



Public Health

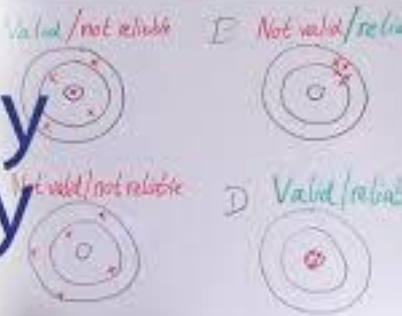
Title :

Lec no : 5

Done By : Raneem alzaben

وَقُلْ رَبِّ زِدْنِي عِلْمًا

Reliability & Validity



Theory

it is important one of the characteristics of a screening test, it should be valid and it should be reliable



Validity of Screening Test L5

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Learning Objectives

- ② So then from this comparison we are going by using the sensitivity, specificity, positive and negative predictive value of screening test to see whether it is valid, reliable or not

After completing this lecture, the student will be able to:

- ① Define what is meant by the **validity and reliability** of a screening test.
- ② Define, **calculate**, and interpret the **sensitivity, specificity, positive predictive value and negative predictive value** of a screening test.
- ③ Explain how **increasing or decreasing the (cut-off value)** used to identify an abnormal test **result influences sensitivity and specificity** of the screening test.
- ④ Explain how **predictive value** is influenced by **prevalence** of disease.
- ⑤ Discuss the potential **harms of screening**

advantage with رح نحكي عن
disadvantage

VALIDITY
screening solutions

زي ما بنعرف انه screening test فيه continuous data
قيمة لكل test مثلا blood glucose او blood pressure
او creatinine او حتى hemoglobin كلها هاي فيها ارقام
فكيف نحكي انه هاذ الشخص positive او negative لازم نحط
good cut off يعني الي اعلى من قيمة معينة او اقل من هاي
القيمة حسب المرض ما ناخذ الارقام مثل ما هي مش مثل
Diagnostic test مثل random blood test رقم معين بكون



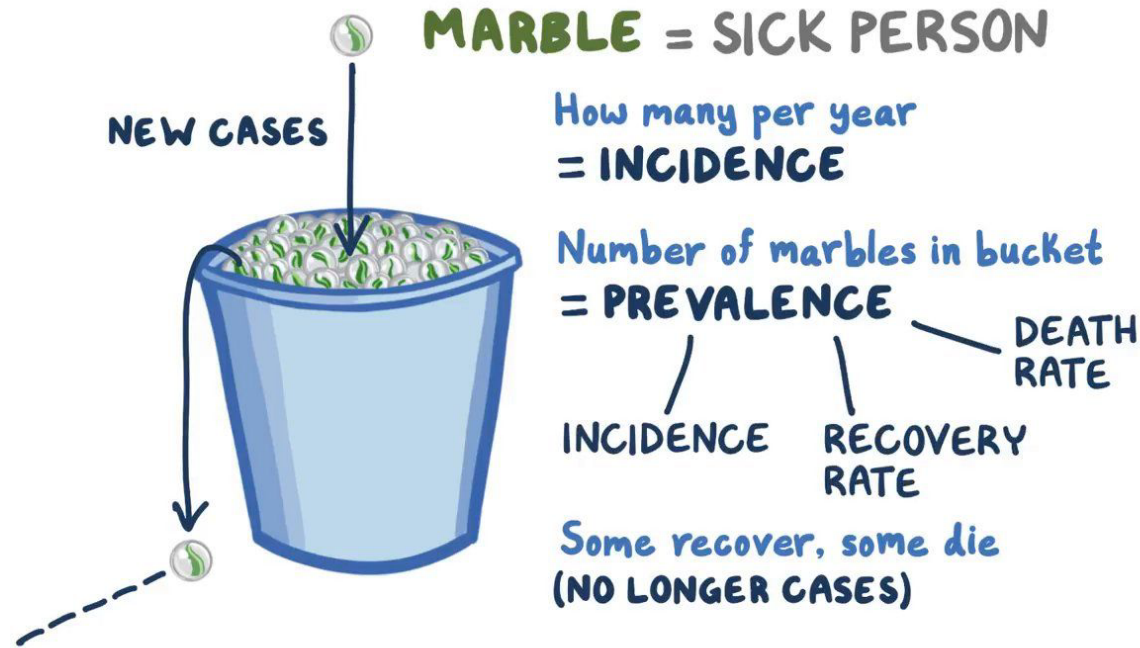
Incidence refers to the occurrence of **new cases** of disease or injury in a population

Prevalence is a measure of the burden of disease in a population in a given location and at a particular time, as represented in a count of the number of people affected



existing case of disease in the community

In summary, you'll see "prevalence" to refer to the number of people currently diagnosed with a disease, and you'll see "incidence" when referring to the new cases being diagnosed over a period of time. We need both measures to help assess the risk and burden of diseases on our community.



