

Embedding QUM principles for off-label use of medicines in MI

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BACKGROUND

Off-label prescribing includes use of medicines for a different indication, at a different dose, via a different route of administration (ROA) or for a patient that differs from that specified in the approved Product Information.

It may be necessary in certain situations such as when other options are not available, exhausted, not tolerated or unsuitable. However, there are clinical, safety, ethical, legal and financial issues that should be considered to ensure patient safety.

DESCRIPTION

The Council of Australian Therapeutic Advisory Groups (CATAG) 'Guiding Principles for the quality use of off-label medicines' (available via QR code below) provides detailed guidance.

An evaluation of evidence supporting safety and quality should be undertaken to determine whether use is appropriate (see Figure 1. CATAG Overall Guide for decision-making). A Medicines Information (MI) service can assist in this process.

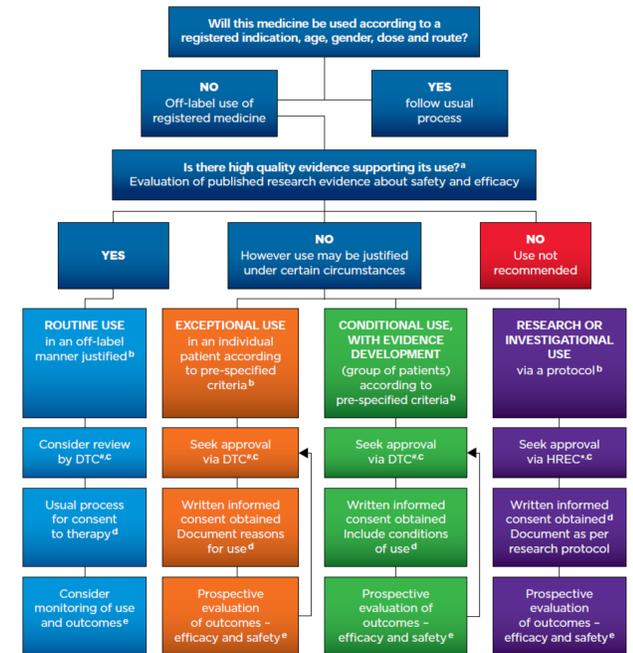


Figure 1. CATAG overall guide for decision-making

ACTION

- An audit of enquiries received by our MI service over an 18 month period was conducted to identify enquiries involving off-label use.
- Enquiries were categorised according to the type of off-label use and overall recommendations according to the Guiding Principles.
- Internal processes for providing responses were examined.

EVALUATION

- 44 enquiries were analysed (see Figure 2. Enquiry breakdown and examples).
- One third involved high risk medicines.
- 80% enquiries were from pharmacists.
- Approximately 50% of off-label indications were categorised as 'Routine Use'.
- Use was 'Not Recommended' in 8 cases (n=6 indications; n=1 ROA; n=1 dosage).

IMPLICATIONS

CATAG Guiding Principles are now embedded in the delivery of medicines information involving off-label use of medicines. The need for patient consent is highlighted.

MI pharmacists can raise clinician awareness of the various issues to consider when using medicines in an off-label manner, enhancing delivery of optimal patient care.

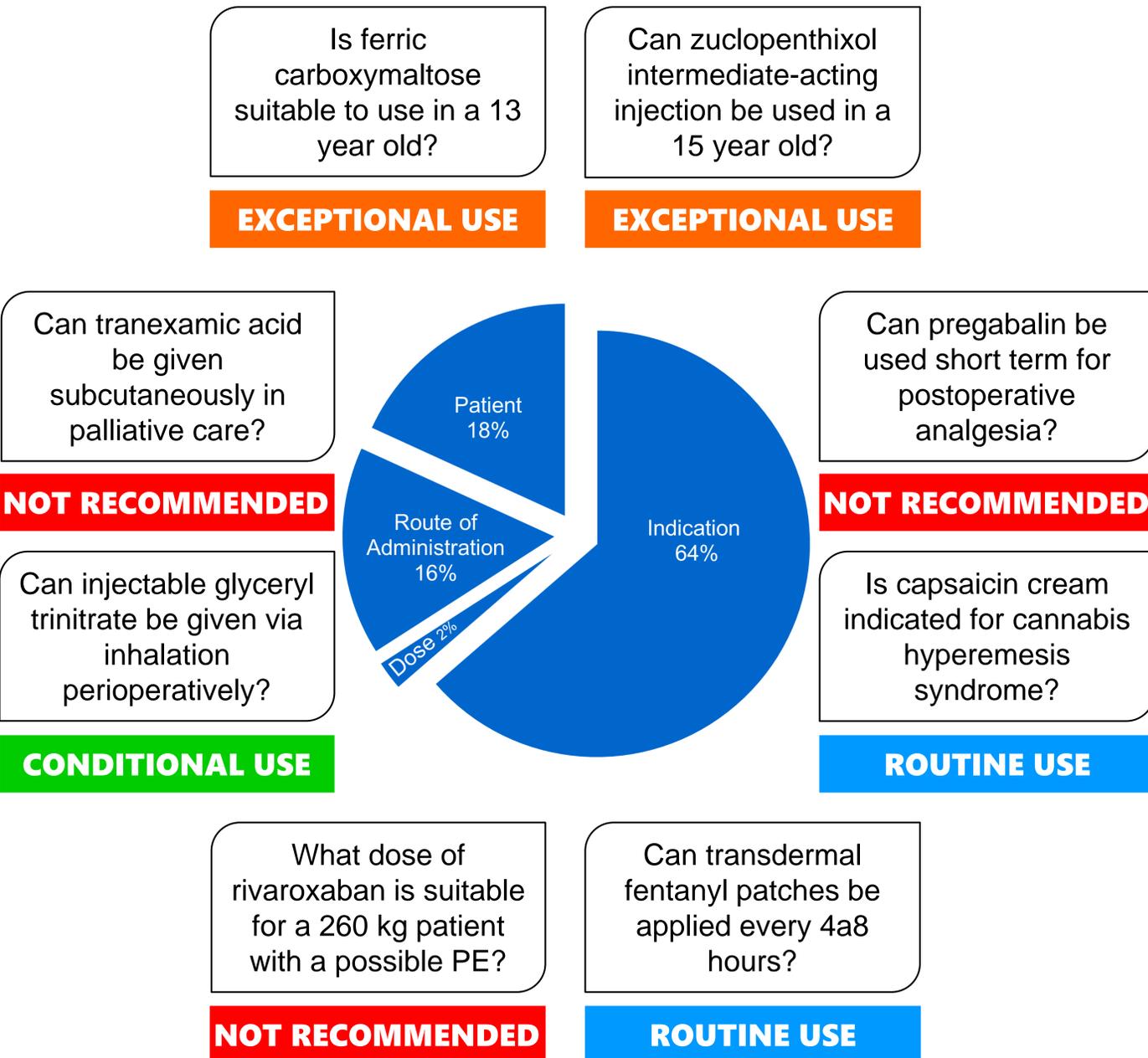


Figure 2. Enquiry breakdown and examples

Medicines Information (MI) services support healthcare professionals by providing current, accurate, patient-specific, evidence-based therapeutic advice in a timely manner.

