JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Choosing Monitoring Boundaries: Balancing Risks and Benefits

Statistical Issues in Clinical Trials

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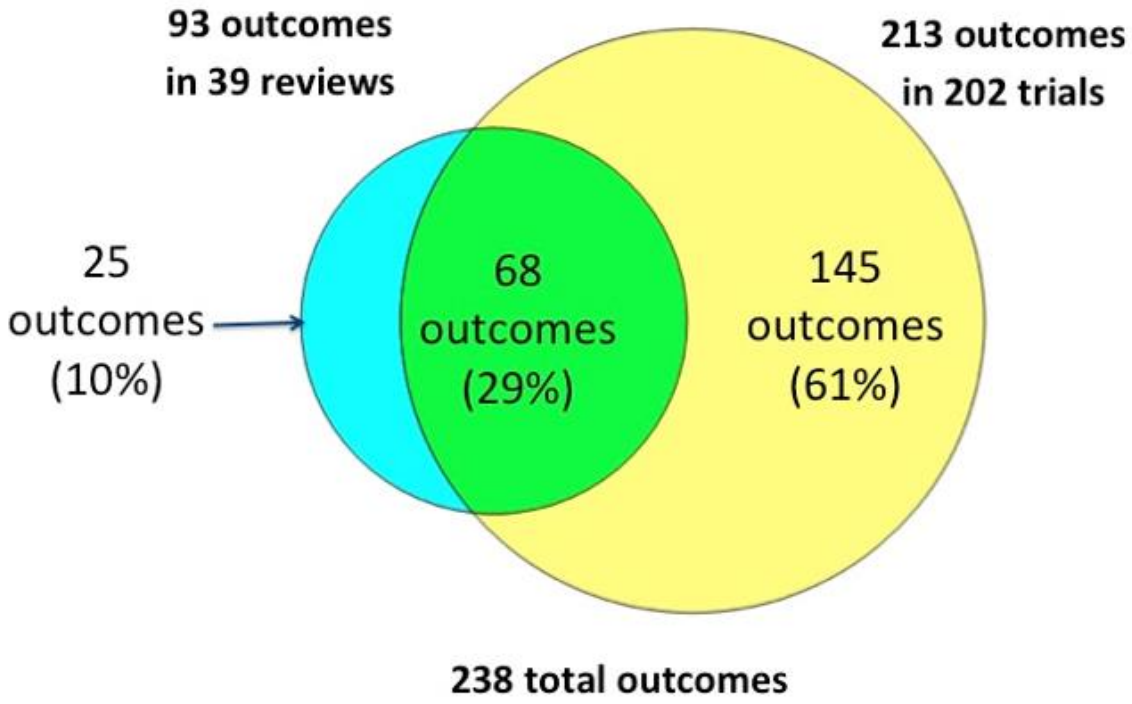
Comments

- Stopping rules are population-based, “important” outcomes (eg, 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



Benefits vs harms

Patients want to know:

- All benefits and harms
- Contextual information
  - Duration
  - Severity
  - Reversibility.