Screening

Part Two: Validity of screening test

Learning objectives

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

1. describe elements of screening tests
2. calculate sensitivity and specificity
3. explain the implications of false positives and false negatives
4. understand and calculate predictive values

What is validity?

- The term validity refers to what extent the test accurately measures what it is supposed to measure.
- In other words, validity expresses the ability of a test to separate or distinguish those who have the disease form those who do not have it.
- Validity has two components: sensitivity and specificity

1. Sensitivity is the ability of a screening procedure to identify correctly those who have the disease.
The proportion of persons *with* the disease who have a *positive* test result is "True positive"

It is 100% sensitive if it is positive in every case.
Cases which are missed are called " False negative".

2. Specificity is the ability of a screening procedure to identify correctly those who do not have the disease.
The proportion of persons without the disease who have a *negative* test result "is True negative".
Non-diseased individuals who are tested positive are called "False positive".

		Standard test Results/ Disease		Total
		Present	Absent	
Screening test Results	Present	True Positive (A)	False Positive (B)	A + B
	Absent	False negative (C)	True Negative (D)	C + D
	Total	A + C	B + D	A+B+C+D

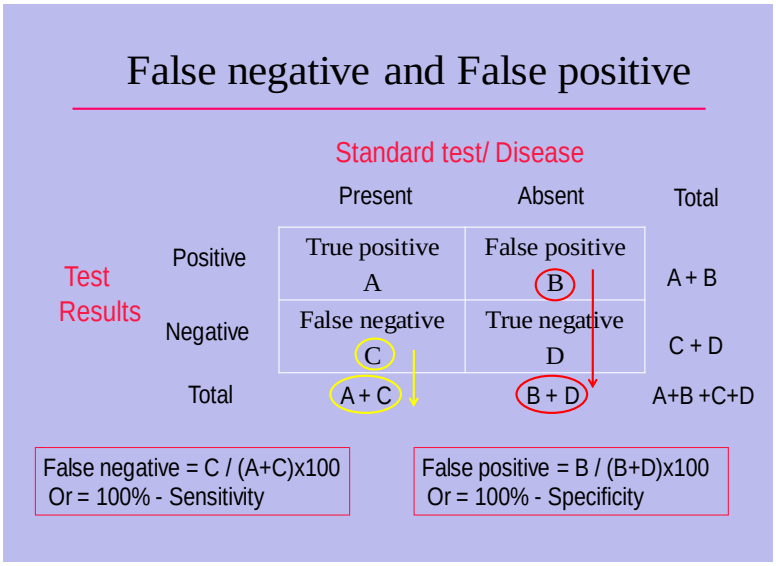
Measures of the Validity of Screening Tests

1. Sensitivity & specificity

Screening Results	True Characteristics in Population		Total
	Disease	No Disease	
Positive	80	100	180
Negative	20	800	820
Total	100	900	1,000

Sensitivity =80/100 = 80% **Specificity** = 800/900 = 89%

$$\text{Sensitivity} = \frac{TP}{TP + FN} \qquad \text{Specificity} = \frac{TN}{TN + FP}$$



2. Predictive values

- **Positive Predictive value**: The proportion (percentage) of true diseased (positive) individuals that is correctly identified by the screening test out of the total positives by the screening test (TP/TP+FP x100).

- **Negative Predictive value**: The proportion (percentage) of true negative people that is correctly detected by the screening test out of the total negatives by the screening test (TN/TN+FN x100).

Predictive values

Screening test Results	Standard test Results/ Disease: Present	Standard test Results/ Disease: Absent	Total
Present	True Positive (A)	False Positive (B)	A + B
Absent	False negative (C)	True Negative (D)	C + D
Total	A + C	B + D	A+B+C+D

Positive predictive value = A / (A+B)x100

Negative predictive value= D / (C+D)X100

Predictive Value

TABLE 4–3. *Predictive Value of a Test*

Test Results	Population: *Disease*	Population: *No Disease*	Total
Positive	80	100	180
Negative	20	800	820
Total	100	900	1,000

$$\text{Positive predictive value} = \frac{80}{180} = 44\%$$

$$\text{Negative predictive value} = \frac{800}{820} = 98\%$$

Sensitivity= 80/100 x100= 80%
Specificity= 800/900 x100= 88.9%
Overall agreement (accuracy) rate= 80+800/1000 x100= 88%
Misclassification rate= 100+20/1000 x100= 12%
PR $_{(True)}$= 100/1000 x1000= 100/1000 pop.
PR $_{(Test)}$= 180/1000 x1000= 180/1000 pop.

Other Measures from the 2 x 2 Table

- Accuracy of a screening test (Agreement rate): determined by the formula: (a+d)/(a+b+c+d) x 100.
- Prevalence (Prevalence True): determined by the formula: (a+c)/(a+b+c+d) x1000
- Prevalence according to the screening results: (a+b)/(a+b+c+d) x1000

Highly sensitive test

- Highly sensitive test is needed in screening for a rare and fatal disease, because we don't want to miss any case of the disease.
- e.g. in myocardial infarction and cancer we need a highly sensitive screening test.

