“Critical Appraisal of Epidemiological Studies and Clinical Trials, 3rd Edition”
Mark Elwood, 2007, 570 pages, Oxford University Press, $69.95
Review by Norman M. Goldfarb

“Critical Appraisal of Epidemiological Studies and Clinical Trials, 3rd Edition” clearly and comprehensively explains how to design and evaluate clinical trials and observational studies through the lens of causation, which is usually the main point of such research.

For example, the book sets forth twenty questions for assessing evidence of a causal relationship:

A. Description of the evidence
   1. What was the exposure or intervention?
   2. What was the outcome?
   3. What was the study design?
   4. What was the study population?
   5. What was the main result?

B. Internal validity: consideration of non-causal explanations
   6. Are the results likely to be affected by observation bias?
   7. Are the results likely to be affected by confounding?
   8. Are the results likely to be affected by chance variation?

C. Internal validity: consideration of positive features of causation
   9. Is there a correct time relationship?
  10. Is the relationship strong?
  11. Is there a dose-response relationship?
  12. Are the results consistent within the study?
  13. Is there any specificity within the study?

D. External validity: generalization of the results
   14. Can the study results be applied to the eligible population?
   15. Can the study results be applied to the source population?
   16. Can the study results be applied to other relevant populations?

E. Comparison of the results with other evidence
   17. Are the results consistent with other evidence, particularly evidence from studies of similar or more powerful study design?
   18. Does the total evidence suggest any specificity?
   19. Are the results plausible in terms of a biological mechanism?
   20. If a major effect is shown, is it coherent with the distribution of the exposure and the outcome?

The book consists of 15 chapters:
- The importance of causal relationships in medicine and healthcare
- Study designs which can demonstrate and test causation
- The results obtained from studies of causation
- Selection of subjects for study
• Error and bias in observations
• Confounding
• Chance variation
• Combining results from several studies: systematic review and meta-analysis
• The diagnosis of causation
• Critical appraisal of a randomized clinical trial
• Critical appraisal of a randomized trial of a preventive agent
• Critical appraisal of a prospective cohort study
• Critical appraisal of a retrospective cohort study
• Critical appraisal of a matched case-control study
• Critical appraisal of a large population-based case-control study

Worked examples with most of the heavy duty statistics are in an appendix.

The book is available in bookstores.

Reviewer

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