CENTRE FOR THE HEALTH ECONOMY

MACQUARIE University

ROUNDTABLE HIGHLIGHTS

Breaking new ground in switch:

ENHANCING DECISIONS THROUGH ECONOMICS

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Introduction

The Macquarie University Centre for Health Economy (MUCHE) holds regular roundtable events to bring together stakeholders to discuss important health issues.

A roundtable was held on December 6, 2018 at the Macquarie Graduate School of Management. It brought members of government and the medicine industry together to discuss the reclassification, aka 'switching' or 'down-scheduling', of medicines from Schedule 4 (prescription only) to Schedule 3 (pharmacist only).

MUCHE has been partnering with ASMI (Australian Self Medication Industry) since 2013. MUCHE recently undertook an ASMI-sponsored research project, led by Dr Bonny Parkinson, to develop a new methodology for informing scheduling decisions.

Dr Bonny Parkinson and her team developed a sophisticated economic evaluation framework. One that can be used to identify the benefits and risks of down-scheduling or up-scheduling medicines and predict the likely impacts of making a medicine more or less accessible.

At the roundtable, Dr Parkinson demonstrated how the framework functioned with reference to two economic evaluations of reclassifying the OCP (oral contraceptive pill) and triptans. (These are medicines that have been reclassified in other nations and which regulators have considered reclassifying in Australia.)

Dr Parkinson's proposed framework generated cautious enthusiasm among the assembled guests. These guests included senior figures from the ASMI, major pharmaceutical companies, the TGA (Therapeutic Goods Administration), Medicines Australia and the Pharmacy Guild, as well as prominent health academics from Macquarie and other universities.

There was general agreement that the Advisory Committee on Medicines Scheduling (ACMS) do not pay enough attention to the potential benefits of reclassification. However, there was also vigorous discussion about issues that would need to be explored, before the proposed framework had a realistic chance of being adopted.

"Introducing a significant reform without the support of the nation's doctors and pharmacists is difficult."

Background

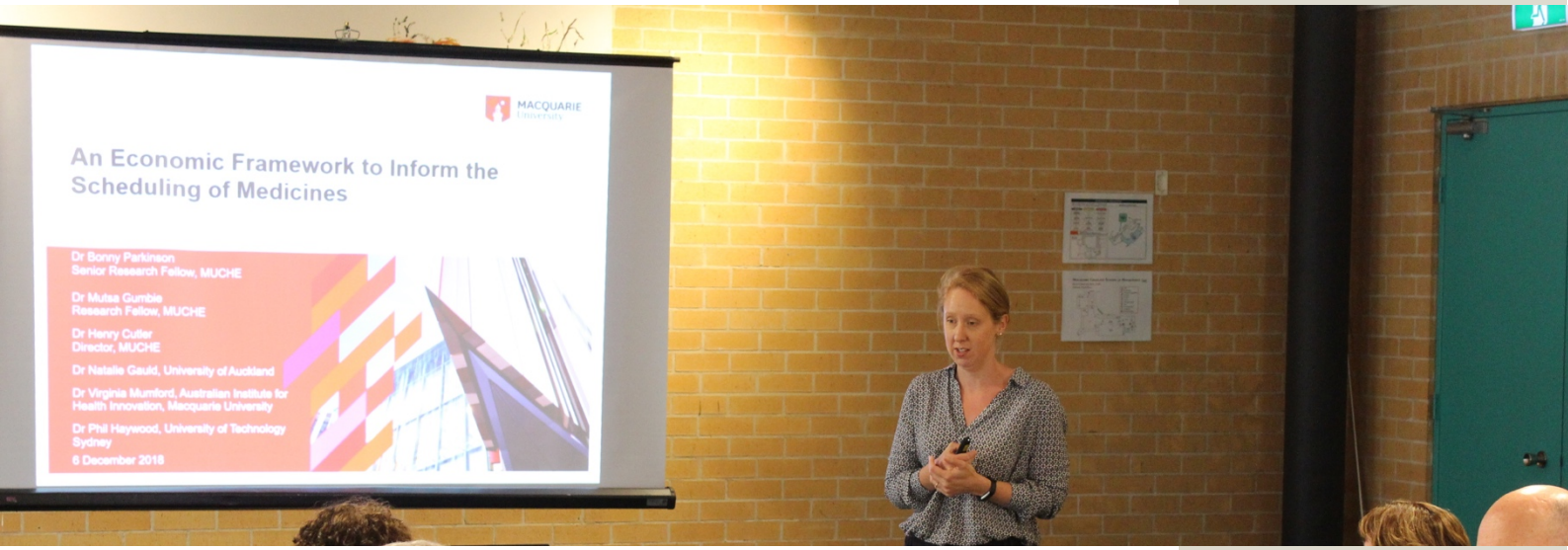
The PBS came into existence in 1948 and was expanded in 1960[1]. In the early 1990s, Australia became the first country to use economic analysis to inform which pharmaceuticals should be publicly subsidised[2].

