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Epidemiology, Biostatistics, and Population Health Concepts

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Overview

Study Designs

- Overview

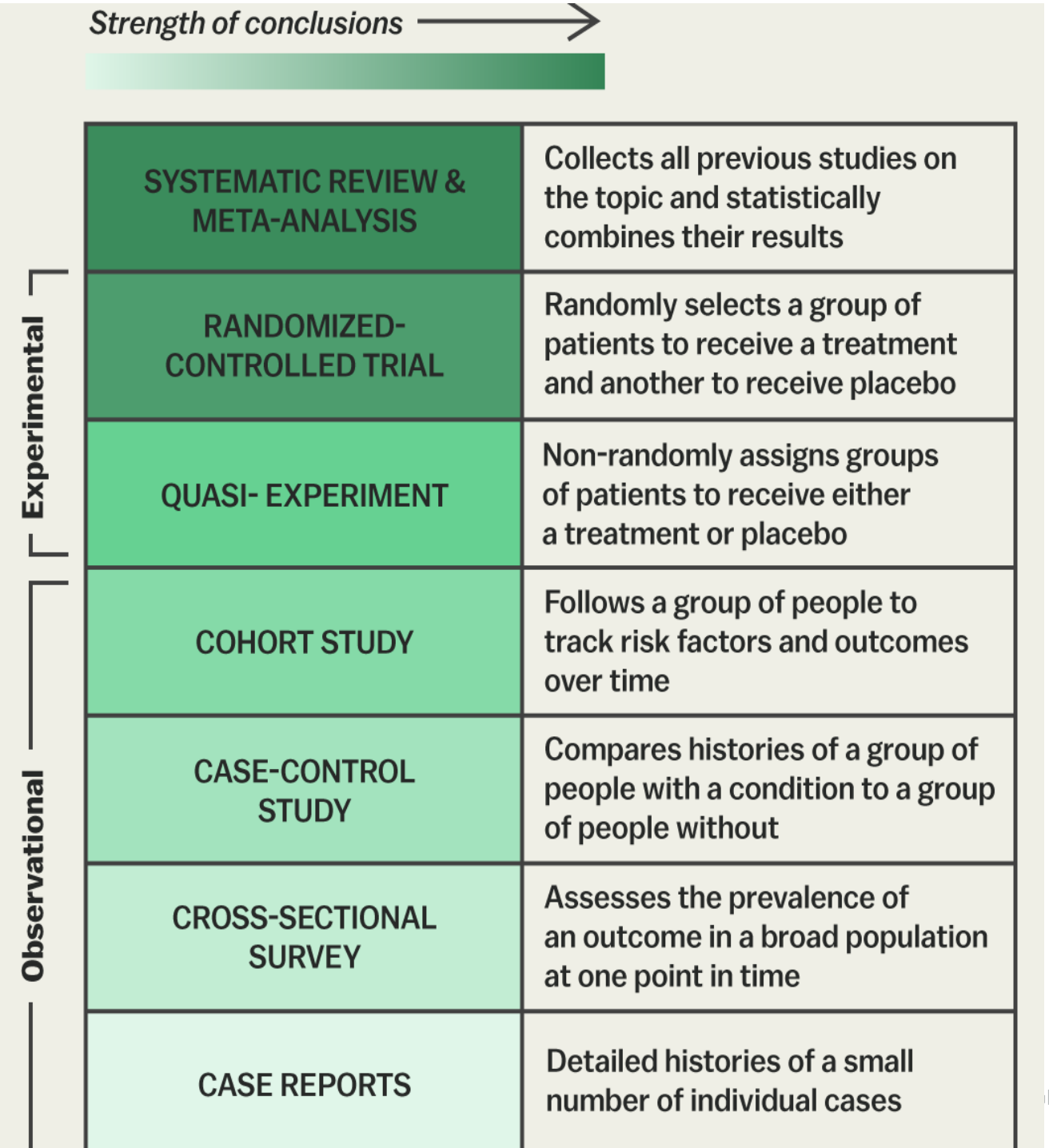
Epidemiology and Biostatistics

- Vocabulary Review
- Reliability, Variability, and Bias
- Diagnostic Testing and Measures of Association

Population Health

- Evidence-Based Medicine
- Interpreting and Evaluating Literature
- Clinical Decision-Making

