

Evidence Based Dentistry

# Appraising Diagnostic Tests

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23 Aug 2001

# Diagnostic Tests

## Why gather diagnostic data ?

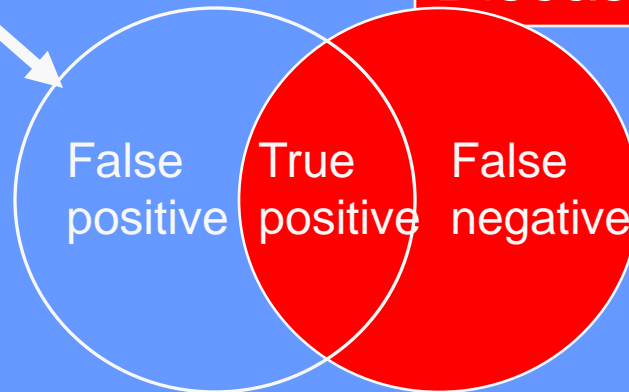
- To make a diagnosis
- To judge severity
- To predict clinical course and prognosis
- To estimate response to therapy
- To determine actual response to therapy

# The diagnostic universe

Positive test



Disease

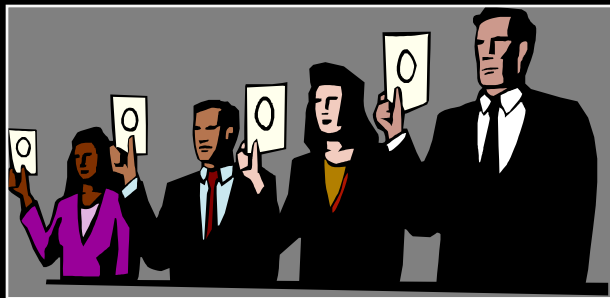


True negative

Negative test

# The diagnostic universe

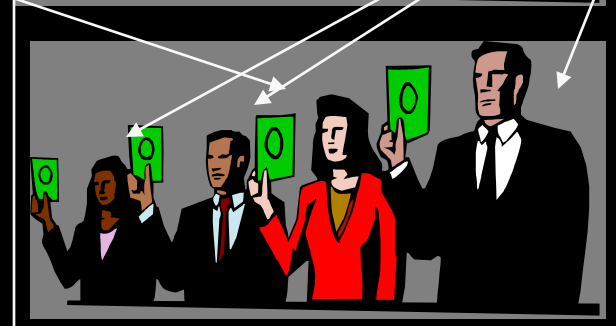
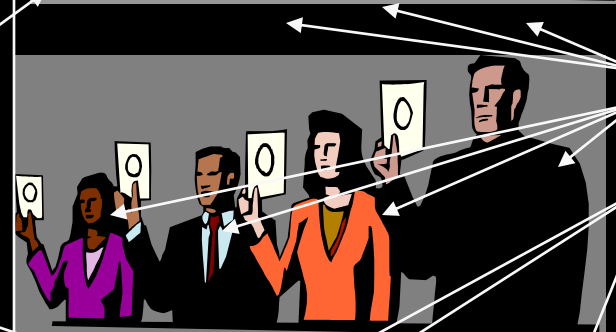
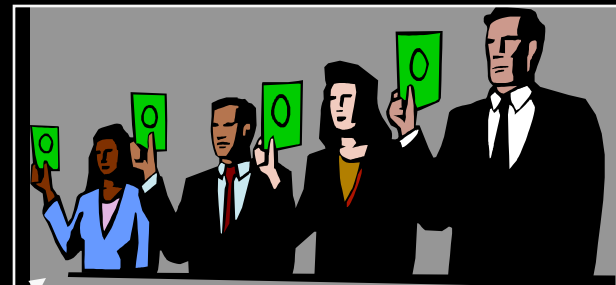
Positive test



True positive

False positive

Negative test



True negative

False negative

# Types of diagnostic tests used in clinical practice

- **Predictive tests**

Identify individuals at risk/ not at risk of developing a specific disease.

Only useful if techniques exist for preventing the development or transmission of the condition.

- **Screening tests**

Identify individuals with a disease or category of disease.

Screening tests cannot replace the patient history and physical examination.

