

Selection of adverse effects to review

- Any systematic review must satisfy the needs of the patient and the clinician, i.e. be relevant to the therapeutic context
- Results must be easily accessible, not hidden amongst information that has no clinical impact - presenting a list of all 83 side effects of a drug is not helpful in therapeutic decisions.
- Unlike the situation with therapeutic effect, a drug may have numerous adverse effects. Attempting to analyse all possible adverse effects can be difficult and time consuming, while resources are limited

It is therefore necessary to decide on which specific adverse effects the analysis should focus. It may not be possible to identify in advance exactly which effects will be the most relevant to review, although one often has some idea. There are two main factors which help in selecting the type of adverse effects for review:

- Duration of treatment (single dose, short-term, or lifelong)
- Level of benefit (e.g. life-saving, symptomatic relief, or prophylaxis)

When dealing with an immediate life-saving therapy e.g. for heart attacks, “headache”, “lethargy” and “cough” are probably not important potential adverse effects. They may, however, be important for long-term prophylactic therapies (e.g. epilepsy or hypertension), when troublesome symptomatic adverse effects can influence compliance. Reviewers should decide, in consultation with health-cares and patients, which adverse effects are most important in that therapeutic area.

Reviews obviously need to be flexible in their approach, but we would suggest that a good starting point would be to plan to review:

1. Five to ten of the most common AEs
2. Selected, serious AEs that are of particular concern (e.g. gastrointestinal haemorrhage with aspirin, teratogenicity with antiepileptics, neuropsychiatric effects of mefloquine)
3. The five most common AEs leading to withdrawal.

Attempts to analyse all AEs ever associated with a particular drug may waste valuable time and resources, and could produce long lists of information from which it is difficult to extract clinically useful data. More is not necessarily better!