Study Designs

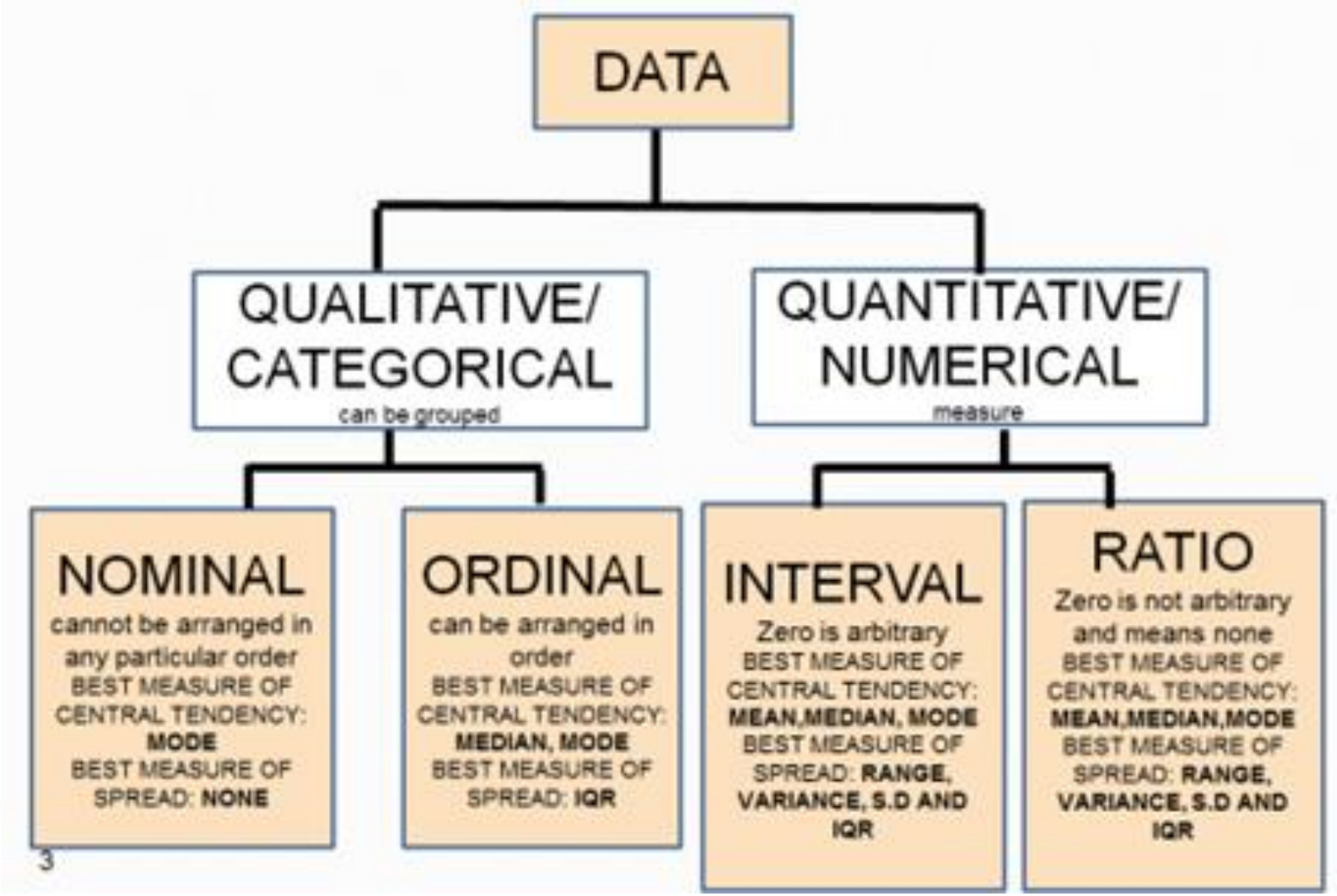


What is a study design?

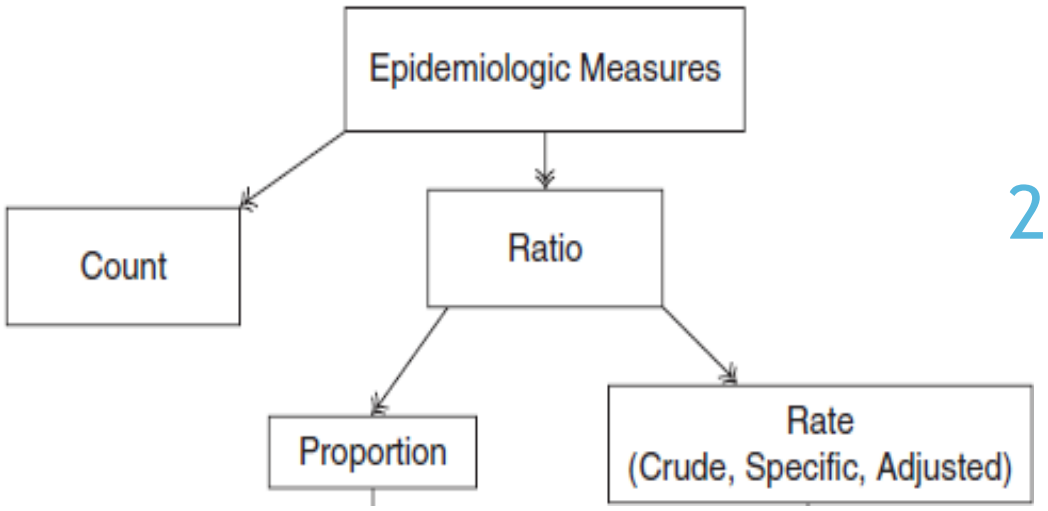
- Framework, or set of methods and procedures, used to collect and analyze data on specific variables denoted by a research problem
- Types of design employed to answer different types of research questions
- Design types have strengths and limitations

Epidemiology and Biostatistics

Variable Scales Measurement



Counts, Ratios, Rates, and Proportions



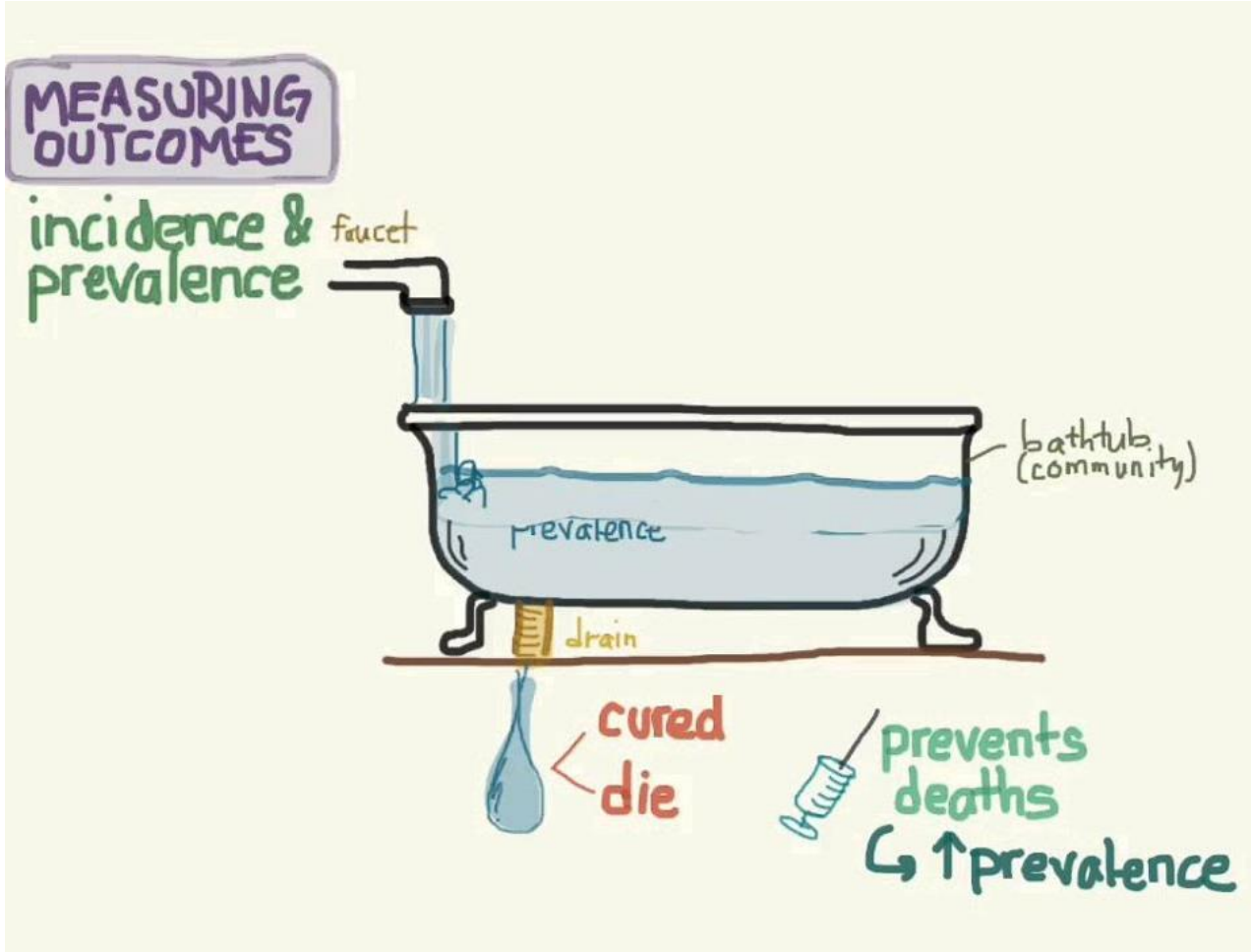
1. Count
   - Simplest and most frequently performed quantitative measure
   - Number of cases of a disease or health phenomenon

