Lab Values in Research: an Introduction

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Lab Values in Research: an Introduction

Steven Hatch, MD
Goals

- This is from a *clinical* (ie not primarily *statistical*) research perspective
- Discuss sensitivity and specificity
- Discuss predictive value
- Review Type I & Type II error
- Consider reliability, validity
Case presentation

- 24 yo F presents with fever, cough x 3d (whitish/yellow sputum), dyspnea
- Exam: Temp 39.1, HR 122, BP 106/78, O2 88%
- Crackles diffusely, no dullness
- You order a CBC & chemistries
- WBC 6.8
- Cr 1.2
Chest X-Ray
Question: what to make of the WBC (6.8)?

- *Maybe* it’s “normal” (range ~4-11)?
- *Maybe* it’s low (wouldn’t we expect it to be high)?
- ..or *maybe* it’s high?

- How could it be *high*?!
Well, what if the CXR was like *this*:
This is a story about a test’s accuracy

- The *sensitivity* of the WBC can be thought of as: “how many pneumonias will be picked up by a high white count?”

- The *specificity* of the WBC can be thought of as: “how many high white counts indicate pneumonia?”

- We normally treat a high white count as fairly sensitive (pneumonias are typically associated with high WBC) but not very specific (lots of things cause high WBC *besides* pneumonia)
Mathematical expression of sens/spec

- Sensitivity:
  - true positive tests/# of people with disease

- Specificity:
  - true negative tests/# of people who don’t have the disease (this is counter-intuitive!)
<table>
<thead>
<tr>
<th>Predicted condition</th>
<th>True condition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total population</td>
</tr>
<tr>
<td></td>
<td>Condition positive</td>
</tr>
<tr>
<td>Predicted condition</td>
<td></td>
</tr>
<tr>
<td>positive</td>
<td>True positive</td>
</tr>
<tr>
<td>negative</td>
<td>False negative,</td>
</tr>
</tbody>
</table>
Sensitivity & Specificity are not predictive value

- Predictive value tells you whether the test is actually telling you what you want to know.
- Meaning: is a positive test really positive? Does this mean they really have the disease?
- This is not the same thing as sens & spec...
- Because it’s affected by prevalence
- Let’s take mammograms as an example
Screening Mammography in US women age 40-50 with (theoretical) 99% Sensitivity & Specificity (21.5 million women in this age range)

• 1% of 21.5 million women = 215,000 **false positives**
• 35,000 cases invasive breast cancer = 360 false negatives (basically, zero)
• Total positive mammograms: 250,000 (215K + 35K)
• Positive predictive value: 35,000 / 250,000
• Equals **14 percent**
Population without disease

Population with disease

Total number of positive tests:

False Positive

False Positive

True positive
How probability affects predictive value: Urine Culture

- 55 yo F with urgency but no dysuria, hematuria, fever, pelvic or bladder pain
- Urine culture grows 100K *E. coli*
- Does this mean she has a UTI?
- The symptoms (or lack thereof) and signs (or lack thereof) affect the *pre-test probability*, which works a bit like how prevalence affects predictive value as well
- Low pre-test prob increases false positives!
Reliability & Validity

- **Reliability** refers to how many times you can reliably produce the same (or almost the same) outcomes doing a test the exact same way.

- **Example**: CBC, chemistries, other serum labs.

- Less reliable tests might include chest x-rays (dependent on movement, inhalation, rotation).

- Validity refers to whether the test you are using is measuring the thing you want to measure.
Validity refers to whether the test you are using is measuring the thing you want to measure.

A scale that gives you the same weight each time you step on it is reliable.

A scale that is calibrated accurately is valid.

Not my feet or weight!
What a test aims for in terms of reliability and validity.

Reliable
Not valid
Questions?
Type I & II errors in continuous variables

H₀

H₁

β

α

Type II error

Type I error
The diagram illustrates the relationship between the standard of proof and the appearance of guilt, impacting the outcomes of Not Guilty and Guilty verdicts.

- **Innocent Suspects**: On the left side, representing individuals who are actually not guilty, the curve peaks to the left of the standard of proof line, indicating a lower probability of guilt being perceived.

- **Smart Criminals with top notch lawyers**: On the right side, representing individuals who are guilty but have skilled legal representation, the curve peaks to the right of the standard of proof line, indicating a higher probability of guilt being perceived despite their actual guilt.

**Type I Error** and **Type II Error** are depicted as points where the probability of guilt is misjudged, occurring on the left side for Innocent Suspects and on the right side for Smart Criminals.

- **Type I Error**: This occurs when the defendant is wrongly convicted, analogous to Smart Criminals being mistakenly identified as guilty.
- **Type II Error**: This occurs when the defendant is wrongly acquitted, analogous to Innocent Suspects being mistakenly identified as not guilty.

The diagram emphasizes the importance of maintaining a balanced standard of proof to minimize these errors and ensure fair outcomes in legal proceedings.