

Interpreting Clinical Research

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Faculty Disclosures

Speakers Bureau: Eli Lilly

Objectives

By the end of today's session, the learner should be able to:

- 1. Discuss various types of study designs
- 2. Review the interpretation of clinical trials
- 3. Distinguish the difference statistical and clinical significance

THE WHY

WHY ARE YOU HERE TODAY?



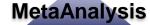
Prospective

Subjects followed forward in time
Endpoints are measured and analyzed in future



Retrospective

Investigators look back in time Endpoints occurred in the past



Systematic Review

Practice Guideline

Randomized Control Trial

Cohort Study

Case-Control Study

THE HOW / Clinical Trial Interpretation

- Superiority Trials
 - Test efficacy of experimental agent to control
 - Placebo or a standard of care
 - When endpoints are ratios (RR,OR,HR)
 - 95% CI excludes 1: statistically significant
 - 95% CI includes 1: not statistically significant
 - When endpoints are differences (ARR,ARI,RRR,RRI)
 - 95% CI excludes 0: statistically significant
 - 95% CI includes 0: not statistically significant

- Non-inferiority Trials
 - Test efficacy of experimental agent to standard of care
 - Pre-defined non-inferiority margin
 - based on previous studies
 - Smallest value considered clinically meaningful

- Internal Validity
 - How well study was conducted

- External Validity
 - How well study can be applied to other groups

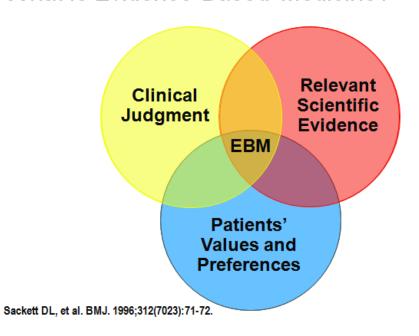
- Things to consider
 - Study limitations
 - Side effects
 - Access

THE WHEN



THE WHO

What Is Evidence-Based Medicine?



References

- Herring, Charles, and Abby Harris. Quick Stats Basics for Medical Literature Evaluation. Sixth ed.
- "Research Guides: Critical Appraisal of Research Articles: Home." Home Critical Appraisal of Research Articles -Research Guides at George Washington University, guides.himmelfarb.gwu.edu/CriticalAppraisal. Accessed 20 Aug. 2023.
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- "Research Guides: Evidence-Based Medicine: What Is Evidence-Based Practice?" What Is Evidence-Based Practice? - Evidence-Based Medicine - Research Guides at George Washington University, guides.himmelfarb.gwu.edu/ebm. Accessed 20 Aug. 2023.