باختصار بيكون قادر على تميز
وتقسيم الناس على حسب النتائج

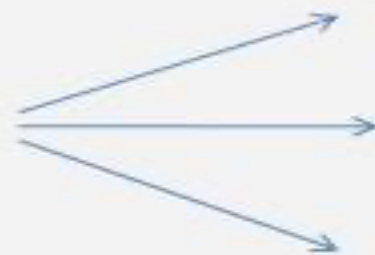
VALIDITY

Screening test. is not a
confirmatory test.

Validity is the ability of a test to measure what is intended to measure

- It expresses the ability of a test to separate those who have the disease from those who do not.
- A test with little systematic **error** is a valid test.

Components
of
VALIDITY



Sensitivity

Specificity

Predictive Accuracy



حتى نقدر نقيس validity الي هي Sensitivity
و specificity و predictive accuracy نقارن نتائج screening
test ب gold standard test الي هو confirmatory test

for example

فحص anemia عند الاشخاص by physical examination
بعدها نبعثهم لل gold standard test لقياس hemoglobin
بعدها زي ما حكينا نقارن النتائج لقياس ال validity

SENSITIVITY

The ability of a test to correctly identify those who have the disease (True Positives)-
 "Proportion of Truly Ill Population"

| Screening test | GOLD STANDARD | | Ds (Disease) |
|----------------|--------------------------------------|--------------------------------------|---------------|
| | Ds present | Ds absent | |
| Test positive | Group (a) True Positive TP(a) | Group (b) False Positive FP(b) | |
| Test negative | Group (c) False Negative FN(c) | Group (d) True Negative TN(d) | |
| Total | TP+FN (a+c) | TP(b+d) | |

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

ami =

Expressed as percentage..... TP/ TP+FN.

فكرة الجدول بسيطة

الفكرة باختصار نقارن نتائج screening ب gold standard

Screening test

$$a + b = \text{positive}$$

$$c + d = \text{negative}$$

GOLD STANDARD

$$a + c = \text{positive}$$

$$b + d = \text{negative}$$

بعدها بنشوف اذا في تطابق بينهم لكل حالة

$a = \oplus$ by both = true positive

$b = \text{False positive}$

People who do not have a disease, but the results in the screening test appeared positive

$c = \text{False negative}$

People who have a disease, but the results in the screening test appeared negative

$d =$ People who have a disease and the results appeared similar in the two tests

Sensitivity is the proportion of people **with the disease** in the screened population who are **identified as ill by the screening test**; the ability of a test to correctly identify true diseased persons. It is also called true positive rate.

(When the disease is present, how often does the test detect it?)

حتى هاذ ال test مر بمراحل كث Weight, height, vision and

gold standerd test ك hearing examination لحتى يقبلوه ك

The validity of a screening test is **assessed against the results of a test known or thought to be more accurate**. This test is called **Gold standard**, reference or validating test.

Weight, height, vision and hearing examination blood pressure

anxiety

The screening test may be a **specific question**, a **physical examination procedure**, a **laboratory test** or other methods intended to identify unrecognized disease.

TP(a)

$$\text{Sensitivity} = \frac{\text{TP}}{\text{TP} + \text{FN}} \times 100$$

TP+FN(a+c)

$$\text{False negative rate} = 100 - \text{Sensitivity}$$

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

SPECIFICITY to Screening Test ✖ ✖ ✖ ✖

The ability of a test to correctly identify those who **do not have** the disease. (True Negatives)

Proportion of Truly Healthy Population.