# Types of diagnostic tests used in clinical practice

- **Discriminatory tests**

For differential diagnosis

Of little use if the result does not influence treatment or outcome.

- **Monitoring tests**

To describe changes in the disease underlying pathology or primary symptom.

Variable measured should dosely reflect the change in the process and/or effects of therapy.

# Is the trial on diagnostic test valid?

- Did the study address a clearly focussed issue?
  - population
  - test
  - outcomes
- Was there an independent, blind comparison with a reference standard?
  - was an appropriate reference test used
  - was there independent or blind assessment of the result

# Is the trial on diagnostic test valid?

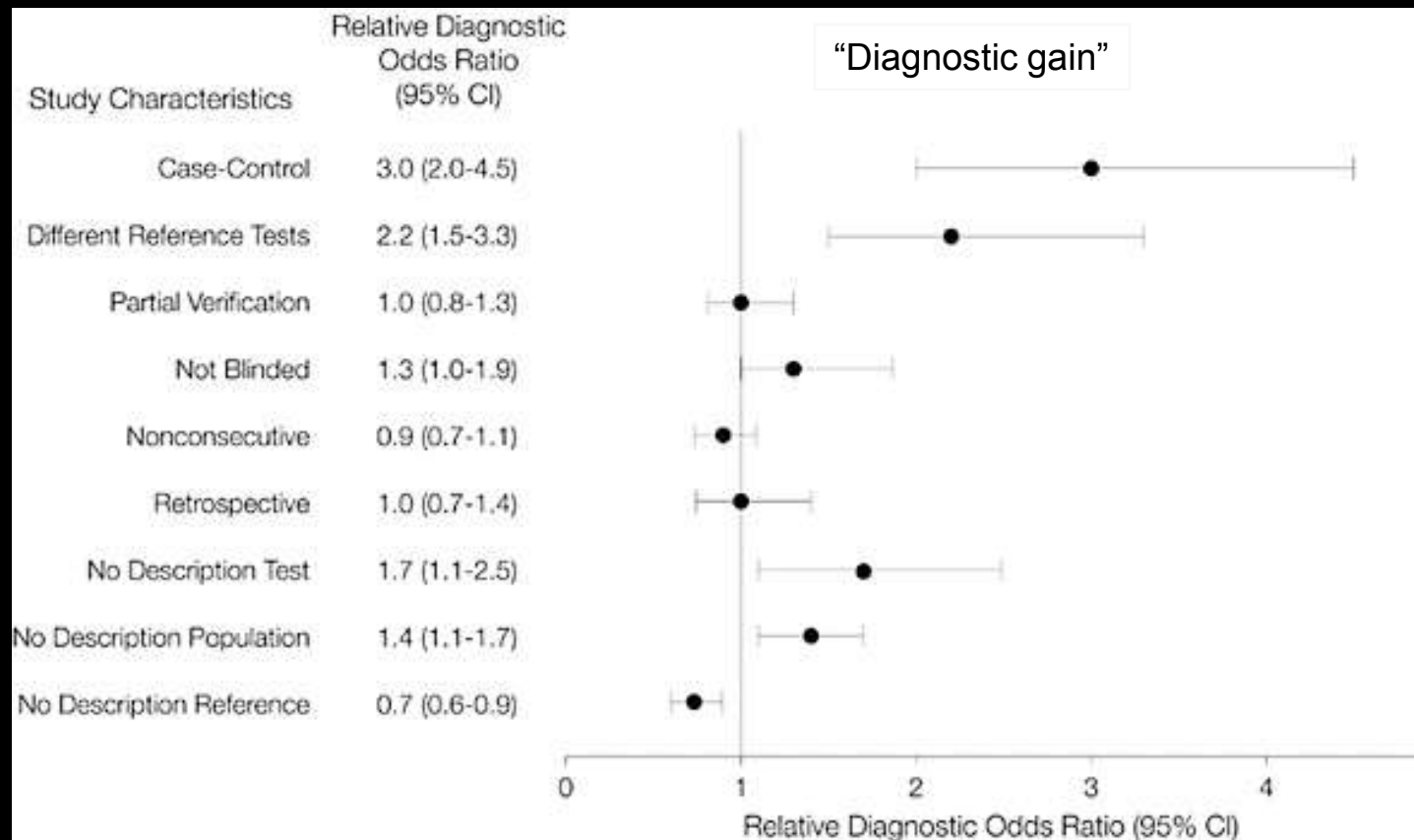
- Did the patient sample include an appropriate spectrum of patients
  - Consider, age, sex and severity of disease



