Choosing Monitoring Boundaries: Balancing Risks and Benefits

Statistical Issues in Clinical Trials
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Comments

• Stopping rules are population-based, “important” outcomes (e.g., ratio of benefits to harms) are personal.

• Identification of “important” adverse events may not be as hard as prioritizing them (e.g., for stopping rules)
  – How do we do this?

• Benefits may be easier to prioritize than harms.

• “Serious” adverse events are not systematically collected.

• “Serious” adverse events are defined by regulatory agency not the patients.
Trials collect “too many” outcomes

Figure 2 – Overlap between outcomes in reviews and trials, by type of intervention

2a. Clinical management

- 93 outcomes in 39 reviews
- 213 outcomes in 202 trials
- 25 outcomes (10%)
- 68 outcomes (29%)
- 145 outcomes (61%)
- 238 total outcomes
Benefits vs harms

Patients want to know:
- **All** benefits and harms
- Contextual information
  - Duration
  - Severity
  - Reversibility.