| | | GOLD STANDARD | |
|-----------------------|---|---|-----------|
| | | Ds present | Ds absent |
| Screening test | | | |
| Test positive | <div style="border: 1px solid black; background-color: #e0f0ff; padding: 5px; display: inline-block;"> TP </div> | <div style="border: 1px solid black; background-color: #ffe0e0; padding: 5px; display: inline-block;"> FP </div> | |
| Test negative | <div style="border: 1px solid black; background-color: #e0f0ff; padding: 5px; display: inline-block;"> FN </div> | <div style="border: 1px solid black; background-color: #ffe0e0; padding: 5px; display: inline-block;"> TN </div> | |
| Total | <div style="border: 1px solid black; background-color: #e0f0ff; padding: 5px; display: inline-block;"> TP+FN(a+c) </div> | <div style="border: 1px solid black; background-color: #ffe0e0; padding: 5px; display: inline-block;"> TN+FP(b+d) </div> | |

$$\text{Specificity} = \frac{\text{TN}(d)}{\text{FP} + \text{TN}(b+d)} \times 100$$

$$\text{Specificity} = \frac{\text{TN}}{\text{TN} + \text{FP}}$$

False positive rate = 100 - Specificity

negative **مث** = Positive

FALSE NEGATIVES: *If a Person with disease is labeled Negative:*

للتسهيل

False اذا كان موجود كلمة

معناها عكس المكتوب

- False reassurance
- Ignores any disease signs and symptoms
- Postponement of treatment.
- Detrimental to overall health

Low Sn
High Sp

- The disease may be fatal and/or very communicable (develop complications or transmission of the disease).

FALSE POSITIVES: *If a Person without disease is labeled Positive:*

يعني صعب انه نشيل الفكرة من المريض انه ما عنده مريض فيصير نفسياً بحس حاله مريض وما يقتنع بكلام طبيب ثاني للاسف

- Further testing with long, expensive tests. (unnecessary)
- Discomfort, inconvenience, anxiety
- Burden on health facilities (costly)
- Emotional trauma
- Difficulty in "de-labeling"

High Sn
Low Sp

type of disease **FP AND FN** احنا نسعى لتقليل من لكن تختلف من مرض لآخر وتعتمد على

| Screening test | Standard test | | |
|----------------|---------------|---------------|---------------|
| | Positive | Negative | Total |
| Positive | a (true +ve) | b (false +ve) | a + b |
| Negative | c (false -ve) | d (true -Ve) | c + d |
| Total | a + c | b + d | a + b + c + d |

$$\text{Sensitivity} = \frac{a \text{ (true +ve)}}{a + c} \times 100$$

$$\text{False positive rate} = \frac{b \text{ (false +ve)}}{b + d} \times 100$$

$$\text{Specificity} = \frac{d \text{ (true -Ve)}}{b + d} \times 100$$

$$\text{False negative rate} = \frac{c \text{ (false -ve)}}{a + c} \times 100$$

وين تطابقوا باي مجموعة

+ve by both + -ve by both

a + d ✓ ✓

$$\text{overall agreement rate} = \frac{\text{grand total}}{\text{grand total}} \times 100 = \frac{a + d}{a + b + c + d} \times 100$$

(Repeatability)

وين اختلفوا

false +ve (b) + false -ve (c)

$$\text{Misclassification rate} = \frac{b + c}{a + b + c + d} \times 100$$

• Sensitivity and specificity are characteristics of the test and are only influenced by the test characteristics and the criterion of **positivity that is selected.**

reliability
accuracy

Tests For Continuous Variables

- At times we need to test for a **continuous variable**, e.g. BP or blood sugar level for which there is no “positive” or “negative result”.
- A decision must therefore be made in establishing a cut-off level above which a test result is considered positive and below which a result is considered negative.

زي ما حكينا قبل بيكون **rang** مش رقم وخلص

15

Predictive Accuracy or Values

■ When evaluating the feasibility or the success of a screening program, one should also consider the positive and negative predictive values.

رح نطلعه من الجدول السابق لكن رح تفرق بالحساب

■ These are also computed from the same 2 x 2 table, but the perspective is entirely different.

■ **Positive predictive value** is the probability that subjects with a positive screening test truly have the disease.

$$a+b$$

screening test positive يعني عكسنا المفهوم كم شخص من الي معهم مرض طلع عندهم

■ **Negative predictive value** is the probability that subjects with a negative screening test truly don't have the disease.

$$b+d$$

screening test negative كم شخص ما معه مرض طلع

■ The positive predictive value of a test, is very dependent on the prevalence of the disease in the population being tested. The higher the prevalence of disease is in the population being screened, the higher the positive predictive values

صحيح جدا

When thinking about predictive value of a test.....



...imagine you are a physician discussing the results of a screening test with the patient...

