular risk data from the United Kingdom Prospective Diabetes Study, [3] statin-related risk reduction data from the Heart Protection Study, [1] and epidemiological data from the Australian Bureau of Statistics' National Health Survey. [4] For one part of the study I also referred to unpublished data from the Perth Risk Factor Survey.

In order to integrate these data to provide an answer to my research question, I had to learn statistical methods and familiarise myself with software that I had never previously used, which was also very challenging and at times frustrating, although good supervision helped to somewhat offset this! I have no doubt that the skills learned will be of use in the future. I then had to present my research methodology and findings in the format of a journal article.

The project allowed me to learn about access to pharmaceuticals in Australia and how the decision-making process is conducted for subsidising medicines for particular patient groups. I gained a much better understanding of the relative effect size for drugs aimed at reducing cardiovascular risk in patients with high baseline risk compared to patients with low baseline risk. I also came to appreciate the trade-off between cost (and in some other cases, adverse effects) and benefits of a drug. If the cost outweighs the benefit, access to the drug may not be feasible or defensible from a public funding perspective. It can be difficult to determine how much society is prepared to pay to prevent a particular health outcome as this will depend on many economic, social and attitudinal factors. A detailed

analysis of health economics was not within the scope of my paper, but writing and reflecting on the paper has prompted me to wish to conduct further research on this subject.

Writing the paper has broadened my understanding of and interest in public health. One aspect in particular included is the concept of a government health insurance provider as a facilitator of treatment; and conversely, its non-subsidy of a treatment as a barrier to evidence-based health care. In particular, while the Pharmaceutical Benefits Scheme (PBS) in Australia does not constitute clinical guidelines for best practice itself, it should facilitate the adoption of current evidence within the limits of what the taxpayer can reasonably fund. It should be able to do this in a timely fashion, and should be able to do so independently.

In other words, the non-subsidisation by the PBS of a medicine that is cost-effective in a particular group represents a barrier to healthcare. This is not something that I found well characterised in the literature to date, possibly because the PBS has been overwhelmingly a facilitator of access rather than a barrier. Nonetheless, examples appear to exist of indications for medicines that are not PBS subsidised, despite clear evidence for benefit. One reason for this might be that PBS listing is driven by applications to the Pharmaceutical Benefits Advisory Committee (PBAC) by sponsors of drugs. Drugs that are off-patent or are otherwise less profitable to their sponsors may therefore not come before the PBAC for consideration.

Overall I learned a great deal in completing this project about epidemiological study design and the use of statistics; about the subsidisation process for drugs in Australia and the public health implications thereof; and of the complexity of political, economic, corporate, societal and medical research factors involved in providing preventive healthcare in Australia.

I was delighted to be selected as the Western Australian finalist for the Australasian Faculty of Public Health Medicine's John Snow Scholarship, and I thank it for the opportunity to present my work at the 2011 Royal Australasian College of Physicians' annual conference in Darwin. I would encourage others to consider completing a research project in the area of public health.

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