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RCPA
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PBS Post Market
Department of Health and Ageing
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Canberra ACT 2601

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Dear Madam / Sir

RE: Review of Anticoagulation Therapies in Atrial Fibrillation

Thank you for asking The Royal College of Pathologists of Australasia (the College) to provide input into the above review.

The College presumes the Australian Government's review, led by Professor Sansom will include an evidence based assessment of the literature on this topic, so the College has not attempted to cover this in its comments which are more general.

Firstly, while limiting the scope of the review to anticoagulation for atrial fibrillation may make sense from a TGA regulatory and PBS funding viewpoint, it seems artificial from a clinical viewpoint. The clinical issue of how to best manage/optimize long term anticoagulation is a much broader topic and any measures that are implemented to "*optimize the use of currently available anticoagulant treatments used in patients with atrial fibrillation*", should also be applicable to patients with other indications for anticoagulation. This broader scope should obviously be considered in the costing of any recommendations.

The two main areas where improvement can be made in the use of existing anticoagulants (ie warfarin) are:

1. Education of clinical staff regarding protocols for initiation of warfarin and perioperative management of anticoagulation with measures to facilitate communication with GP's/the patients usual warfarin dosing service on discharge from hospital; and
2. improving the functioning of the current '*dosing services'*.

In terms of models of service delivery for warfarin dosing, two ends of a spectrum could be explored.

- The first is a decentralised service, where local health providers look after their own patients anticoagulation – probably using Point-Of-Care INR devices in their clinic rooms. The benefits of this model are patient convenience (unless booking appointments is restricted) and utilizing a well established relationship with the GP who is aware of the patients other medical conditions/medications. However, the

disadvantages are increased cost (the GP is likely to bill for a consultation, as well billing for the point of care testing of the INR), difficulty with consistency (various levels of experience of the dosing GPs), ensuring quality and regulatory requirements are met (the billing for the testing of an INR will require the 'clinic' to be an approved 'laboratory' under the NPAAC standards) and ensuring the availability of the service 7 days a week (with cover when the GP is not available). The previous Department of Health & Ageing Quality Use of Pathology Program (QUPP) Study on POCT in GP's for INR is an important reference for consideration for this appoach.

- The other end of the spectrum would be a centralised model – an entirely nationalized service with the health department looking after the collection, transport and testing of samples and the dosing done by government employed GPs/nurses. Centralized models of service delivery are likely to be more cost-effective than de-centralised models, (although the College is not aware of any locally published evidence) and are more likely to provide a more consistent level of anticoagulation. The Netherlands has operated a national anticoagulation service for many years and there are publications on the benefits of this model. The disadvantage of this government-run service would be the huge initial cost to establishing and then running the service. Even within states, different laboratories are not necessarily networked together to allow centralized dosing.

The best model is likely to be somewhere between these two extremes. Currently, in some states, private pathology service providers run warfarin dosing services that appear to be very efficient/effective. However, the cost of running these services is not reflected in the medicare fee for the INR test which is the same whether or not dosing advice is included with the result. The College thinks it would be useful to investigate the expansion of these current services with support through a MBS item for warfarin dosing (by an approved service provider). An approved service provider would be required to be NATA accredited/meet NPAAC standards and perhaps could be required to provide data on certain KPIs such as frequency of testing, % in therapeutic range, time from testing to dosing etc. This would then maximize patient convenience by utilizing existing networks of collection centres, couriers and testing laboratories therefore avoiding massive start-up costs while still being answerable to the health department for ongoing funding.

Yours sincerely

Dr Debra Graves
Chief Executive Officer