RESEARCH METHODS FOR CLINICAL INVESTIGATORS
Session 6:

Sensitivity, Specificity, and Predictive Values:

What the clinician should know?

Veronica G. Brown, PhD, MSPH

Objectives

At the end of the presentation, the audience will be able to:

- Explain the concept of the “gold standard” in research
- Understand the importance of sensitivity and specificity
- Understand the importance of predictive values
  - Positive Predictive Values (PPV)
  - Negative Predictive Values (NPV)

"Gold Standard"

- What does it mean?

  Model or diagnostic tool (i.e. test kits) that has been thoroughly tested and used repeatedly yielding reputable and reliable results

  Identifies the proportion of those in a given population that are:

  TRUE POSITIVES OR TRUE NEGATIVES

Cardoso, J., et. al (2014). *What is gold standard and what is ground truth?*. Dental Press Journal of Orthodontics. 19(5): 27-30

“Gold Standard”

Measurements for the accurate identification of TRUE POSITIVES & TRUE NEGATIVES

1. Sensitivity
2. Specificity
3. Predictive Values

Sensitivity

Why are they important in research?

- Ability to identify "True Positives"
  - Ex. Screening/Diagnostic Tests

- Correctly determine those with the outcome of interest
  - Minimize false negatives → Ex. Population that test negative for the disease but ACTUALLY **do** have the disease

Johns Hopkins Bloomberg School of Public Health. (2020) https://www.centerforhealthsecurity.org/resources/COVID-19/COVID-19-fact-sheets/201207-sensitivity-specificty-factsheet.pdf

Specificity

Why are they important in research?

- Ability to identify "True Negatives"
  - Ex. Screening/Diagnostic Tests

- Correctly determine those that **do NOT** have the outcome of interest
  - Minimize false positives → Ex. Population that test positive for the disease but ACTUALLY **do NOT** have the disease

Johns Hopkins Bloomberg School of Public Health. (2020) https://www.centerforhealthsecurity.org/resources/COVID-19/COVID-19-fact-sheets/201207-sensitivity-specificty-factsheet.pdf

Predictive Values

Why are they important in research?

- Predict how accurate the positive and negative tests results are expected in a specific population

- Dependent on prevalence
  - Positive Predictive Value (PPV)
  - Negative Predictive Value (NPV)

Johns Hopkins Bloomberg School of Public Health. (2020) https://www.centerforhealthsecurity.org/resources/COVID-19/COVID-19-fact-sheets/201207-sensitivity-specificty-factsheet.pdf

Predictive Values

Positive Predictive Value (PPV)

- Proportion of true positives out of ALL positives
  - Ex. Test results for COVID-19

PPV=(True Positives) / (True Positives + False Positives)

- Measures the accuracy of tests

Johns Hopkins Bloomberg School of Public Health. (2020) https://www.centerforhealthsecurity.org/resources/COVID-19/COVID-19-fact-sheets/201207-sensitivity-specificty-factsheet.pdf

Predictive Values

Negative Predictive Value (NPV)

- Proportion of true negatives out of ALL positives
  - Ex. Test results for COVID-19

NPV=(True Negatives) / (True Negatives + False Negatives)

Johns Hopkins Bloomberg School of Public Health. (2020) https://www.centerforhealthsecurity.org/resources/COVID-19/COVID-19-fact-sheets/201207-sensitivity-specificty-factsheet.pdf

Understanding the Concept

	Disease	No Disease	
Positive Test Result	True Positive (TP)	False Positive (FP)	Positive Predictive Value (PPV)
Negative Test Result	False Negative (FN)	True Negative (TN)	Negative Predictive Value (NPV)
	Sensitivity	Specificity	

Gordis, Leon. (2018). *Epidemiology*. Saunders Elsevier.

Understanding the Concept

FALSE RESULTS = TESTING ERRORS

PROBLEM

Ex. False Negative for COVID-19

"Test negative; however, you are around others when in fact, you are **INFECTED**"

Summary

- Sensitivity
  - Identification of TRUE POSITIVES
- Specificity
  - Identification of TRUE NEGATIVES
- Predictive Values
  - PPV
  - NPV
- Predict the accuracy of positive and negative tests