1. if a test was Positive

How likely is it that is he really has the disease?

How worried should be he?

$$\text{Positive predictive value} = \frac{a}{a + b} \times 100$$

المجموعة الإيجابية **

2. if a test is Negative

How likely is it that is he really does not have the disease?

How reassured should be he?

$$\text{Negative predictive value} = \frac{d}{c + d} \times 100$$

المجموعة السلبية →

Positive

Negative

antenatal care ? screening طيب اي واحد من هو test

laboratory test ? gold standard test ومين

Let us use an example: In a study carried out to evaluate the ability of doctors in antenatal care to detect anemia in pregnancy among users of the services. The validating test (standard) is the Hb level by laboratory test .

The study was carried out on 800 pregnant women and the results were as follows: Of these 800 pregnant women, 440 were considered anemic by the laboratory test (standard). Of this anemic group, doctors in ANC (screening) were able to identify 230. In addition, they labeled 55 of the non anemic as anemic. → False positive

How accurate (valid) was the judgment of doctors in ANC in detecting anemia among pregnant women?

To answer the question, we arrange the data given in a convenient table (the so called 2x2 table).

| | |
|--------------------------------------|--------------------------------------|
| Group (a) True Positive TP(a) | Group (b) False Positive FP(b) |
| Group (c) False Negative FN(c) | Group (d) True Negative TN(d) |

$d = 800 - 440 = 360$
 $360 - 55 = 305$

$c = 440 - 230 = 210$

| Screening test (ANC Doctor) | Laboratory test-Hb level (standard) | | Total |
|--------------------------------|--|---------------------------------------|-------------------|
| | Positive | Negative | |
| Positive | 230 a (true +ve) <i>مباشرة من سوال</i> | 55 b (false +ve) <i>بمباشرة</i> | 285 a + b |
| Negative | 210 c (false -ve) | 305 d (true -Ve) | 515 c+ d |
| Total | 440 a + c <i>بمباشرة</i> | 360 b + d | 800 a +b+ c+ d |

From the table we see that:

Total **anemic** by the **laboratory test** = 440 (a+c)

The doctor in ANC identified correctly = 230 (a)

$$\text{The sensitivity of doctor} = \frac{230 \text{ } a}{440 \text{ } a+c} \times 100 = 52.3\%$$

The total non **anemic** by the **laboratory test** = 360(b+d)

The doctor in ANC identified correctly = 305(d)

$$\text{The specificity of doctor} = \frac{305}{360} \times 100 = 84.7\%$$

$$\text{Positive predictive value} = \frac{230 (a)}{285 (a + b)} \times 100 = 80.7\%$$

Among those who had a positive screening test, the probability of disease was 80.7%.

$$\text{Negative predictive value} = \frac{305 (d)}{515 (c + d)} \times 100 = 59.2\%$$

Among those who had a negative screening test, the probability of not having disease was 59.2%.

The **overall agreement rate** = $(230 + 305) \times 100 / 800 = 66.9\%$

This may be called **repeatability**.

The **overall misclassification rate** = $(210 + 55) \times 100 / 800 = 33.1\%$

Notes:

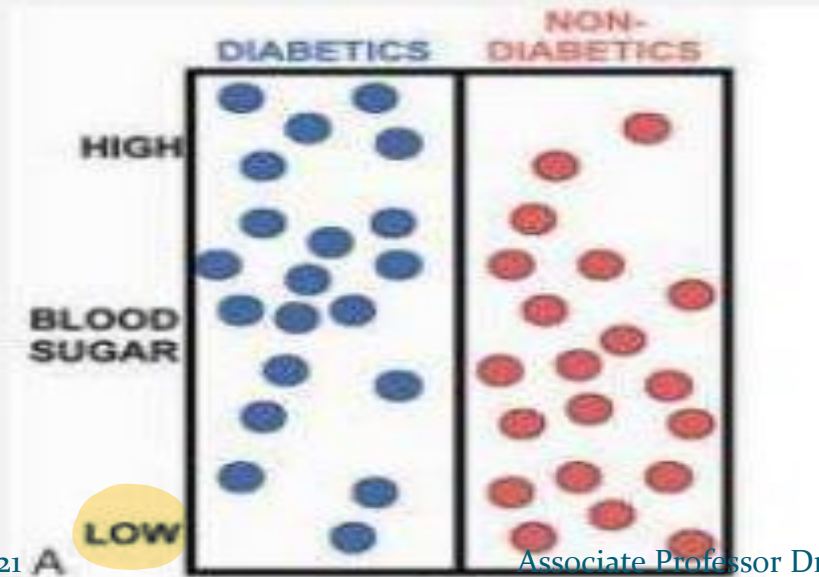
- Sensitivity and specificity do not change with the change of prevalence of disease but do change with the changing of cut off points between normal and abnormal.
- Any screening test is highly preferable to have high sensitivity and specificity to avoid misclassification of screened people.
- A highly sensitive test is required for the screening of fatal disease and highly communicable disease to avoid missing any case.
- A highly specific test is required for the screening of non-fatal and fairly common disease to avoid over diagnosis and flooding the health care facilities with false positive case.

