

Component 2: Evidence- Based Medicine

Unit 5: Evidence-Based Practice Lecture 3

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Using EBM to assess questions about interventions

- Questions concerning benefit of a clinical intervention to treat or prevent disease
- Can include drug therapy, diet therapy, surgery, alternative medicine, etc.
- Best evidence comes from a randomized controlled trial (RCT) or meta-analysis of RCTs
 - Patients similar in all regards with exception of intervention applied

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Why are RCTs the best evidence for interventions?

- Reduction in bias
 - Vitamin C to prevent the common cold (Douglas, 2004)
 - Women's Health Initiative (2002)
- Emphasis on clinical end-points and patient-oriented outcomes
 - Cardiac Arrhythmia Suppression Trial (Epstein, 1993)
- "New" treatments are not necessarily better
 - In radiation oncology, trials of new treatments are as likely as not to be successful (Soares, 2005)

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Other issues for RCTs

- Quality of study inversely related to magnitude of treatment effect (Moher, 1998)
- Lower-quality (e.g., non-RCT) studies more likely to be later “overturned” (Ioannidis, 2005)
- But well-designed observational studies may be just as good (Benson, 2000)

History of RCTs

- James Lind, British naval doctor and surgeon (1717-1794) demonstrated that lemons and oranges improved health of sailors with scurvy over those who did not receive them (Lindemann, 1999)
- First true RCT performed in UK in 1940s, demonstrating superiority of streptomycin over placebo for tuberculosis (BMJ, 1948)

How do we critically appraise an intervention study?

- Remember the questions to be asked of any study
 - Are the results valid?
 - What are the results?
 - Can the results be applied to patient care?

Questions to ask about a study on intervention

- Are the results valid?
 - Did experimental and control groups begin the study with a similar prognosis?
 - Were patients randomized?
 - Was randomization concealed (blinded or masked)?
 - Were patients analyzed in the groups to which they were randomized?
 - Were patients in treatment and control groups similar with respect to known prognosis?

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A study on an intervention (cont.)

- Are the results valid? (cont.)
 - Did experimental and control groups retain a similar prognosis after the study started?
 - Were patients aware of group allocation?
 - Were clinicians aware of group allocation?
 - Were assessors aware of group allocation?
 - Was follow-up complete?

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A study on an intervention (cont.)

- What are the results?
 - How large was the treatment effect?
 - What was the relative risk reduction?
 - What was the absolute risk reduction?
 - How precise was the estimate of treatment effect?
 - Were the confidence intervals or p-values stated?
- Can the results be applied to patient care?
 - Were the study patients similar to my patient?
 - Were all clinically important outcomes considered?
 - Are the likely treatment benefits worth the potential harm and costs?

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