



Medicine & the Media

The Challenge of Reporting on Medical Research

Analizzare gli studi sui test diagnostici



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Firenze, 13 ottobre 2023

A cosa servono i test in medicina?

Predisposizione al rischio

Stratificazione del rischio

Screening

Diagnosi

Stadiazione

Prognosi

Monitoraggio malattia

Selezione trattamento

Monitoraggio trattamento

Sorveglianza

Accuratezza

Utilità Clinica



Studi su test diagnostici

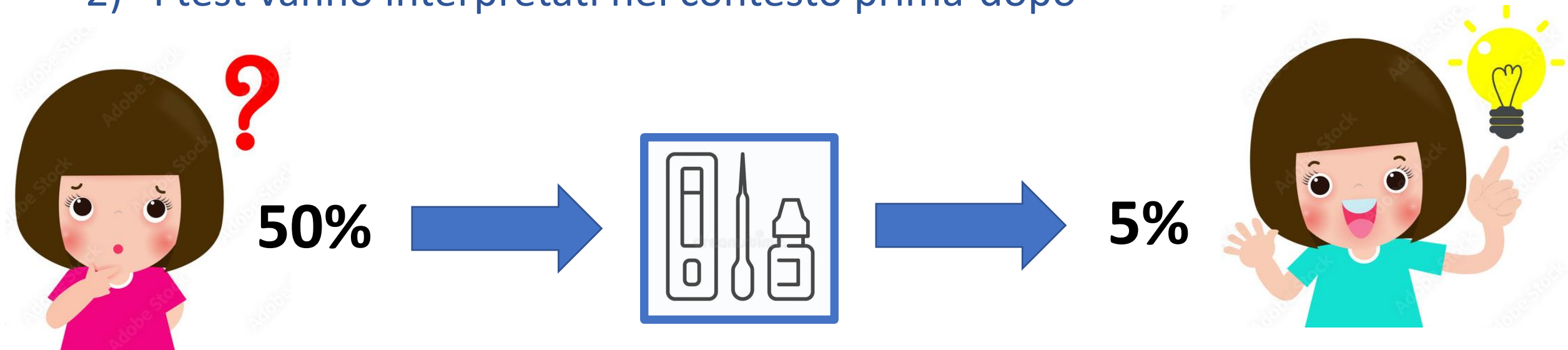
I test diagnostici in medicina...