# Is the trial on diagnostic test valid?

- Did the results of the test being evaluated influence the decision to perform the reference standard.
  - Was the reference test performed on all patients?
- Were the methods for performing the test described in enough detail to permit replication.
  - Look for details of patient preparation, test technique, and analysis and interpretation of the result

# Effect of study methodology on validity



Studies of lower methodological quality, particularly those including non-representative patients or applying different reference standards, tend to overestimate the diagnostic performance of a test. Lijmer et al. JAMA, 1999; 282: 15.

# What are the results?

- Are likelihood ratios given or can they be calculated from the data?
  - Look for
    - Sensitivity and Specificity
    - Positive and negative predictive values

# Assessment of the efficacy of a diagnostic test

<u>Parameter</u>	<u>Description</u>
<b>Sensitivity</b>	Ability to identify patients in a patient population
<b>Specificity</b>	Ability to identify non-patients in an asymptomatic population
<b>Positive predictive value</b>	Ability of a diagnostic test to identify a patient correctly, given that the test is positive
<b>Negative predictive value</b>	Ability of a diagnostic test to identify a non-patient correctly, given that the test is negative
<b>Measurement validity</b>	The accuracy of a measurement technique when compared with a known standard
<b>Measurement reliability</b>	The variability of the measurements over time and in different environments
<b>Diagnostic validity</b>	The ability to separate those with the disease from those without the disease

# Sensitivity and Specificity

- Sensitivity
  - Probability that a subject with the disease will screen positive
- Specificity
  - Probability that a subject who is disease free will screen negative

# 2 x 2 Tables

	Disease Present	Disease Absent	
Test Positive	a	b	a+b
Test Negative	c	d	c+d
	a+c	b+d	a+b+c+d

# Sensitivity

	Disease Present	Disease Absent	
Test Positive	215	16	231
Test Negative	15	114	129
	230	130	

$\frac{215}{230} = 93\%$

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

# Specificity

	Disease Present	Disease Absent	
Test Positive	215	16	231
Test Negative	15	114	129
	230	130	

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


$$\frac{114}{130} = 87\%$$



# Positive and Negative Predictive Values

- Positive Predictive Value
  - probability of those testing/screening positive actually having the disease
- Negative Predictive Value
  - probability of those testing/screening negative NOT actually having the disease

Relevant when you know the prevalence of the disease in the population.

# Positive Predictive Value

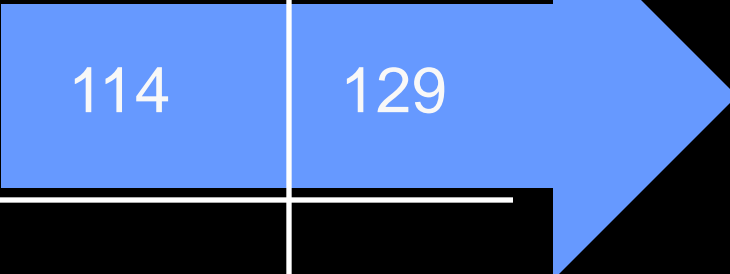
	Disease Present	Disease Absent	
Test Positive	215	16	231
Test Negative	15	114	129
	230	130	

$\frac{215}{231} = 93\%$

Positive predictive value =  $a / a+b$

# Negative Predictive Value

	Disease Present	Disease Absent	
Test Positive	215	16	231
Test Negative	15	114	129
	230	130	



