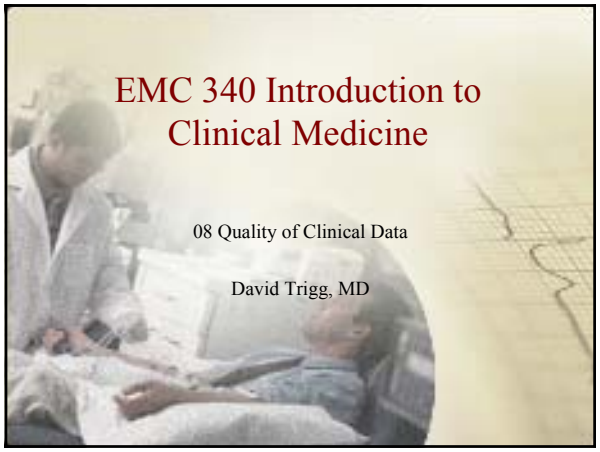
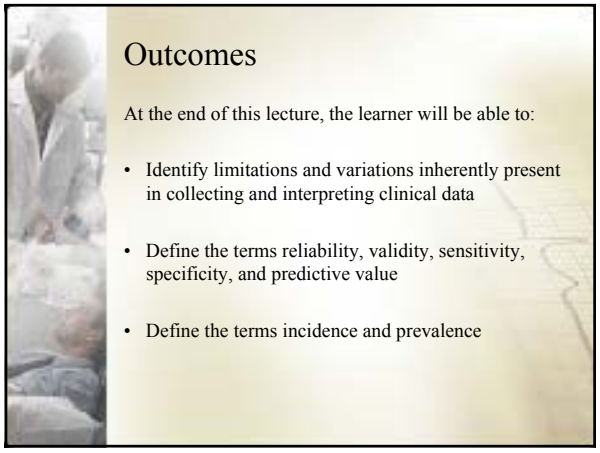


EMC 340 Introduction to Clinical Medicine

08 Quality of Clinical Data

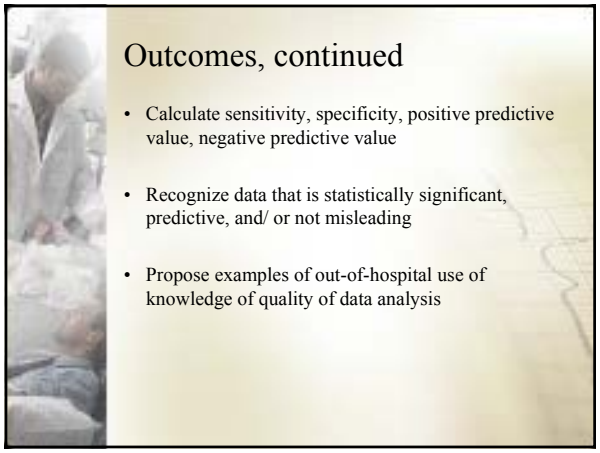
David Trigg, MD



Outcomes

At the end of this lecture, the learner will be able to:

- Identify limitations and variations inherently present in collecting and interpreting clinical data
- Define the terms reliability, validity, sensitivity, specificity, and predictive value
- Define the terms incidence and prevalence



Outcomes, continued

- Calculate sensitivity, specificity, positive predictive value, negative predictive value
- Recognize data that is statistically significant, predictive, and/ or not misleading
- Propose examples of out-of-hospital use of knowledge of quality of data analysis

Link for Bates

- Quality of Clinical Data
  - Reliability, validity…

Quality and Limitations of Clinical Data

- Limitation of the medical model
  - Some symptoms defy simple analysis
  - Single verses multiple or systemic problems
- Holistic vs. fragmented approach
- Unmanageable array of the variables
- Lack of perfect reliability, validity, and predictive value of clinical observations

Data Terms

- Reliability - Reproducibility
- Validity - Very close measure of reality
- Sensitivity - Ability of observation to find or detect an abnormality
- Specificity - Ability of an observation to exclude a disease

Data Terms, continued

- Predictive value - How well an observation predicts the presence or absence of disease in a given population
- Prevalence - Cases present at a point in time
- Incidence - New cases present over time

Reliability

- Reproducibility
- Intrarater or intraobserver reliability
  - one observer consistently obtains the same observation
- Interrater or interobserver reliability
  - more than one observer consistently finds the same observation

Validity

Does the observation or early test/tool accurately measure "what it says it does?"

Sensitivity

- Ability of observation or test to find an abnormality or disease when it is present in the population (true positive)
- Sensitivity = $\frac{TP}{TP + FN}$.

Specificity

- Power of test or observation to determine that patient does not have disease or abnormality (true negative)
- Specificity = $\frac{TN}{TN + FP}$.

Positive Predictive Value

- What percentage (probability) of positive tests are true positives?
- Positive predictive value = $\frac{TP}{TP + FP}$.

Negative Predictive Value

- What percentage (probability) of negative tests are true negatives?
- Negative predictive value = $\frac{TN}{TN + FN}$.

Prevalence

- At any point in time, how many cases are present?
  - As number of cases increases, positive predictive value of the test increases:
  - (more postive [TP] cases .) / TP+FP
- As number of disease cases increases, the negative predictive value of the test decreases:
  - (less negative [TN] cases .) / TN+FN

Practical Application

- A patient's chest pain history is 95% sensitive for detecting acute coronary disease for patients presenting emergently.
- If this is so, then of 100 prehospital patients who have chest pain, if the paramedic takes a careful history, how many false negatives will occur? (how many times will the medic miss the diagnosis)
- Prehospital spot cardiac enzyme testing for MI [infarction only – not all coronary disease] might have a sensitivity of only 80 - 85% for patients presenting emergently.
- Based only on history taken from the patient, the paramedic will be likely to be able to correctly "pick up" what % of coronary disease?

Summary

We have discussed:

- Limitations and variations inherently present in collecting and interpreting clinical data
- The concepts of reliability, validity, sensitivity, specificity, predictive value, incidence, and prevalence
- The method of calculating sensitivity, specificity, positive predictive value, and negative predictive value
- Recognizing data that is clinically significant, predictive, and/ or not misleading
- Examples of out-of-hospital use of knowledge of quality of data analysis