~~Positivo = Malato~~

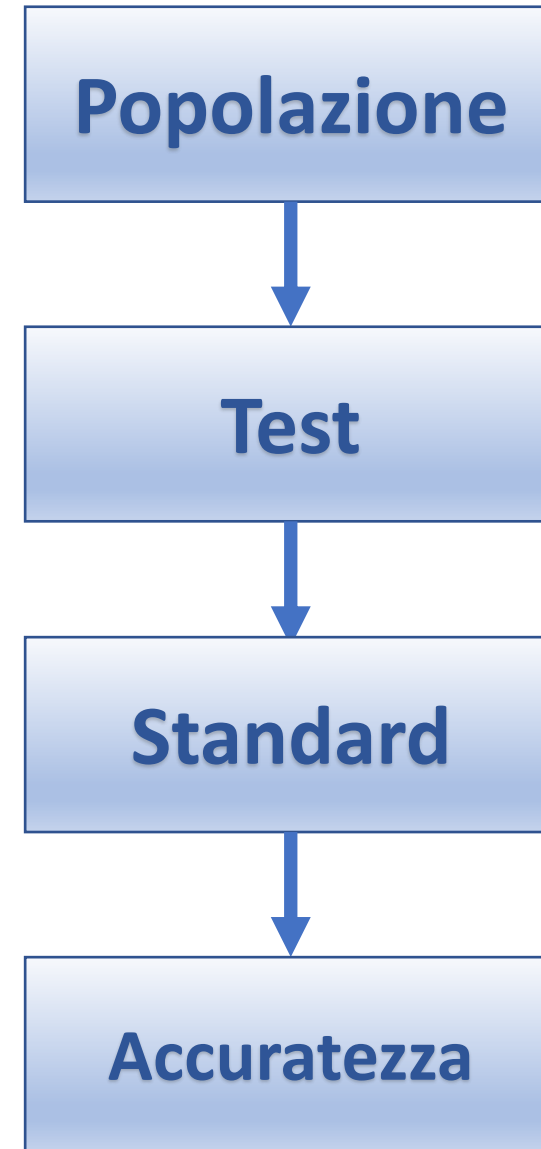
~~Negativo = Sano~~

1) Non esistono test perfetti

2) I test vanno interpretati nel contesto prima-dopo

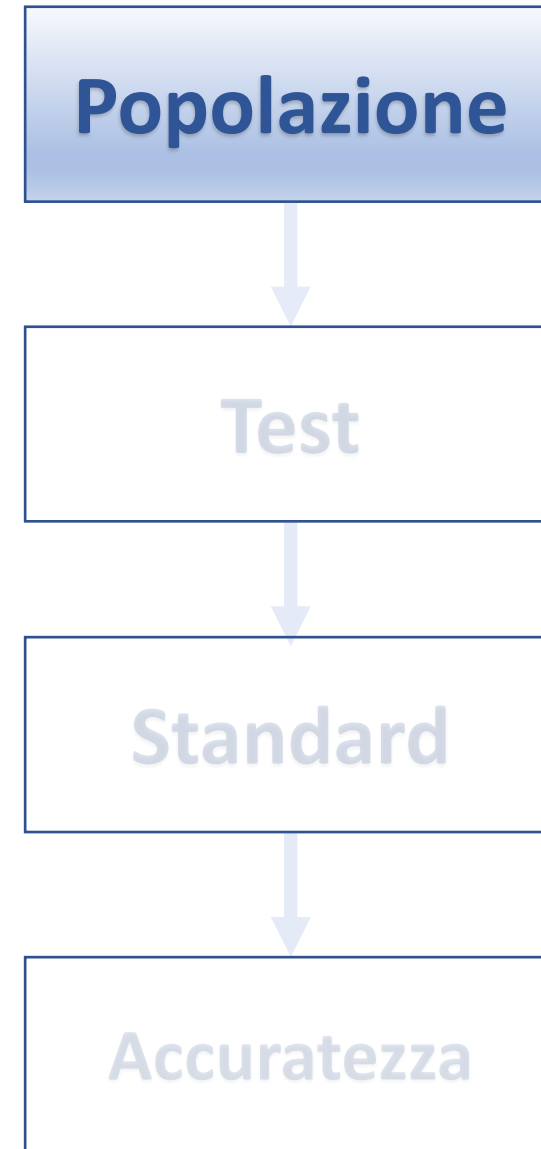


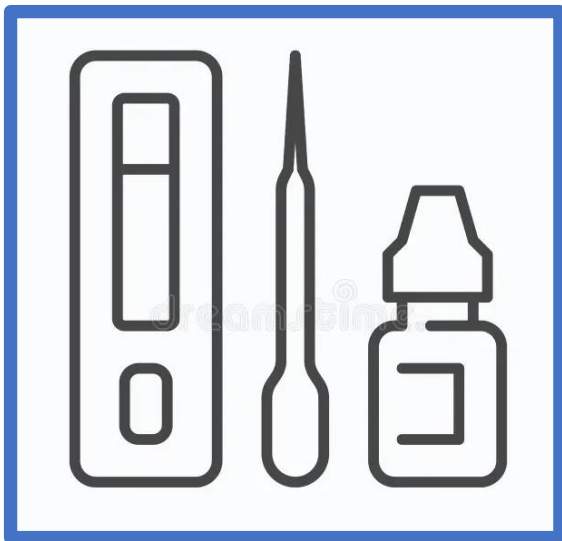
Studi su test Diagnostici



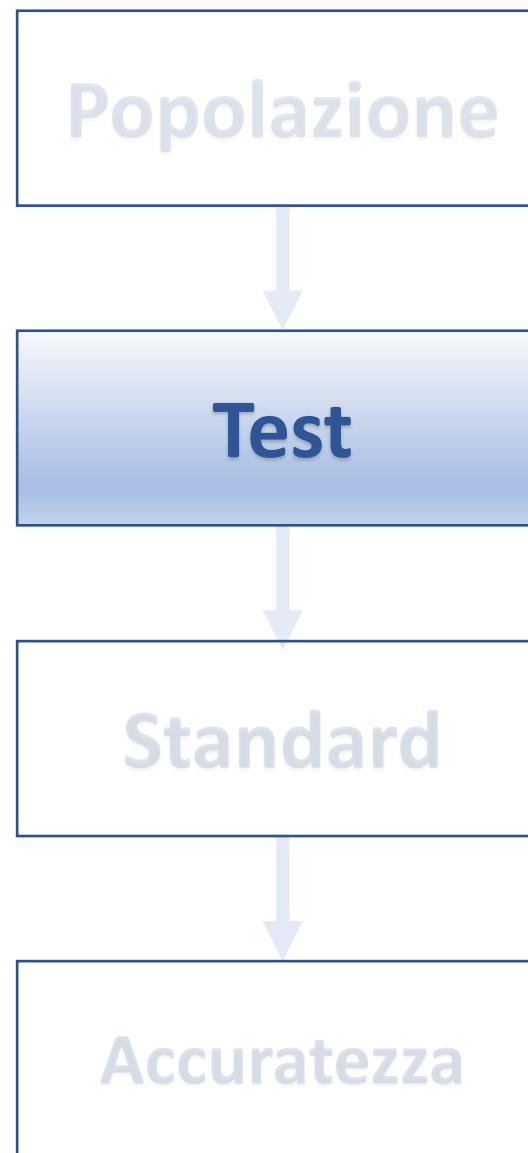