CHD OR CANCER

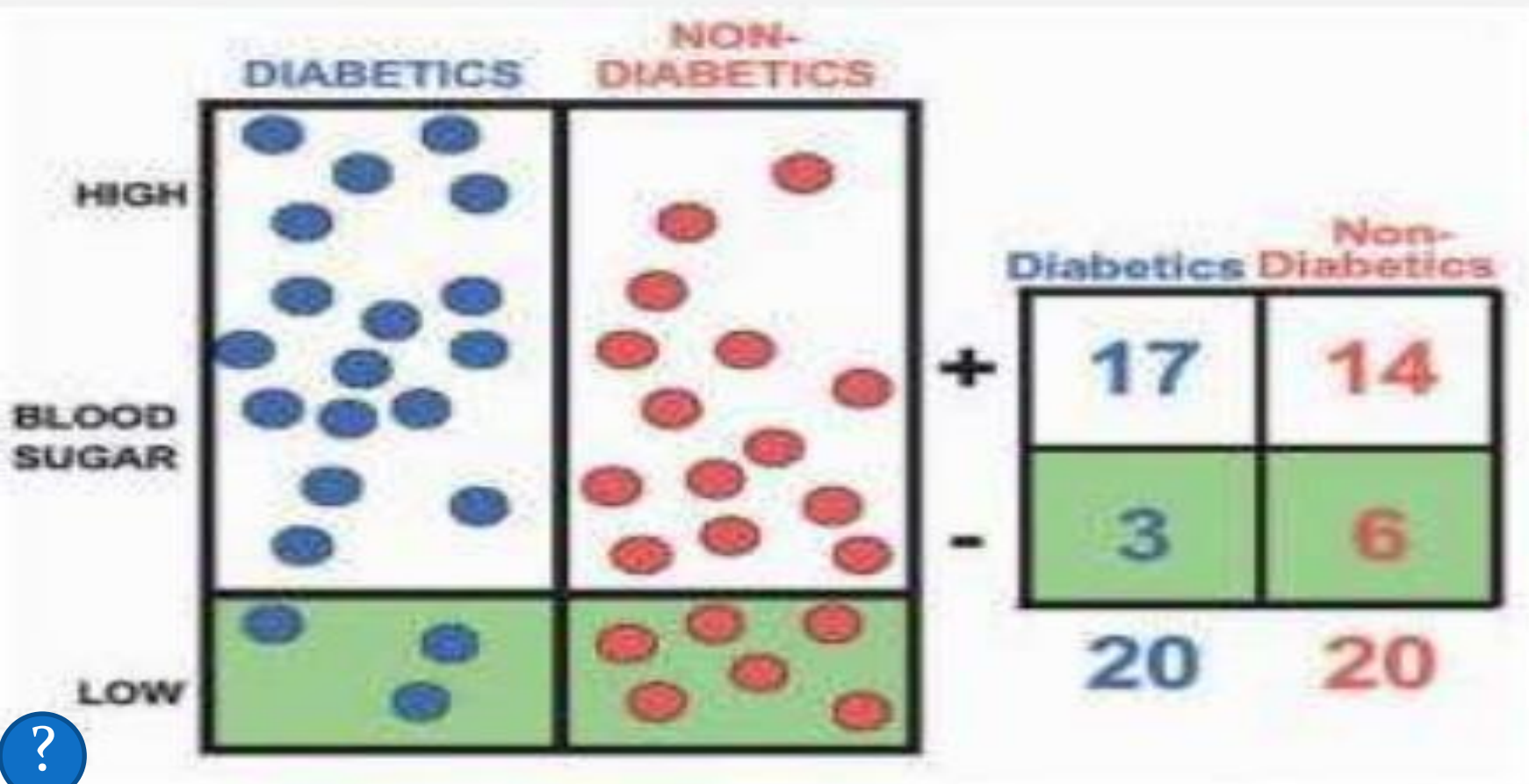
CONCEPT OF CUT-OFF POINT

→ Sensitivity + Specificity
في الحد

- Unlike in Bimodal Distribution(Dichotomous), Some diseases comes in Continuous Variables (Ex: Diabetes, HTN). In these Cases, It is difficult to calculate Sensitivity & Specificity.
- So, A Cut Off Point must be set to distinguish between Positive and Negative Result.