2. Ratio
   - Division of one quantity by another (fraction!)

   A. Proportions
      - Ratio where numerator is part of denominator.
      - May be expressed as a *percentage (Proportion * 100%)*

   B. Rates (*risk!)*
      - Ratio where time forms part of the denominator.
        - Disease frequency, time period, population unit size

Incidence and Prevalence



- Incidence = new cases
  - Rate of (# new cases) / (# people at risk in given time frame)
  - Measuring how fast the disease is occurring = risk
- Prevalence = all cases (in total)
  - Proportion (%) of (# cases) / (# total people)
  - How much disease is in the population? = burden of disease

Validity and Reliability

- Validity = degree measurement reaches correct conclusion
  - (1) Internal Validity
    - Results accurately reflect true situation of study population, defined by boundaries of the study
    - Provides a true estimate of effect, given the limits of the population studied
  - (2) External Validity
    - Results are applicable to other populations (generalizability)
    - Do these results apply to other patients, such as patients who are older, sicker, or less economically advantaged than subjects in the study?

- Reliability = degree to which an instrument can produce precise, consistent results, repeatedly over different occasions, with there is no evidence of change.

Bias

- Can be random or systematic
  - Systematic error that leads to distortion of results
- Can occur anywhere; big concern in observational studies because of lack of randomization
- (3) categories of systematic bias
  1. Selection bias
  2. Information bias
  3. Confounding

1. Selection bias
   - Distortion because of how subjects are sampled/selected
   - The selection process increases or decreases chance a relationship between exposure and outcome will be detected
     - Volunteers may differ from non-volunteers
     - Selecting participants based on referral to clinical facilities
       - Potential disconnect with diagnosis and subsequent eligibility
     - Hospitalized v. non-hospitalized patients

Bias (cont.)

2. Information Bias (aka misclassification)

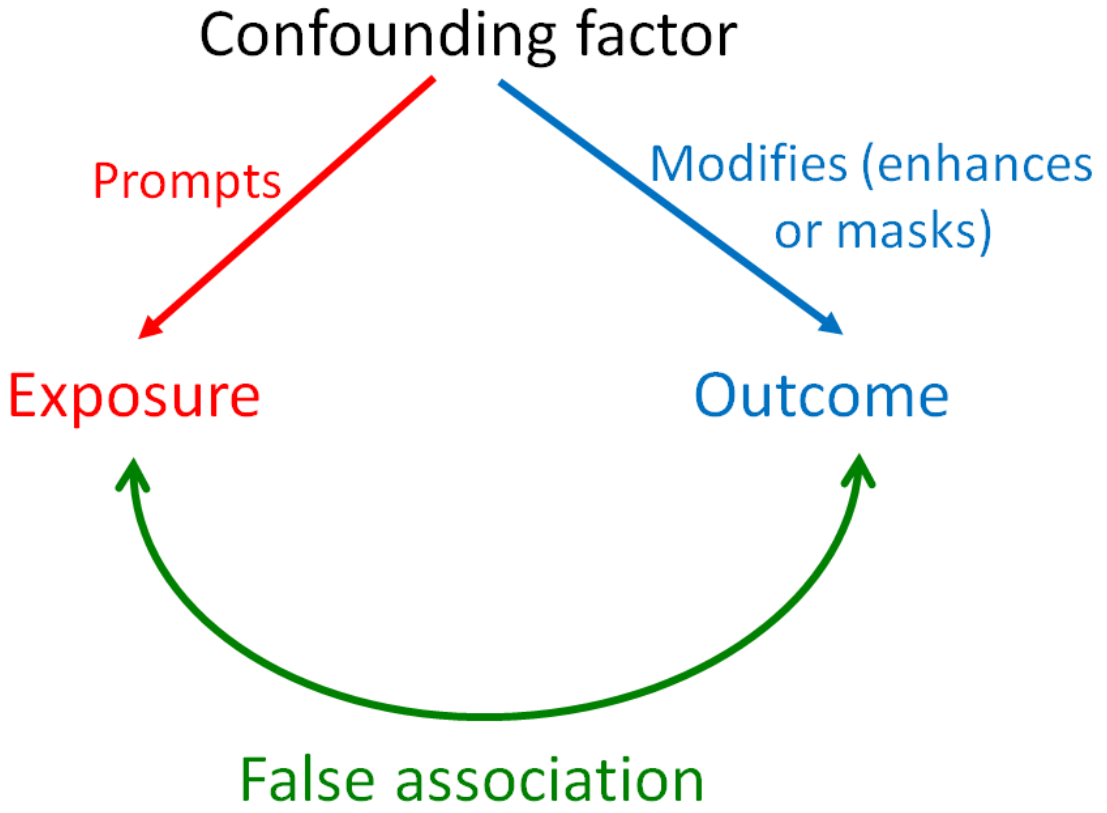
- Distortion because of manner data are collected or classified
  - Random or systematic inaccuracy of measurement
    - Investigator may assign correctly or incorrectly, leading to increase in true positives, true negatives, false positives, false negatives
- (2) Types:
  - *Nondifferential:* errors in classification of exposure/disease that do not depend on the other variable; underestimates the true association
  - *Differential:* errors in classification of exposure/disease that depends on the other variable; may over or underestimates the true association
    - Recall bias: differential ability of subjects to remember previous activities and exposures
    - Interviewer bias: results may be influenced by how the interviewers collect information

Bias (cont.)

