IRISH MEDICATION SAFETY NETWORK

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Safety Alert

New Oral Anticoagulants & Antiplatelet agents – Bleeding Risks

Rivaroxaban (**Xarelto**®) Dabigatran (**Pradaxa**®) & Prasugrel (**Efient**®)

Issue:

Rivaroxaban and dabigatran are anticoagulants and, like warfarin, may cause bleeding or haemorrhage. Prasugrel is an oral antiplatelet drug and, like aspirin and clopidogrel, may cause bleeding or haemorrhage. No routine laboratory monitoring is required during therapy with these agents. There is no reversal agent for rivaroxaban, dabigatran or prasugrel.

These medicines have been shown to have positive risk-benefit profiles in large randomised controlled trials, however they are high-risk drugs. The anticoagulants rivaroxaban (Xarelto®) and dabigatran (Pradaxa®) are currently licensed for the primary prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. The antiplatelet agent prasugrel (Efient®) is licensed for the prevention of atherothrombotic events in patients with specific coronary indications. It is likely these agents will be licensed for other indications in the future, leading to more widespread use.

Lack of familiarity of healthcare professionals and patients with these high-risk medicines increases the risk that serious adverse drug reactions and medication errors will occur.

Examples of Harm:

- A patient discharged from hospital on rivaroxaban once daily took it two to three times a day for three days, mistaking it for analgesia. The patient required readmission and surgery for a haematoma.
- A patient already on clopidogrel was co-prescribed prasugrel. The prescriber was not familiar with the action of prasugrel. The near miss was detected and corrected before administration to the patient.
- A patient started on dabigatran in the community, was admitted to hospital 4 days later with profound melaena and fall in haemoglobin, requiring transfusion and intervention with subsequent recovery.
- A patient was discharged from hospital on rivaroxaban and diclofenac, in addition to his usual medication which included aspirin and celecoxib. The patient suffered a major GI bleed one week following discharge, necessitating hospital admission, including intensive care treatment.

How to reduce the risk:

- **Healthcare professionals must understand these medicines**; indications, contra-indications, cautions, dosing recommendations and drug interactions, and how to counsel patients on their safe use.
- **Patients must understand these medicines**; the indication, dose and duration of therapy, how to recognise signs of bleeding or anaemia and to seek medical help if bleeding occurs. **Patients require counselling** and written patient information leaflets, which may be accessed on www.medicines.ie.
- **Risk-benefit assessment is necessary for patients already taking medicines which increase bleeding risk,** e.g.
  - Anticoagulants (e.g. warfarin, heparins)
  - Antiplatelets (e.g. aspirin, clopidogrel)
  - NSAID & COX 2 inhibitors (e.g. ibuprofen, diclofenac, celecoxib, etoricoxib)
  - SSRI and other antidepressants (increased bleeding risk with concomitant oral anticoagulant use)

  Example: For a patient who requires anticoagulation and is already taking diclofenac and an SSRI antidepressant, it may be more appropriate to change diclofenac to an alternative analgesic
- **Report any medication errors or adverse drug reactions** involving the above agents via local incident reporting and/or to the Irish Medicines Board (www.imb.ie) as appropriate.

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The Irish Medication Safety Network (IMSN) is an independent group of pharmacists and other specialists working in the acute sector, whose principal aim is to improve patient safety with regard to the use of medicines through collaboration, shared learning and action.
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