Consider 20 diabetics and 20 Non-diabetics screened using a blood sugar test – Vertical axis From Low to High.

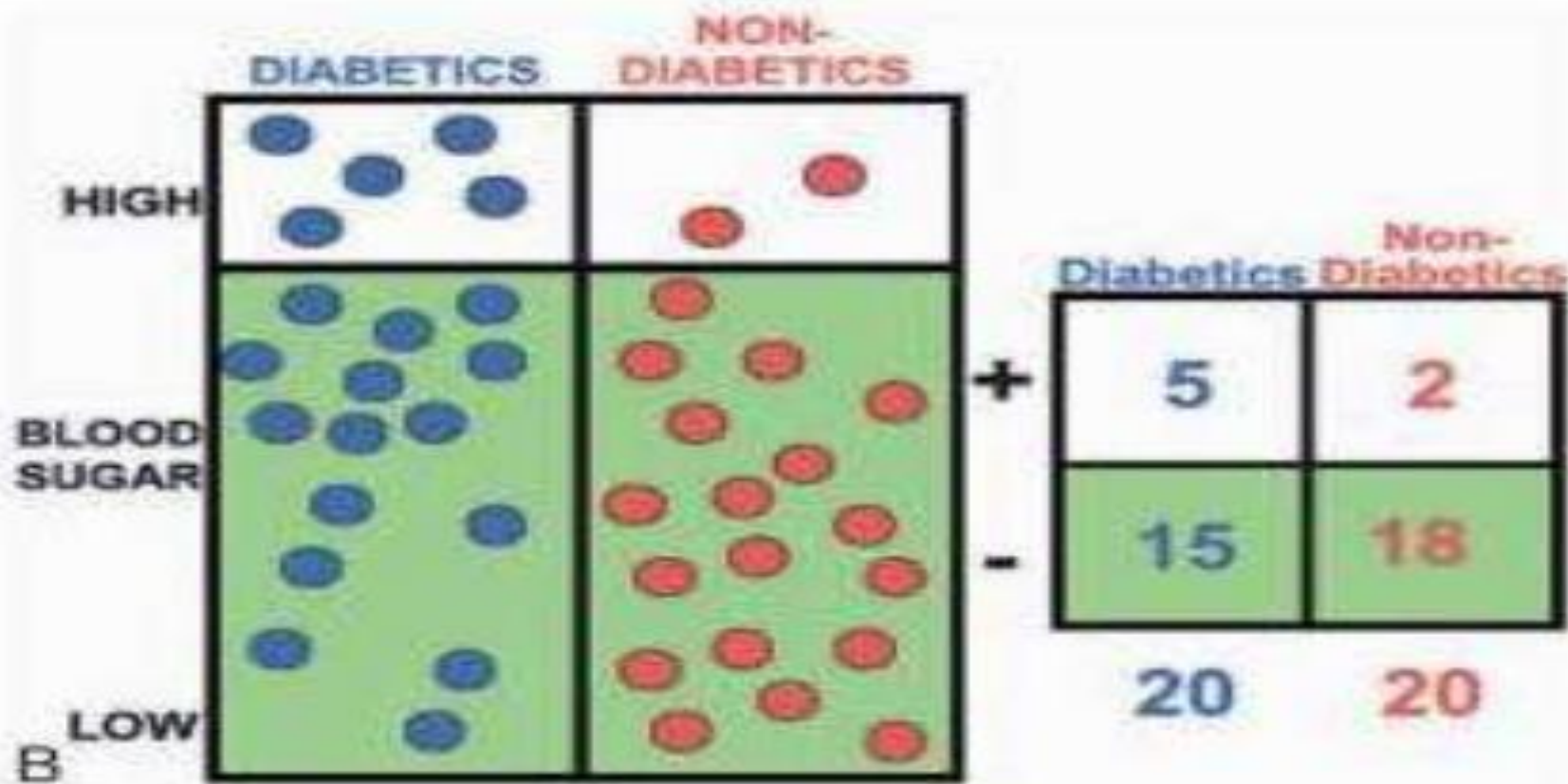


Low Cut-Off Point

Sensitivity= 85%
Specificity= 20%

- False Positives originate (More Non-diabetics are diagnosed positively)