- Campione adeguato come dimensione, scelto grazie al caso
- Eterogenea
- Rappresentativa





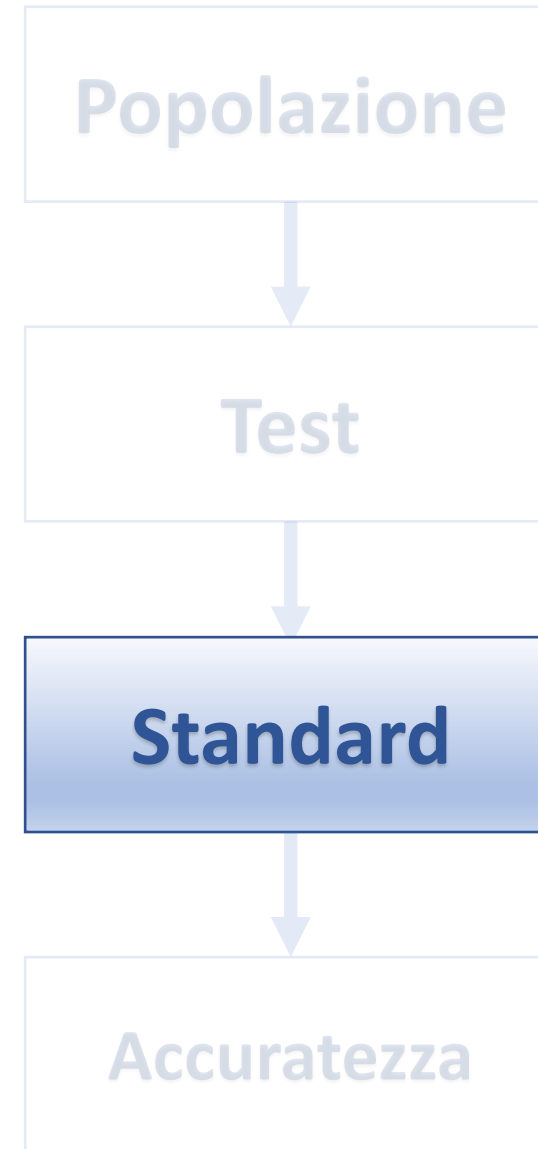
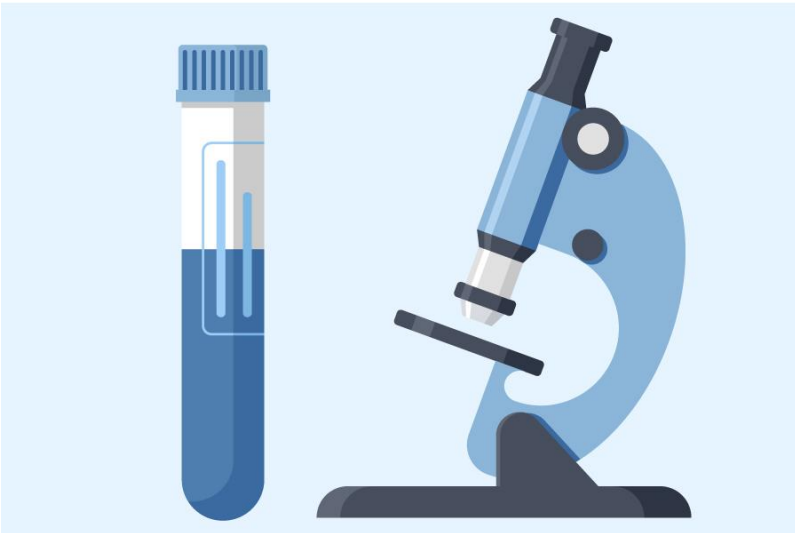
- E' più rapido?
- E' meno invasivo o meno doloroso?
- E' più facile da fare?
- Costa meno? E chi ci guadagna?



