NUR 627

"Advanced Epidemiology and Biostatistics for Nursing"

Session III: Validity and Reliability of a Diagnostic Test

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Objectives of the session

- Define and describe validity of a diagnostic test and its components
- Apply and interpret validity of a diagnostic test and its components
- Define and describe reliability of a diagnostic test and its types
- Apply and interpret reliability of a diagnostic test
- Assess the relationship between relaibility and validity

Assessment of the validity of a diagnostic test

- Validity: ability of a test to distinguish between who has the disease and who does not.

- It has two components:
  - Sensitivity: ability of a test to identify correctly those with the disease
  - Specificity: ability of a test to identify correctly those who do not have the disease

What is Truth?

- Gold Standard
  - The test that is used to determine if a disease is truly present or not

  - Other tests are compared to it to determine their accuracy

Sensitivity = Ability to correctly detect diseased persons

$$\text{Sensitivity} = \frac{a}{a+c}$$

DISEASE

		Present	Absent	
TEST	**Positive**	**a** True Positive	**b** False Positive	**a+b**
	Negative	**c** False Negative	**d** True Negative	**c+d**
		a+c	**b+d**	**n**

Reasons for False Negative Reactions:

- Natural or induced tolerance
- Improper timing for testing
- Improper selection of test
- Analytically insensitive tests
- Non-specific inhibitors e.g. anti-complementary serum; tissue culture toxic substances
- Antibiotic induced immunoglobulin suppression
- Incomplete or blocking antibody

Specificity=Ability to correctly detect non-diseased subjects

$$\text{Specificity} = \frac{d}{b+d}$$

DISEASE

		Present	Absent	
TEST	**Positive**	**a** True Positive	**b** False Positive	**a+b**
	Negative	**c** False Negative	**d** True Negative	**c+d**
		a+c	**b+d**	**n**

Reasons for False Positive Reactions:

- Cross-reaction
- Non-specific inhibitors
- Non-specific agglutinins
- Contamination

Predictive Value of a Positive Test

$$\text{Predictive Value(+)} = \frac{a}{a+b}$$

DISEASE

		Present	Absent	
TEST	**Positive**	**a** True Positive	**b** False Positive	**a+b**
	Negative	**c** False Negative	**d** True Negative	**c+d**
		a+c	**b+d**	**n**

Probability that a patient which is positive, according to the test, is actually positive

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Predictive Value of a Negative Test

$$\text{Predictive Value(-)} = \frac{d}{c+d}$$

DISEASE

		Present	Absent	
TEST	**Positive**	**a** True Positive	**b** False Positive	**a+b**
	Negative	**c** False Negative	**d** True Negative	**c+d**
		a+c	**b+d**	**n**

Probability that a patient which is negative according to the test is actually negative

Use of Multiple Tests

- *Sequential Testing*
  - Net sensitivity: decreased
  - Net specificity: increased

- *Simultaneous Testing*
  - Net sensitivity : increased
  - Net specificity: decreased

Reliability

- A measure of the reproducibility of a result
  - How closely do repeated measurements on the same object agree.
- Agreement between two or more measures of the same thing (i.e., Repeatable / reproducible / consistent)

  - Reliability is the degree to which a measurement provides the same result each time it is performed on a given subject or specimen

  - *If a measure is unreliable, it is not capable of producing valid results*

Relationship Between Validity and Reliability

Good Reproducibility

Poor Validity

Poor Reproducibility

Good Validity

Good Reproducibility

Good Validity

Poor Reproducibility

Poor Validity

Reliability

- *Intra-observer variation*
  - Variation occurs between two or more readings of the same test made by same observer.

- *Inter-observer variation*
  - Variation between observers.
  - Two examiners do not derive the same result

Measures of Validity, Reliability and Agreement
"Dichotomous variables"

- **Validity**
  - One measure is made on a person by an instrument and <u>truth is specified</u>
    - Sensitivity
    - Specificity
    - Predictive value of positive test
    - Predictive value of negative test

- **Reliability**
  - Two measurements are made by the <u>same instrument</u> on the same person but <u>truth is not specified</u>

- **Agreement**
  - The extent to which similar results are obtained when the same measurement is performed by <u>different instruments</u>

Overall Percent Agreement

reading no. 1

	abnormal	suspect	doubtful	normal
abnormal	A	B	C	D
reading no. 2 suspect	E	F	G	H
doubtful	I	J	K	L
normal	M	N	O	P

letter indicated number of reading in each cell

percent agreement= A+F+K+P/TOTAL READINGS X 100

Practice:

- Physical exam: positive (1600 cases; 1000 normal)
- 2400 biopsy proven cases
- 6000 normal
- Sensitivity?
- Specificity?
- PVP
- PVN

- *See spreadsheet table and calculations*