

# encapsulate

## Welcome to 'encapsulate'

In this issue we present the latest initiative from the Victorian Medicines Advisory Committee High Risk Medicines Working Party, PINCH. We also provide an update on 'off-label use' of medicines, and highlight the risks associated with Warfarin.

You can obtain further copies of **encapsulate** via our website - [www.slade.net.au](http://www.slade.net.au). Please forward any comments or suggested topics for our next issue to [marketing@slade.net.au](mailto:marketing@slade.net.au).

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## PINCH

High risk medicines (HRM) are defined as medicines with an increased risk of causing substantial or fatal harm when used in error. This includes:

- medicines with a narrow therapeutic index
- medicines that present a high risk when administered via the wrong route or
- when any errors occur associated with high risk medicines.

The Victorian Medicines Advisory Committee (VMAC) High Risk Medicines Working Party is currently focusing on a HRM alert system for the following drugs and categories:

- P** - potassium
- I** - insulin
- N** - narcotics
- C** - chemotherapy
- H** – heparin (and other anticoagulants)

The acronym "PINCH" has been developed by VMAC to raise awareness and assist health professionals to remember medicines that are considered high risk.

The purpose of the HRM alert system is to warn health professionals:

- about serious known medication risks
- outline the action required to minimise risks
- provide tools to facilitate risk minimisation

Slade Pharmacy and Galen Health have actively promoted the risks associated with many of these medicines in the form of Medication Safety Alerts. Recommendations to minimise harm are outlined in these alerts.

These will continued to be developed and issued as developed. For further information about these alerts or to obtain a copy, please contact the Clinical Services Team on (03) 8420 0200.

Further details about PINCH will be communicated to all hospitals when the program is officially launched by VMAC.

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## 'Off label use' of Medicines

The term "off-label use" refers to a registered medicine used for a non-TGA approved indication, dose, age or route of administration. The term does not refer to:

- conditions imposed under the Pharmaceutical Benefits Scheme (PBS), or
- the use of medicines not registered in Australia.

It is the responsibility of the sponsor, normally a pharmaceutical company, to seek initial approval for marketing of medicines. Any changes to the initial approval must be initiated by the sponsor. Some of the reasons why medicines may remain off label are:

- Therapeutic advances are achieved rapidly while the TGA approval process may be slow (i.e. the labelled indication may not reflect current knowledge)
- The labelled indication may not include proven uses of a medicine
- There are changes to the manufacturing process or location that have not yet been approved by the TGA
- Once patents have expired and generic brands become available, there is no financial incentive for pharmaceutical companies to undertake studies for new indications
- If a new indication is beneficial to a small number of patients, the cost associated with an application for approval may outweigh any financial incentive

Off-label use of medicines is associated with a number of clinical, safety and ethical issues.

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This practice is an important issue in hospitals as:

- These institutions are at the leading edge of care and research
- Suitable licensed products may not be available
- These products may be a last resort treatment

It is important that hospitals have policies and procedures to ensure that off label prescribing is only ever considered if use is supported by appropriate safety and efficacy data. Informed patient consent must also be obtained.

Whenever supplying consumer medicine information (CMI) leaflets to patients for medicines which are used off-label, it is important to counsel the patient about any inconsistencies which appear in the CMI's. This may prevent unnecessary confusion or concerns for patients.

### Warfarin

Warfarin is a widely used drug with a narrow therapeutic index, considerable risk of drug and food interactions, and potentially serious adverse reactions such as spontaneous bleeding. For this reason, monitoring is mandatory and dosage adjustment may be frequently required.

The anticoagulant effect of warfarin is monitored by calculating the International Normalised Ratio (INR) – a ratio of the patient's prothrombin time to the mean normal prothrombin time. For most patients requiring warfarin, the target INR range is between 2 and 3.

Bleeding is the most common and serious complication of warfarin and there is a strong relationship between INR levels and bleeding. The risk of bleeding is markedly increased once the INR exceeds 4. Regular INR monitoring and review allows timely identification of elevated INR levels and necessary dose adjustment.

More frequent monitoring is required when:

- A patient commences warfarin

- There are changes in a patient's medication therapy
- There are changes in a patient's condition, including intercurrent illness

This includes patients on warfarin who are hospitalised for conditions not related to their warfarin therapy.

To further minimise the risks associated with warfarin therapy and ensure continuum of care, patients need to be educated and involved in their therapeutic plan. Appropriate counselling and written information must be provided to patients. Research shows provision of written information to patients is suboptimal in content, especially with regard to daily warfarin management. Patients state they want "detailed information to increase their confidence in therapy, including better explanations of the reasons for taking warfarin, how it works, how dose adjustments are made, and observed phenomena (e.g. bruising, variable INR results)." Although this information is most important when warfarin is initiated, it is appropriate to provide written drug information at every opportunity. The information provided should be targeted to individual patient needs and be appropriate to age, language and cognition. Your clinical pharmacist can assist in the education of patients and the provision of appropriate written warfarin information.

In the hospital setting, warfarin education, INR monitoring, dose review and adjustment must be explicitly documented on the patient's medication therapy chart and medical history. Good documentation supports quality patient care and is a critical component of management for high risk medicines such as warfarin.

<sup>1</sup> Bajorek BV, Ogle SJ, Duguid MJ, Shenfield GM, Krass I. Management of warfarin in atrial fibrillation: views of health professionals, older patients and their carers. Medical Journal of Australia 2007; 186:175-80.

*This publication is intended to provide a general outline and is not intended to be and is not a complete or definitive statement of the information on the subject matter. Further professional advice should be sought before any action is taken in relation to the matters described in this publication. To obtain further copies of all documents referred to in this publication please see your pharmacist.*