3. Confounding

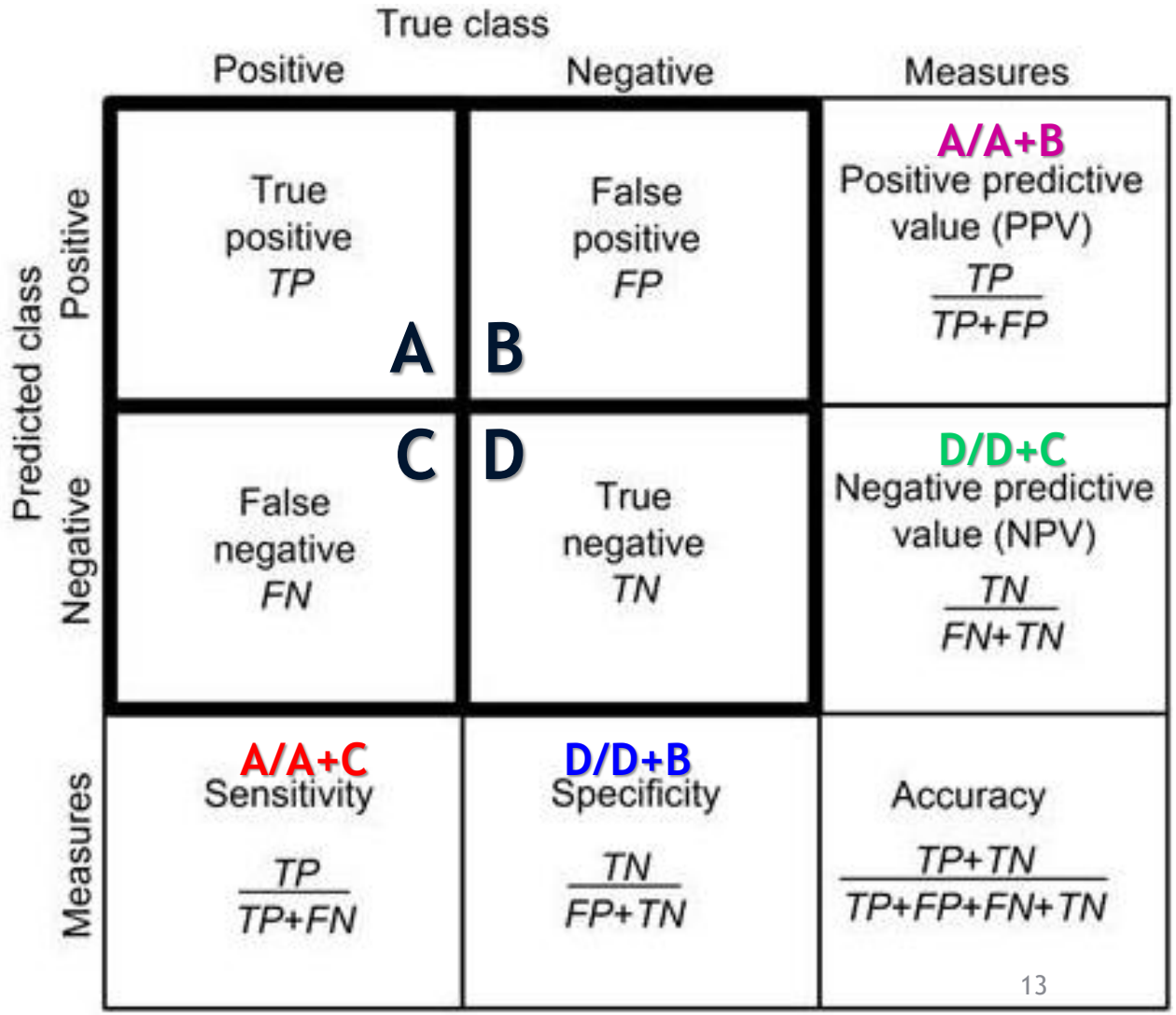
- Extraneous factors distorts true association being examined
- Mixing of the effect of an extraneous "lurking" variable with the effects of exposure and disease

- Confounding Requirements:
  1. The confounding factor must be associated with the outcome
  2. The confounding factor must be associated with the exposure
  3. A confounder cannot be an intermediary step in the causal pathway from the exposure to the outcome



Determining Validity of a Clinical Test

- Descriptors of Test Accuracy
  - Sensitivity (SNout)
    - Proportion of persons with disease who test positive (a/a+c)
  - Specificity (spIN)
    - Proportion of healthy persons who test negative (d/d+b)
- Probability Estimates:
  - Positive Predictive Value (PPV)
    - Proportion of persons with positive test who actually have disease (a/a+b)
  - Negative Predictive Value (NPV)
    - Proportion of persons with negative test who do not have disease (d/d+c)



Measures of Association: Odds Ratio (OR)

- Odds that outcome will occur given exposure v. odds of outcome occurring in absence of exposure
- ratio of two odds
  - outcome $_{exposed}$/outcome$_{unexposed}$
- What OR means…
  - OR = 1.0: no difference
  - OR > 1.0: increase in odds
  - OR < 1.0: decrease in odds

Odds ratio calculation

$$OR = \frac{a / b}{c / d} = \frac{ad}{bc}$$ where

Exposure	Cancer ✔	Cancer ✖
✔	a	b
✖	c	d

Example

$$OR = \frac{354 / 143}{293 / 511}$$ where

Exposure	Cancer ✔	Cancer ✖
✔	354	143
✖	293	511

$$OR = 4.32$$

The odds of lung cancer is 4.32 times greater among smokers compared to non-smokers.

