



Safety Notice 002/14

24 March 2014

Distributed to:

- Chief Executives
- Directors of Clinical Governance

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- ED Clinicians
- Medical and Surgical Department Heads
- Directors of Pharmacy
- Drug and Therapeutics Committees

Expert Reference Group

Content reviewed by:

- Clinical Excellence Commission
- Medication Safety Expert Advisory Committee

Clinical Excellence Commission

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<http://www.health.nsw.gov.au/quality/sabs>

Intranet Website
<http://internal.health.nsw.gov.au/quality/sabs/>

Review date

March 2017

Newer Oral Anticoagulants (Update)

In 2011 NSW Health published Safety Notice 014/11 Newer Oral Anticoagulants <http://www.health.nsw.gov.au/sabs/pages/default.aspx>
This Safety Notice should be read in conjunction with the above document.

Background
The following TGA approved newer oral anticoagulants are now funded by the Pharmaceutical Benefits Scheme (PBS). It is likely that there will be a significant increase in the use of these medicines:

Apixaban (Eliquis®), dabigatran (Pradaxa®) and rivaroxaban (Xarelto®)

Several serious incidents involving these agents have been reported. These include incidents where clinicians failed to recognise these agents as anticoagulants and inappropriately prescribed and administered additional anticoagulation.

There is evidence that in complex situations use of new oral anticoagulants pose a considerable patient safety risk. One reported patient death occurred secondary to a stroke following premature cessation of dabigatran before a procedure. Significant bleeding was seen in another case where a patient was being switched from dabigatran to warfarin and was also administered intravenous heparin.

There is also evidence that clinicians are misinterpreting coagulation tests, using measures such as prothrombin time or activated partial thromboplastin time as an indicator of anticoagulation levels. Routine anticoagulation tests are not appropriate for determining levels of anticoagulation with these new oral agents or for dose adjustment. While these tests may provide qualitative information about the anticoagulation effect of newer agents, specific assays are required to quantify the presence of the drug.

Suggested actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant stakeholders.
2. Put mechanisms in place, for example an inservice education program, that enhances clinician recognition of the newer agents as anticoagulants and informs clinicians of the risks associated with these agents.
3. Provide appropriate clinical guidelines for initiating treatment with new oral anticoagulants and for managing patients who are admitted to hospital taking one of these agents.
4. Encourage clinicians to report incidents involving these agents via the incident management system.
5. Encourage reporting of suspected adverse drug reactions to the TGA at adr.reports@tga.gov.au



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Points to be considered

- Patients receiving these newer anticoagulants should not be routinely given other anticoagulants (including heparin or low molecular weight heparins).
- Careful consideration must be given to appropriate patient selection prior to prescribing these medicines. An assessment of risk factors for bleeding must be undertaken. They should be used with caution in patients with an increased bleeding risk.
- Patients and their carers must be counselled on the risks associated with these medicines including the fact that there is no specific reversal agent. They must be advised to seek medical attention immediately if bleeding is suspected.
- All patients taking anticoagulants require careful management of this therapy prior to and post invasive procedure or surgery. Careful consideration must be given to managing the risk of thrombosis and the risk of bleeding.
- Clinicians should refer to the relevant Product Information for specific advice on use of these medicines.

Further information:

NPS MedicineWise 2014. Anti-clotting medicines
<http://www.nps.org.au/medicines/heart-blood-and-blood-vessels/anti-clotting-medicines>

NSW Health PD2012_003 High-Risk Medicines Management Policy Directive
<http://www.health.nsw.gov.au/policies/Pages/default.aspx>

NSW Health Safety Notice 014/11 Newer Oral Anticoagulants
<http://www.health.nsw.gov.au/sabs/pages/default.aspx>

TGA Safety Information May 2013 Dabigatran (Pradaxa) and risk of bleeding:
Information for health professionals
<http://www.tga.gov.au/safety/alerts-medicine-dabigatran-111005.htm>

TGA Safety Information September 2013 Apixaban (Eliquis), dabigatran (Pradaxa) and rivaroxaban (Xarelto)
Information for health professionals
<http://www.tga.gov.au/safety/alerts-medicine-apixaban-hp-130924.htm>