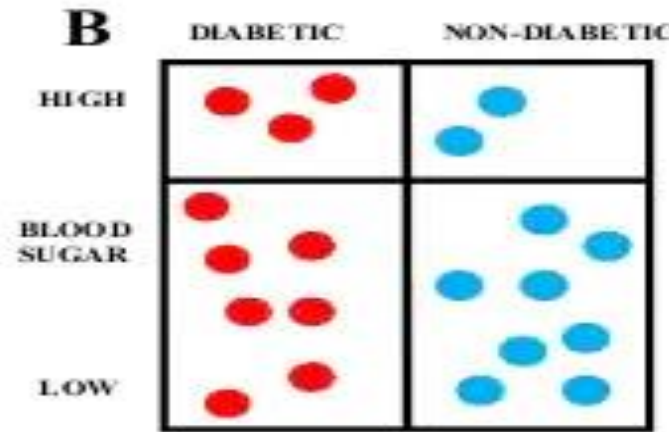
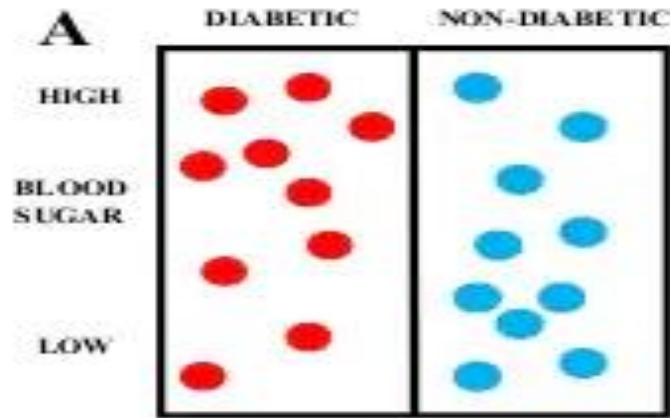


High Cut-Off Point

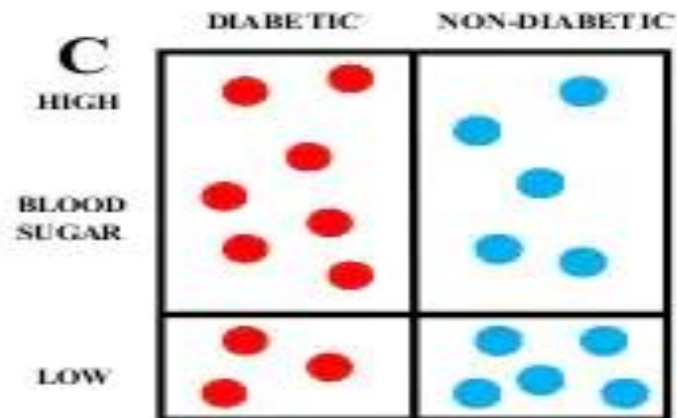
Sensitivity= 25%
Specificity= 90%

- False Negatives originate (More diabetics are not diagnosed positively)

Screening For Diabetes In Hypothetical Population With A Prevalence Of 50 %.
Effects Of Choosing Different Cutoff Levels For A Positive Test:



| | DIABETIC | NON-DIABETIC |
|---|----------|--------------|
| + | 3 | 2 |
| - | 7 | 8 |
| | 10 | 10 |



| | DIABETIC | NON-DIABETIC |
|---|----------|--------------|
| + | 7 | 5 |
| - | 3 | 5 |
| | 10 | 10 |

SO,

- Different Cut-off points → different sensitivities and specificities.
- The cut off point that identifies more true negatives will also identify more false negatives.
- The cut off point that identifies more true positives will also identify more false positives.
- ✓ *The choice of a high or low cut off level for screening therefore depends on the importance we attach to FPs or FNs.*
- ✓ *In case of Lethal diseases (Early Intervention possible) Cut off point must be set at Low level, as Greater sensitivity is required. (False Positives can be tolerated)*

مثال

Calculating

| 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 = $800/900 = 89\%$

Sensitivity and specificity are expressed as %

An Ideal Screening Test should have 100% Sensitivity, and 100% Specificity. (Not Practically Possible)

Calculating...