Measures of Association: Relative Risk (RR)

Relative risk calculation

$$RR = \frac{a / (a + b)}{c / (c + d)}$$ where

Exposure	Cancer ✔	Cancer ✖
✔	a	b
✖	c	d

Example

$$RR = \frac{354 / (354 + 143)}{293 / (293 + 511)}$$ where

Exposure	Cancer ✔	Cancer ✖
✔	354	143
✖	293	511

$$RR = 2.54$$

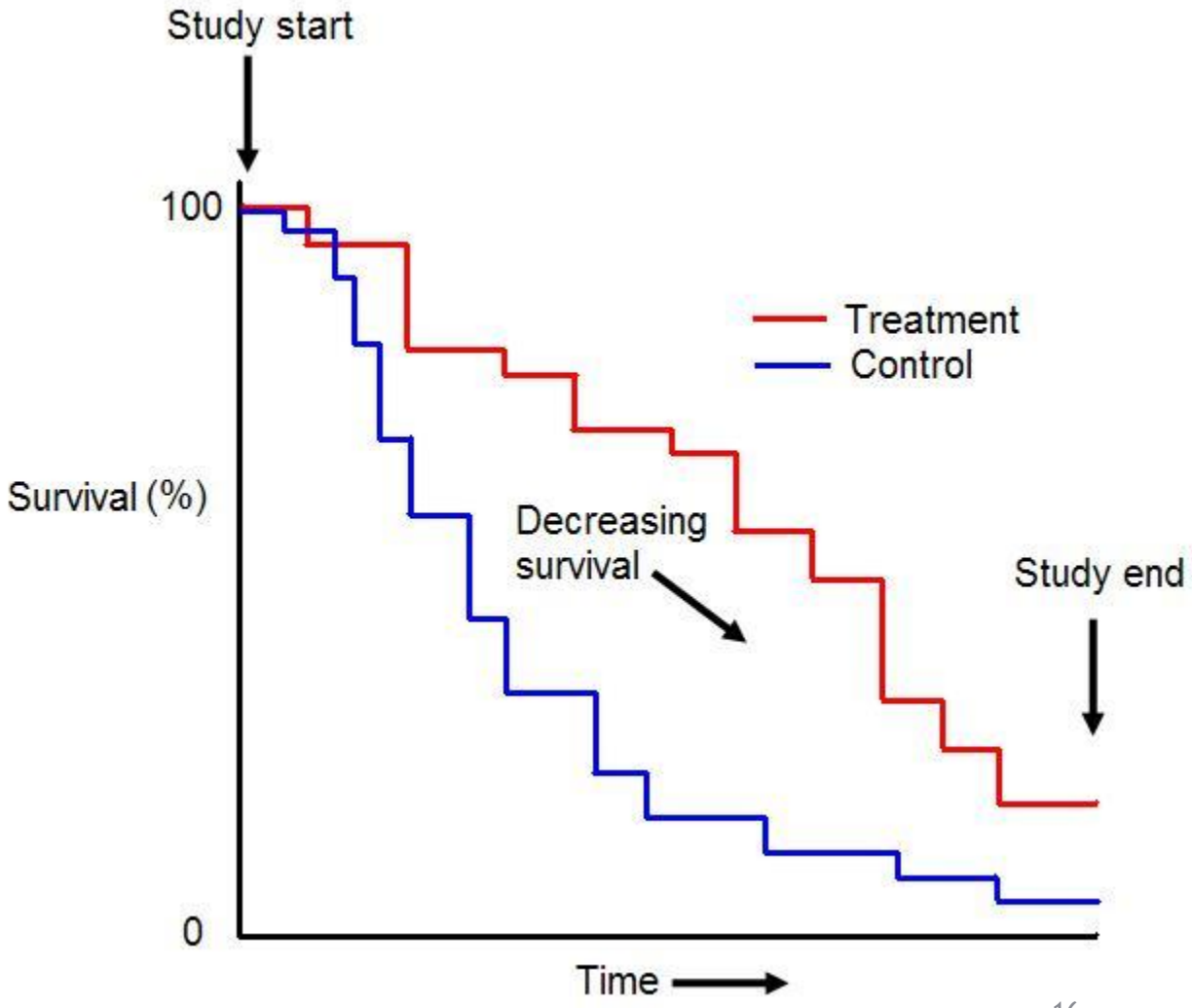
The risk of developing lung cancer is 2.54 times greater among smokers compared to non-smokers.

- Likelihood that an exposed group will develop an outcome relative to those unexposed
  - Compares the risk of a health event among one group with the risk among another group
- AKA “risk ratio” or “rate ratio”
  - $risk_{exposed} / risk_{unexposed}$

Measures of Association: Hazard Ratio (HR)

- Measure of effect of intervention on outcome over time
  - Reported as time-to-event analysis or survival analysis
    - Type of relative risk used to express treatment effects, determine how groups change relative to each other (faster/slower)
  - Rate in which events happen in treatment v. control group as a function of time
    - $hazard_{intervention}$ / $hazard_{control}$

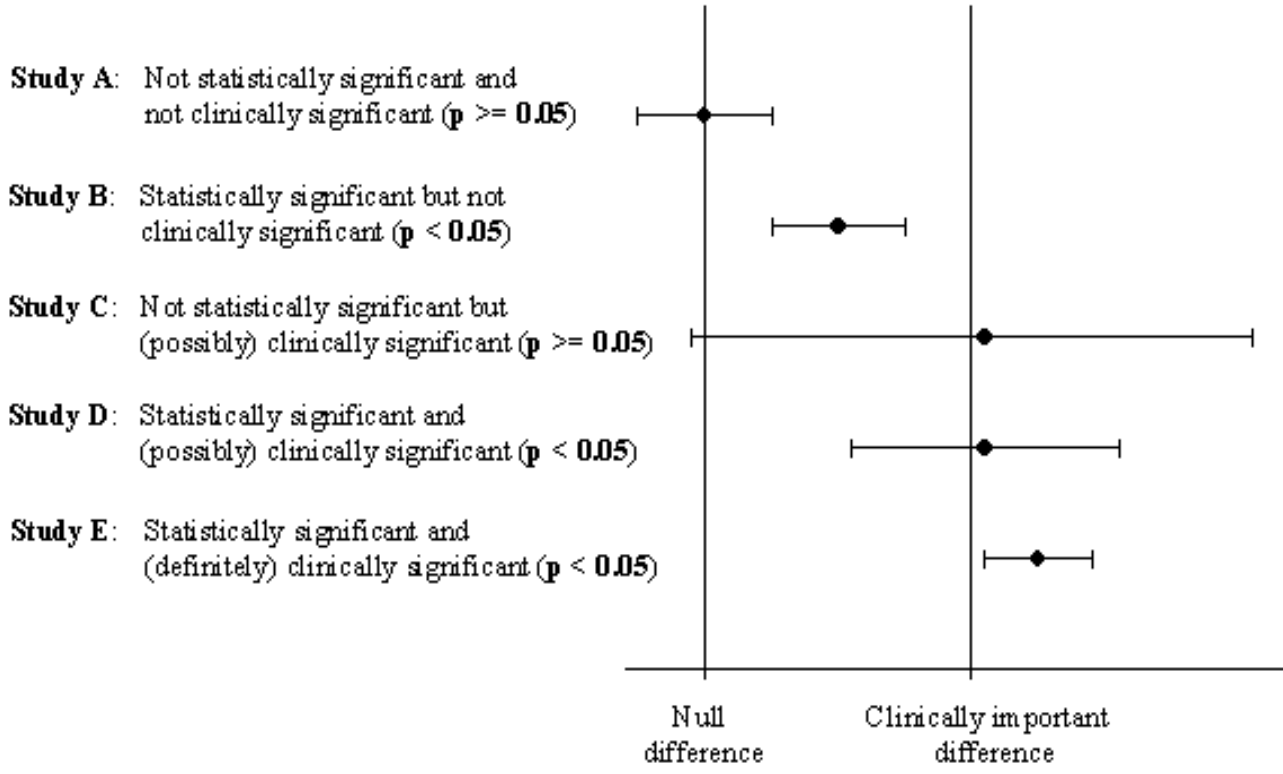
- Kaplan-Meier curves
  - Relative event rate in the groups
  - Y-Axis = prob. of survival (%); X-Axis = time
  - Event hazard = slope of the graph (events/time)