The PBS remains much admired both domestically and internationally. Nonetheless, over the last 15 years or so, reclassification decisions have become increasingly conservative. In the past, many Schedule 4 (prescription medicines) – for example, sinus treatments, nicotine-replacement patches and antifungal creams – were reclassified to Schedule 3 or 2 in a timely manner. In recent years, several medicines – the OCP (oral contraceptive pill) being the highest-profile example – have failed to be recommended for reclassification by the ACMS, despite being available over-the-counter in many other nations.

The ACMS, which makes reclassification recommendations, and decision-makers in State and Territory health departments, who consider these recommendations, focus on potential risks. This is entirely reasonable given these risks – inaccurate or delayed diagnosis, inappropriate use, the possibility of adverse events – can be serious. But this focus on risks has resulted in insufficient weight being placed on the potential benefits – reduced barriers to treatment, reduced time to symptom relief, improved quality of life – of making medicines more available. (Tellingly, decision makers are not even formally obliged to consider the benefits of making a medicine more available during the decision-making process.)

Industry players – with the possible exception of pharmaceutical companies – may be content with the risk-averse status quo. But it's unclear how much longer that status quo can hold. At the recent Victorian state election, the Liberal Party proposed making the OCP available over-the-counter. The proposal was supported by groups such as Plan International and Marie Stopes Australia and, it can reasonably be assumed, many female voters.

The proposal was opposed by the Australian Medical Association (AMA), which so far seems to have won the battle. But presumably political pressure will continue to build for Australia to make the OCP available over-the-counter, as it is in many other nations.



Presentation

USING AN ECONOMIC EVALUATION FRAMEWORK TO MAKE SCHEDULING DECISIONS

Nations such as Australia, Canada, the Netherlands, Japan and the UK have adopted economic frameworks to make decisions regarding the funding of medicines. A cost-benefit analysis was also conducted before the recent decision to up-schedule codeine.

Using an economic evaluation framework to analyse reclassification decisions is unremarkable. What's innovative about the framework Dr Parkinson has developed is its sophistication. Published economic evaluations of reclassification decisions to date have been relatively simple, often failing to take into account potential adverse events. For example, the impact of condom use declining and STIs increasing if the OCP is made more available.

In contrast, Dr Parkinson's approach aspires to synthesise data from a comprehensive range of sources, identify the benefits and risks, summarise all the potential health outcomes in terms of a single measure - QALYs (Quality Adjusted Life Years), and considers the overall impact on the healthcare system. Powerful tools such as sensitivity analysis and scenario analysis can also be used to help inform decisions regarding the need for more research or whether access should be restricted to certain patient groups.

The data gathering and subsequent calculations require substantial time, effort and, yes, money. But the proposed new framework has two advantages over the current approach to making reclassification decisions. First, superior predictive capacity, second, metrics that can be understood by all stakeholders, including the general public. The MUCHE framework demonstrates how reclassifying a medicine will raise or lower costs and increase or decrease QALYs.

The framework has been used to estimate the impact of reclassifying the OCP and triptans from Schedule 4 (prescription only) to Schedule 3 (pharmacist only). It was found that down-scheduling triptans would see 337 QALYS gained over 10 years, albeit at an increased cost of $5.9 million[3]. Over a 35-year timeframe, down-scheduling the OCP would result in a net health gain and be cost-saving[4].

If reclassifying a medicine results in either increased QALYs and lower costs or decreased QALYs and higher costs, the logical reclassification decision is obvious. When reclassifying a medicine results in increased QALYs but also higher costs, things get more complicated. But, as was discussed at the roundtable, the following concerns will need to be addressed before the proposed new framework has a realistic chance of being adopted.

Issues

HOW WILL THE BUY-IN FROM PHARMACISTS AND DOCTORS BE SECURED?

As anyone familiar with the history of Australia's health system will be aware, introducing a significant reform without the support of the nation's doctors and pharmacists is difficult.