Positive predictive value = $80/180 = 44\%$

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

Negative predictive value = $800/820 = 98\%$

$$\text{PPV} = \text{TP} / \text{TP} + \text{FP}$$

$$\text{NPV} = \text{TN} / \text{TN} + \text{FN}$$

ما يوتر على Sensitivity & Specificity.

Effect of Prevalence :

فقط على predictive values

- Predictive values depend strongly on prevalence of the condition.
- As the prevalence of the condition increases positive predictive value increases and thus more chances of getting true positive results.
- If the condition is uncommon it is more sure that the negative test indicates no abnormality.

Relationship B/W Predictive Value And Disease Prevalence

| Relationship of Disease Prevalence to Positive Predictive Value | | | | | |
|---|--------------|------|----------|--------|---------------------------|
| EXAMPLE: SENSITIVITY = 99%, SPECIFICITY = 95% | | | | | |
| Disease Prevalence | Test Results | Sick | Not Sick | Totals | Positive Predictive Value |
| 1% | + | 99 | 495 | 594 | $\frac{99}{594} = 17\%$ |
| | - | 1 | 9,405 | 9,406 | |
| | Totals | 100 | 9,900 | 10,000 | |
| 5% | + | 495 | 475 | 970 | $\frac{495}{970} = 51\%$ |
| | - | 5 | 9,025 | 9,030 | |
| | Totals | 500 | 9,500 | 10,000 | |

- Higher the prevalence, higher is the predictive value.
- Hence a screening program is most productive and efficient when it is directed to high risk target population.

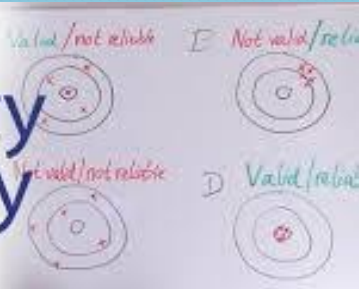
Determining The Cutoff Point

The factors to be considered are :

- **Disease prevalence** : when prevalence of the disease is high in the community the cut-off point is set at low level.

This will increase the sensitivity.

- **The disease** : if the disease is very lethal and early intervention markedly increases the prognosis, cut off point is set at lower level.



RELIABILITY

Theory

Reliability determines the Precision of the Test. (Repeatability)

- It means that **all the results of the test should be similar (Cluster at one place), when conducted each and every time.**
- This is not possible because of the Variations that cause the test to not yield same results every time. (like Lab equipment failure etc.)

3 types of Variation →

ليش القراءات تختلف من شخص لآخر

1. *Intra –subject variation*
2. *Intra –observer variation*
3. *Inter –observer variation*

1. Intra –subject variation

بنفس الشخص

This variation in the results of the test or measurements if it is conducted **over time (short period) on the same individual**, variation in blood pressure during 24 hrs. **يختلف من وقت لآخر**

2. Intra –observer variation

➤ This is the Variation in the results of the test due to the **same observer** examining the result at different times.

يختلف القياس من اول اليوم بكامل طاقتك عن اخر اليوم لما تكون مرهق

EX: Two readings of Blood pressure by the Same observer.

3. Inter –observer variation

➤ This is the Variation in the results of the test due to the **multiple observers** examining the result.

لاكثر من طبيب

EX: Chest X ray read by two different Radiologists.

Exercise

To assess the validity of a screening test in detecting cases of disease (X), the test was performed on 100 patients with the disease (X) and on 800 normal persons. Positive results were obtained in 95 out of the 100 diseased and in 70 out of the 800 normal persons.

Calculate the sensitivity, specificity and overall misclassification rate of this test.

Is this test useful in screening of fatal disease? Explain.



CONCLUSION

- ✓ Screening, despite its flaws, is a major public Health determinant, measured by its effect on Mortality, Morbidity & Disability.
- ✓ Establishing appropriate criteria requires considerable knowledge of the Natural history of disease, adequate facilities for follow up & Rx.
- ✓ It is necessary to ensure that the program is continuously monitored to confirm that effectiveness is maintained.
(benefits>costs)
- ✓ Newer fields such as genetic screening are on the rise which would help the cause.

Thank You