P-Values

P-Value

- Probability that observed result is due to chance alone
- "Is there a statistically significant difference between treatments/groups?
  - Interpretation based on cutoff/ level of significance (e.g. 0.05, 0.01)
- Observed association gives no indication about clinical importance
  - Information from single sample will always leave some level of uncertainty
  - *Confidence intervals!*



Confidence Intervals (CI)

- Range of values for a measure that is believed to contain the true value; within specified certainty level
  - Estimation, magnitude and direction of difference
  - Range of values within which we are reasonably confident that the true association (OR, RR, HR = point estimate)
    - E.g. OR = 2.5; 95%CI: 1.7 - 3.6

- Example: Imagine the study is repeated thousand times
  - About 95% of time the different possible results obtained will lie in this interval.
    - Therefore, we say we are 95% confident that the true population value of what we are estimating in our study lies within the interval.

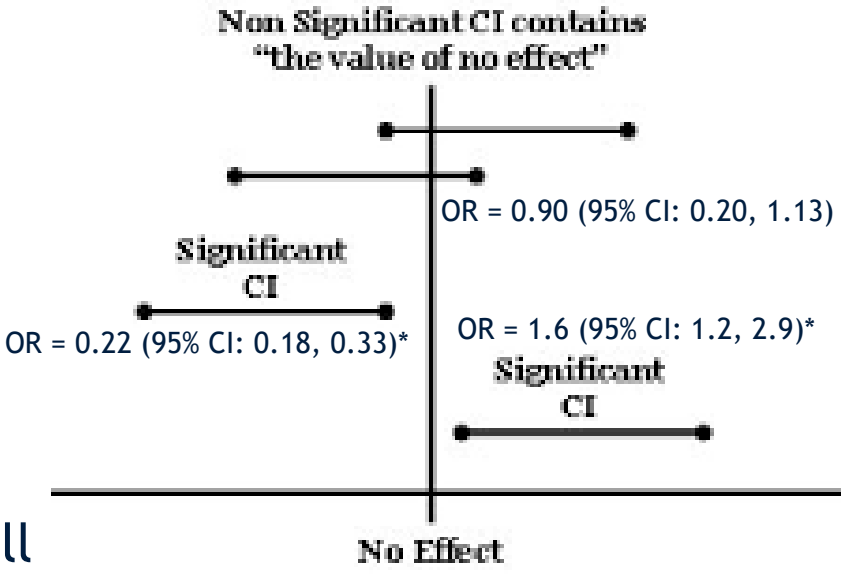
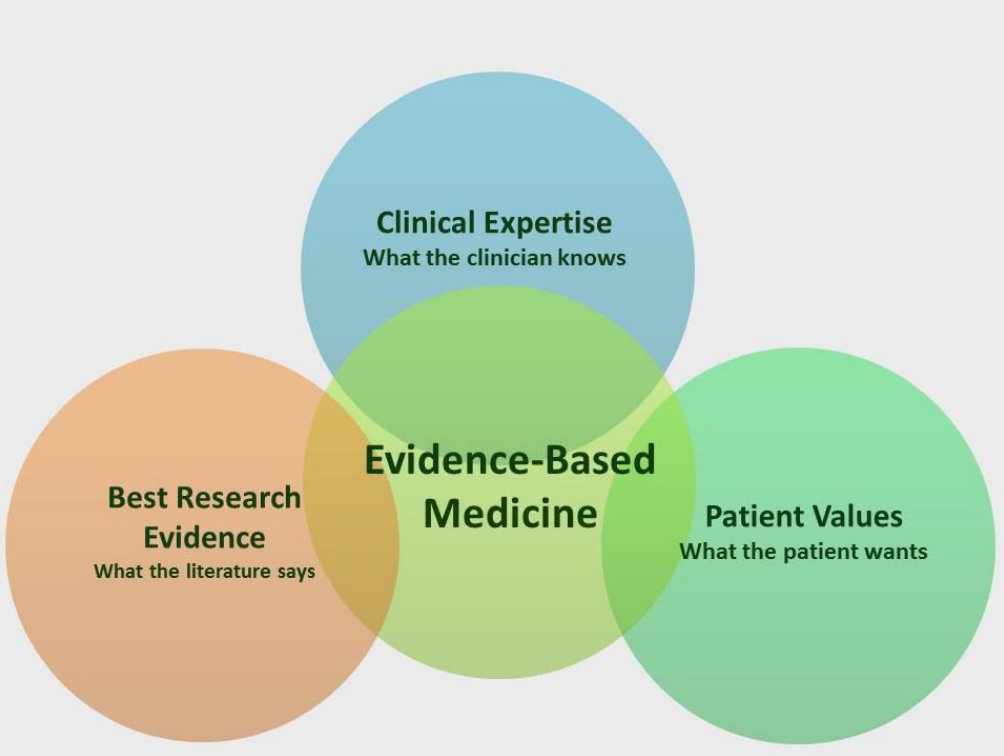