$$\frac{114}{129} = 88\%$$

Negative predictive value =  $d/b+d$

# Likelihood Ratio

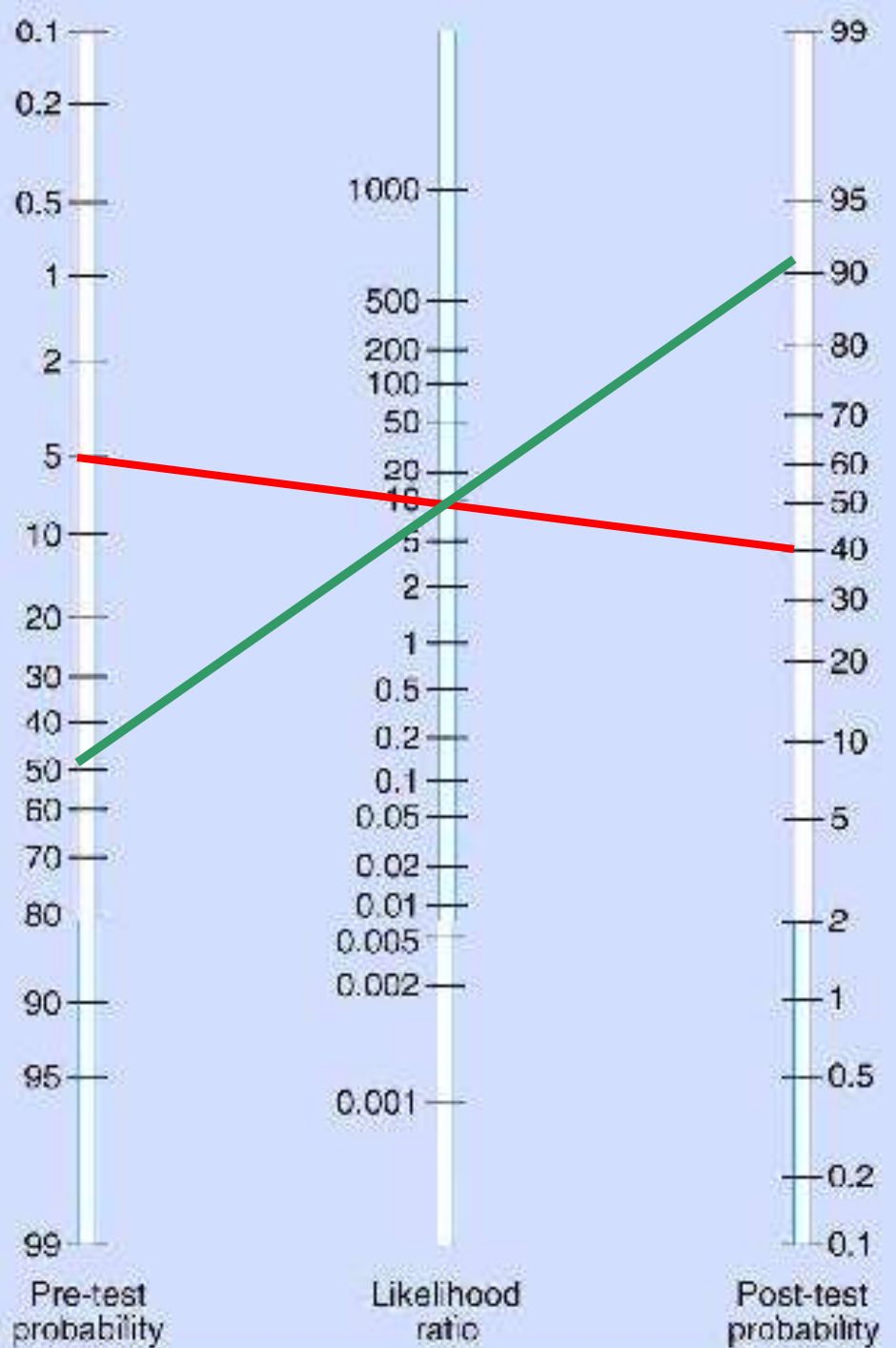
Indicates the value of the test for increasing certainty about a positive diagnosis

Sensitivity

1 - Specificity

$$= \frac{215/230}{1 - 114/130} = 8$$

# Likelihood ratio nomogram



Is this trial of a diagnostic test relevant for me?

Will the reproducibility and interpretability of the test be satisfactory locally?

Consider:

How the test is carried out

Interpretation of the result

Can the results be applied to the local population?

- Is the disease severity similar?
- Are the results generalisable?

Is this trial of a diagnostic test relevant for me?

Will the results change my management?

Are the benefits worth the harms and costs?