By design, reclassification cuts doctors out of the equation. However, it's not clear that the viability of medical practices will be much impacted if a less risk-averse approach to reclassification decisions is adopted, especially given an ageing population, constant pressure to list new medicines on the PBS and ever-growing health budgets. Also, doctors risk the possibility of a public backlash if they come to be perceived as paternalistic or mercenary in their opposition to reclassifying medicines that are freely available in other nations.

The situation for pharmacists is more complicated. Pharmacists don't receive a fee for supplying Schedule 3 medicines, but they do for dispensing Schedule 4 medicines. But it would be possible to change this. It's also the case that reclassification could allow the larger pharmacy chains to promote home-brand products. For example, were triptans to be reclassified, a chain such as TerryWhite Chemmart could offer customers their white-label triptan. Also, today's pharmacists do a lot more than dispense Schedule 4 medicines. They have the opportunity to make up lost dispensing fee revenue by offering services such as medication reviews and flu vaccinations.

WHO PAYS FOR THE MODELLING?

Dr Parkinson estimates it would cost a pharmaceutical company roughly $100,000 to $200,000 to use her framework. That investment might be worthwhile if exclusivity were granted but that is not possible given the current structure of the schedule.

If one brand of a triptan is reclassified, all its competitors will be as well. The cost of the analysis is a real issue but one that could be simply overcome.

The cost of modelling could be borne by taxpayers, who benefit from having more medicines reclassified – similar to analyses for listing services on the Medicare Benefits Schedule. Or it could be borne collectively by any pharmaceutical companies who stand to benefit, potentially through a levy arrangement.

HOW WILL AUSTRALIA'S FRAGMENTED SYSTEM BE NAVIGATED?

For a medicine to be reclassified across Australia, every State and Territory health department needs to agree. Brokering such a consensus is not simple. That noted, it's possible – and may become more common – for a State or Territory to go it alone. Had the Liberal Party won the last Victorian election, it's likely the OCP would have been reclassified to Schedule 3 (pharmacist only) in Victoria while remaining Schedule 4 (prescription only) elsewhere in Australia.

A hodgepodge of scheduling arrangements across the country has drawbacks, particularly on State and Territory borders. But there is also an upside to being able to observe the effects of reclassification in one State before implementing nationwide change.

IS MORE RESEARCH REQUIRED?

As impressive as the framework now is, it still requires further fine-tuning. As with all models, it's a case of rubbish in-rubbish out.

Dr Parkinson observes that better research on things such as switch rates by patients, the impact on pharmacist behaviour, and clinical outcomes is needed for the framework to generate accurate results.

"As impressive as the framework now is, it still requires further fine-tuning."

Recommendations

To summarise, roundtable attendees agreed that the following three steps should now be taken:

- A wide-ranging national conversation involving all relevant stakeholders on the merits of adopting the proposed new framework.
- A dialogue with ACMS to gain a better insight into how it makes reclassification decisions and determine whether it would be amenable to adopting the proposed framework. If feasible, it would be useful to pilot the framework next time ACMS is considering reclassifying a medicine.
- Funding to be sought to further develop the framework and improve the quality of its inputs.

Conclusion

Reform is never easy but the time seems to have come for ACMS and health departments to reconsider their approach to reclassification decisions.

MUCHE and ASMI are proud to have developed a world-leading economic evaluation framework to inform the reclassification of medicines. They eagerly await the discussion that will now take place around this proposed framework's strengths and weaknesses.

[1] Grove, A. (2016) The Pharmaceutical Benefits Scheme: a quick guide. Available: https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/rp1516/Quick_Guides/PBS
[2] Raferty, JP (2008) Paying for costly pharmaceuticals: regulation of new drugs in Australia, England and New Zealand, Medical Journal of Australia, 188(1): 26-28. Available: https://www.mja.com.au/journal/2008/188/1/paying-costly-pharmaceuticals-regulation-new-drugs-australia-england-and-new#0_i1092175
[3] Parkinson, B., Gumbie, M., Cutler, H., Gauld, N., Mumford, V., Haywood, P., Cost Effectiveness of Reclassifying Triptans in Australia: Application of an Economic Evaluation Approach to Regulatory Decisions. Value in Health (EPub ahead of print). Available: https://doi.org/10.1016/j.jval.2018.09.2840
[4] Gumbie, M., Parkinson, B., Cutler, H., Gauld, N., Mumford, V. Is Reclassification of the Oral Contraceptive Pill from Prescription to Pharmacist-Only Cost-Effective? Application of an Economic Evaluation Approach to Regulatory Decisions. Pharmacoeconomics (In Press)

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