Fig. 1: significant & non significant CIs

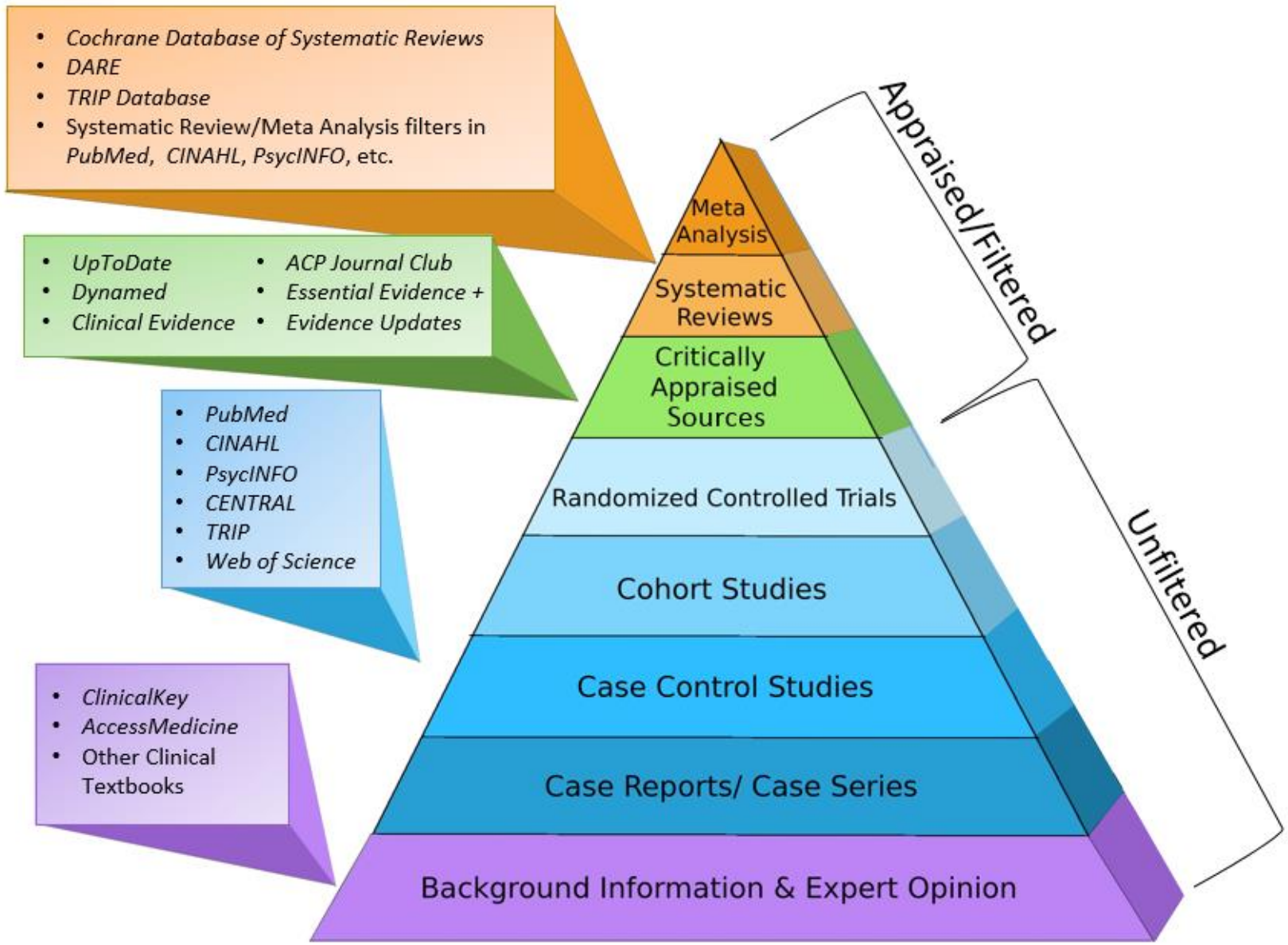
Population Health

Evidence-Based Medicine



- Making health care decisions based on:
  - Current best evidence
  - Clinical expertise
  - Pathophysiological knowledge
- Provide objective basis for selecting strategy for disease management
  - Serve as basis for modifying practice
    - Facilitates assessment
    - Identifies gaps in knowledge
    - Suggest opportunities for improved care quality
- *But what is "evidence"?*

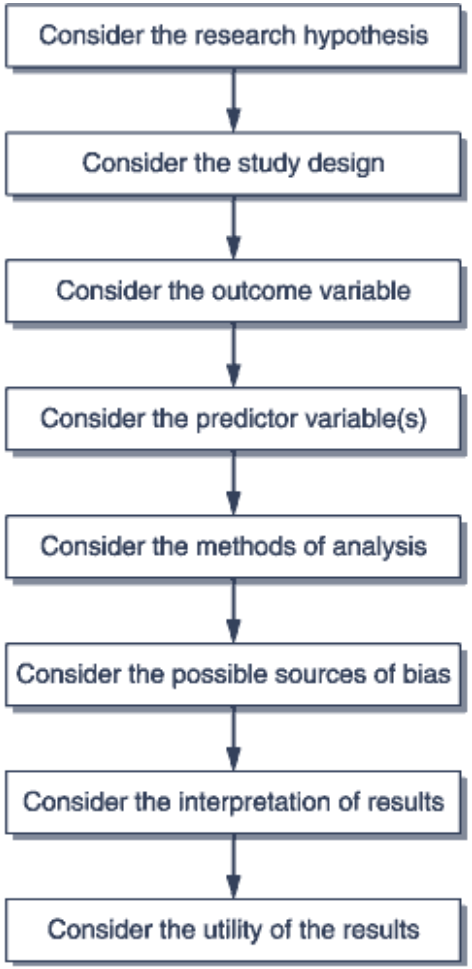
Levels of Evidence



Assessing and Evaluating Literature

- Evaluation of an individual study should include:
  - Research hypothesis
  - Study design
  - Variables
  - Methods of analysis
  - Sources of bias

- Useful to apply a uniform and thorough approach to evaluating the articles



Source: Greenberg RS, Daniels SR, Flanders WD, Eley JW, Boring JR: *Medical Epidemiology*, 4th Edition: http://www.accessmedicine.com

STROBE Statement

Strengthening the reporting of observational studies in epidemiology

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- Home
- Aims
- News
- Available checklists
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- Publications
- Translations
- Commentaries
- Discussion forum
- STROBE group
- Endorsement

STROBE checklists

Version 4 as published in Oct / Nov 2007!

