AlfredHealth

Public consultation on the post-market review of medicines for smoking cessation final Terms of Reference

Alfred Health submission

Alfred Health welcomes the public consultation on the final Terms of Reference of the post-market review of medicines for smoking cessation subsidised through the Pharmaceutical Benefits Scheme (PBS). Alfred Health is widely recognised as a leader in the provision of treatment based healthcare, and more recently in preventative health. Smokefree environments and the clinical management of nicotine dependency are areas of key expertise and international leadership for Alfred Health.

As stated in our previous submission, ensuring that medicines subsidised on the PBS are reflective of the latest clinical evidence has great potential to accelerate the decline in smoking prevalence in Australia by supporting more people who smoke to quit.

Alfred Health notes the finalised Terms of Reference and this submission will provide comments on each (additional information to that provided in our earlier submission):

1. **Collate the current clinical guidelines for medicines for smoking cessation and compare these to the Therapeutic Goods Administration (TGA) and PBS restrictions for these medicines**

Currently there is a lack of national clinical guidelines for medicines for smoking cessation in Australia. The only nationally recognised clinical guideline is the new edition of the Royal Australian College of General Practitioners (RACGP) *Supporting smoking cessation: A guide for health professionals guidelines* which was released in January 2020. This updated guideline was developed by a multidisciplinary Expert Advisory Group including representation from Alfred Health. In keeping with current international best practice of guideline development, the guideline was updated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology to build upon the existing evidence base. (1) This involved the commissioning of the Joanna Briggs Institute (JBI) and the JBI Adelaide GRADE Centre to conduct an evidence review for five clinical questions required for the update.

In light of the above, it would be prudent to consider review of both international and local clinical guidelines alongside expert option, so as to avoid the potential unintended consequence of reviewing limited guidelines which may in turn not necessarily reflect best practice tobacco dependence treatment. Best practice tobacco dependence treatment is to have a health professional deliver a brief intervention, which includes advice to quit and a combination of pharmacotherapy (as clinically appropriate) alongside multi-session behavioural intervention (such as telephone counselling provided by quitlines). (2)

While these guidelines for smoking cessation may differ with respect to audience and setting, their content is similar with respect to the recommendations for evidence-based pharmacotherapy (often beyond TGA recommendations especially NRT in combination therapy, higher dosages and for longer durations). Some examples that Alfred Health are aware of are provided below for consideration as part of the review for this Term of Reference.

The UK's National Institute for Health and Care Excellence is currently updating their guidance *Tobacco: preventing uptake, promoting quitting and treating dependence* (the expected publication date is January 2021).

The Ministry of Health in New Zealand *Guidelines for Helping People to Stop Smoking* accompanied by a *Guide to Prescribing Nicotine Replacement Therapy (NRT)*, released in 2014, supports the use of combination therapy, higher doses and longer durations of NRT as required to support people who smoke to quit.

In Victoria, a project is currently awaiting implementation (led by Quit Victoria, in collaboration with the Department of Health and Human Services (DHHS) and Alfred Health) in four pilot health services. It aims to operationalise a smoking cessation model of care in Victorian health services and involved the development, using co-design principles and processes, of a suite of resources including an evidence-based clinical guideline. It would be our recommendation that this document be reviewed as part of this term of reference.

It is also important to consider priority populations, one of which being pregnant women who smoke. As there are no current national (or state wide) clinical guidelines for NRT prescribing in pregnancy, Alfred Health has been supporting Quit Victoria and the Royal Women's Hospital, Melbourne (who write the national Pregnancy and Breastfeeding Medicines Guide) in developing clinical guidelines to facilitate the delivery of best practice tobacco dependence treatment in maternity settings. These guidelines have been informed by the best available evidence to date alongside good clinical practice, and are intended to provide practical guidance to clinicians working with pregnant women who smoke. The guidelines facilitate NRT prescribing in pregnancy including use of combination therapy for pregnant women who have relapsed in the past or who experience cravings using one form of NRT alone, under medical supervision. While this document is still a final draft awaiting stakeholder endorsement (including RACGP and RANZCOG), it would be our recommendation that this document also be reviewed within this term of reference.

2. **Review the utilisation of PBS-listed medicines for smoking cessation including but not limited to patient demographics, time on treatment, and the proportion using PBS subsidised combination treatment**

It is our view that this term of reference should also review the utilisation of behavioural intervention in combination with those accessing PBS-listed medicines for smoking cessation. This is in recognition that best practice tobacco dependence treatment is a combination of pharmacotherapy and multi-session behavioural intervention. The review would therefore also align with the current PBS clinical criteria; 'Patient must have entered a comprehensive support and counselling program' and 'Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.'

Alfred Health would also suggest this Term of Reference should include review of the utilisation of smoking cessation medicines that are not currently PBS-listed; particularly intermittent forms of NRT such as the nicotine oral mouth spray and nicotine inhalator. Current PBS-listed intermittent formulations such as the nicotine gum and the nicotine lozenge will not be clinically appropriate for all people who smoke (or preferable).

3. **Review the efficacy and safety of nicotine replacement therapy, varenicline and bupropion for smoking cessation including combination therapies those not currently PBS subsidised**

Effectiveness in real world clinical practice as well as the controlled conditions of a clinical trial is critical in understanding the safety and efficacy of medicines for smoking cessation. It would be ideal for all forms of evidence to be included in the review alongside expert opinion, with a particular focus on combination NRT therapy, higher dosages and longer durations.

It would be Alfred Health's recommendation that the technical report summarising the evidence review conducted as part of the updated RACGP guidelines be requested to assist with this Term of Reference around efficacy and safety.

4. **Subject to the findings of Terms of Reference 1, 2 and 3, review the cost-effectiveness of medicines for smoking cessation**

Smoking remains the greatest cause of preventable morbidity and mortality in Australia (AIHW, 2019). In retrospect, smoking cessation is both cost and clinically effective, especially when compared with other preventive measures such as the treatment of hypertension or hypercholesterolemia. (3-5)

While data be limited, investment in PBS- listed medicines is unlikely being optimised currently as restrictions do not align with best practice tobacco dependence treatment nor facilitate the tailoring of treatment to the individual (with respect to combination therapy, dosage or length of treatment).

By the very nature of increased quit attempts, there will be an increase in the number of successful cessations. Every person who quits smoking stands to benefit personally in health, social and financial contexts and likewise at a population level.

Thank you for your consideration of this submission.

If you have questions, please contact [redacted]

REFERENCES

1. Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008;336(7650):924-6.
2. Kotz D, Brown J, West R. Prospective cohort study of the effectiveness of smoking cessation treatments used in the "real world". Mayo Clin Proc. 2014;89(10):1360-7.
3. Ekpu VU, Brown AK. The Economic Impact of Smoking and of Reducing Smoking Prevalence: Review of Evidence. Tobacco Use Insights. 2015;8:TUI.S15628.
4. Parrott S, Godfrey C. Economics of smoking cessation. BMJ (Clinical research ed). 2004;328(7445):947-9.
5. Shearer J, Shanahan M. Cost effectiveness analysis of smoking cessation interventions. Australian and New Zealand Journal of Public Health. 2006;30(5):428-34.