Implications or significance of high false negative rate

1. Severe cases of the disease will be deprived from appropriate treatment. This will lead to more complications and death.
2. False reassurance of patients. This disagrees with characteristics of the screening test, which should diagnose the disease at early stage.

Highly specific test

- A highly specific test is required for screening of a fairly common and non fatal disease, because we don't want high false positive rate to avoid excessive over-diagnosis and its consequences (treatment, side effects of drugs)
- e.g. in Diabetes mellitus, we need a highly specific screening test.

Implications or significance of high false positive rate

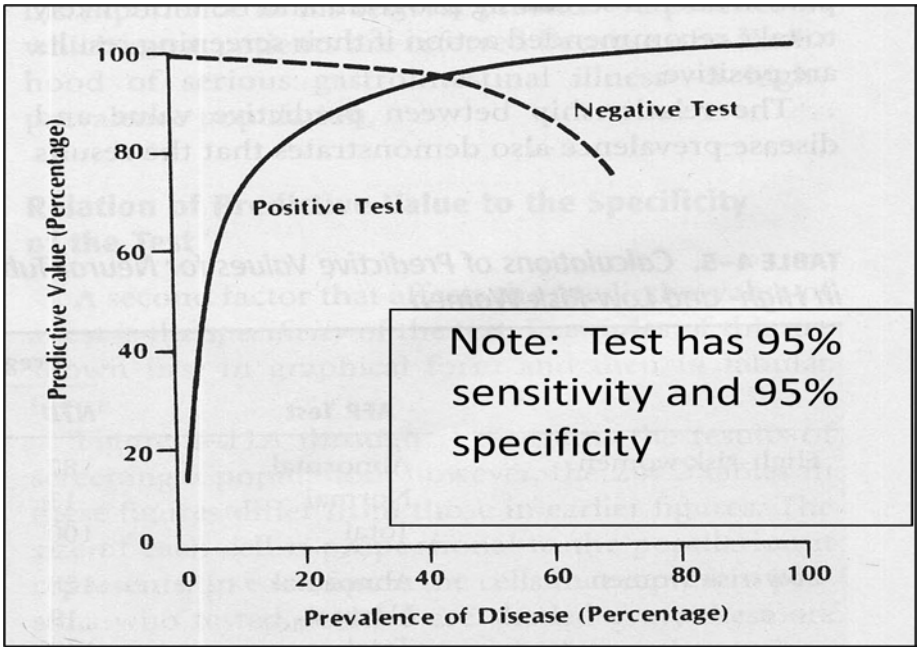
1. Treatment may be given to non-diseased persons with its sequences:
    a. Side effects of drugs
    b. High cost of drugs
2. The test may be harmful and invasive
3. Psychologically harmful to healthy person

Effects of Disease Prevalence on the Predictive Value of a Screening Test

- When the prevalence of a disease increases, the positive predictive value rises, and the negative predictive value falls.

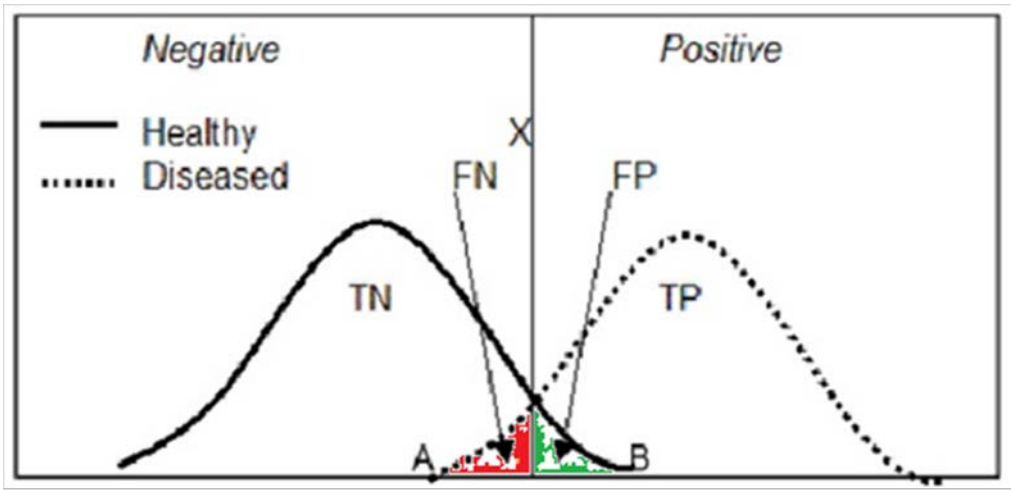
Effect of Prevalence on Predictive Value Positive with Constant Sensitivity and Specificity

Prevalence (%)	PV+ (%)	Sensitivity (%)	Specificity (%)
0.1	1.8	90	95
1.0	15.4	90	95
5.0	48.6	90	95
50.0	94.7	90	95



Relationship between Sensitivity and Specificity

- The sensitivity and specificity are generally constant and don't change with change of prevalence of the disease, but they change in relation to each other if the cut-off point of reading is changed
- To improve sensitivity, the cut-off point used to classify individuals as diseased should be moved farther in the range of the non-diseased (normal).
- To improve specificity, the cut-off point should be moved farther in the range typically associated with the disease.



X= Cut-off value