- STROBE checklist for **cohort, case-control, and cross-sectional studies** (comb
  download PDF / Word
- STROBE checklist for **cohort, case-control, and cross-sectional studies**
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- Checklist for **cohort studies**
  download PDF / Word
- Checklist for **case-control studies**
  download PDF / Word
- Checklist for **cross-sectionalstudies**
  download PDF / Word
- Draft STROBE checklist for **conference abstracts**
  download PDF

STROBE: *Strengthening the Reporting of Observational Studies in Epidemiology*

- 22-item checklist authors needs to fulfil before submitting manuscript
- Guidelines created to aid authors in ensuring high-quality presentation of observational studies

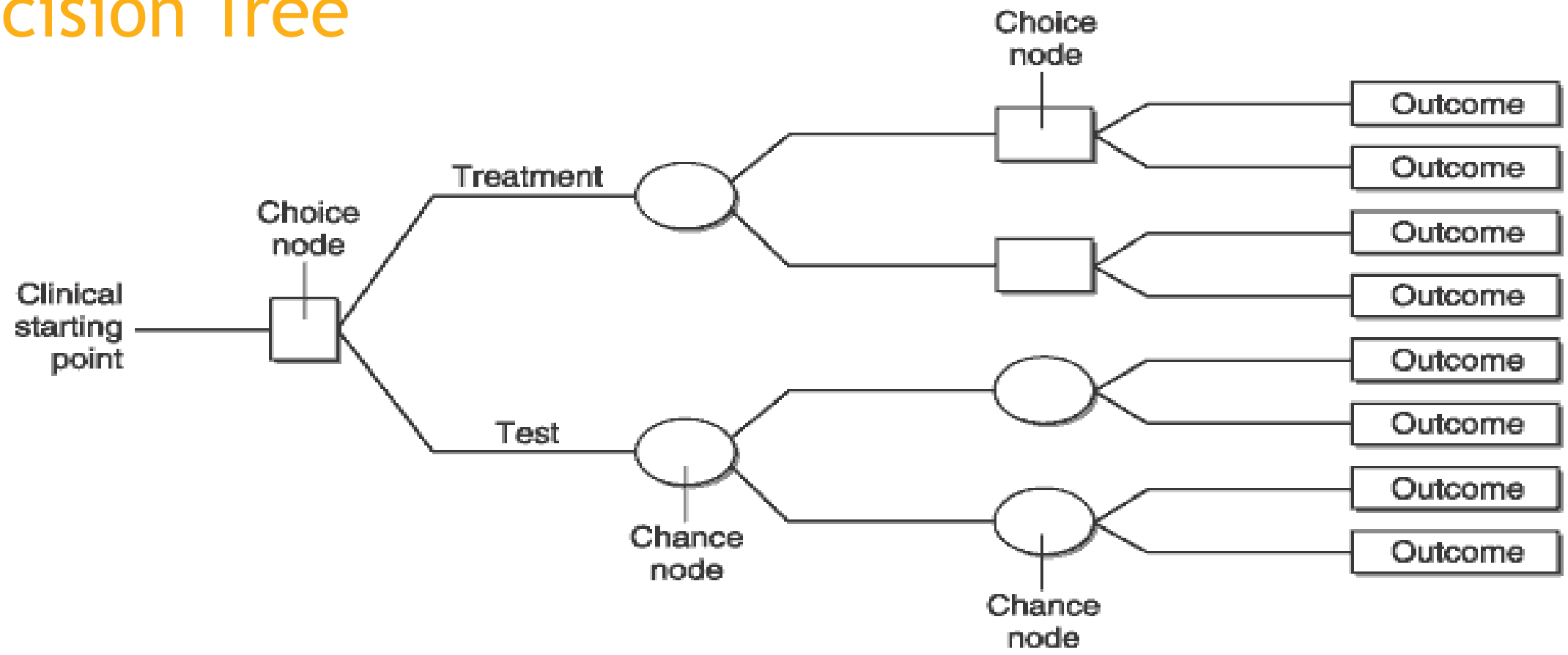
STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable

Clinical Decision-Making

- Understanding of the derivation, calculation, and use of probabilities is important in making clinical decisions
- Formal decision analysis = explicit process, uses information from epidemiologic studies to determine course of action
  - Elements of formal decision analysis:
    - 1. Decision tree diagram
    - 2. Probabilities for uncertain events
    - 3. Test results
    - 4. Alternative outcomes

Decision Tree



Source: Greenberg RS, Daniels SR, Flanders WD, Eley JW, Boring JR: *Medical Epidemiology*, 4th Edition: http://www.accessmedicine.com

Collectively work together to improve the health and wellness of people, places, and communities

References, Further Readings, and Additional Resources

- *Medical Epidemiology* (Greenberg, Daniels, Flanders, Eley, Boring III)
  - https://accessmedicine-mhmedical-com.proxy1.lib.tju.edu/book.aspx?bookid=337
- *Study Designs*
  - *https://www.cebm.net/wp-content/uploads/2014/06/CEBM-study-design-april-20131.pdf*
- *Incidence and Prevalence*
  - https://www.youtube.com/watch?v=1jzZe3ORdd8&feature=emb_title
- *Measures of Association and Significance*
  - http://critical-numbers.group.shef.ac.uk/lecturenotes/Manual.pdf
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  - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2938757/
  - https://www.slideshare.net/terryshaneyfelt7/what-does-an-odds-ratio-or-relative-risk-mean
  - https://sph.unc.edu/wp-content/uploads/sites/112/2015/07/nciph_ERIC11.pdf

References, Further Readings, and Additional Resources

- *Hazard Ratios*
  - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3932959/
  - https://www.statisticshowto.com/hazard-ratio/
- *P-Values*
  - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4111020/#:~:text=The%20width%20of%20the%20confidence,the%20reliability%20of%20the%20estimate
- *Evidence-Based Medicine*
  - https://libguides.ecu.edu/c.php?g=17486&p=97640
- *Evaluating and Assessing Literature*
  - https://lit.libguides.com/c.php?g=664499&p=4701470
- *Decision Analysis*
  - https://accessmedicine-mhmedical-com.proxy1.lib.tju.edu/content.aspx?bookid=337&sectionid=39810370#546354

Questions?

Thank you!

More questions, comments, or suggestions?
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