~~GOLD STANDARD~~

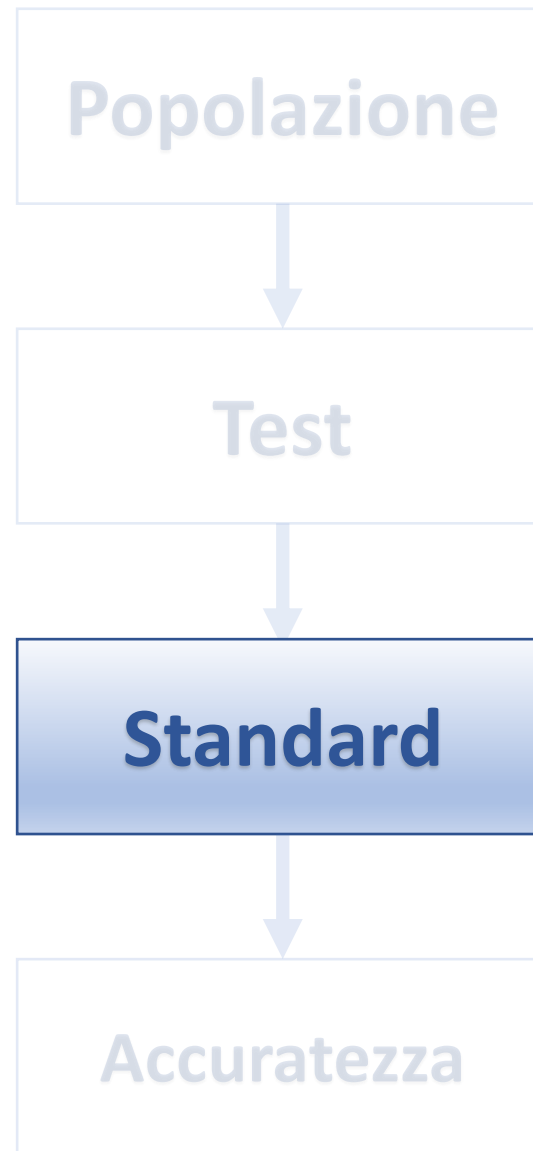
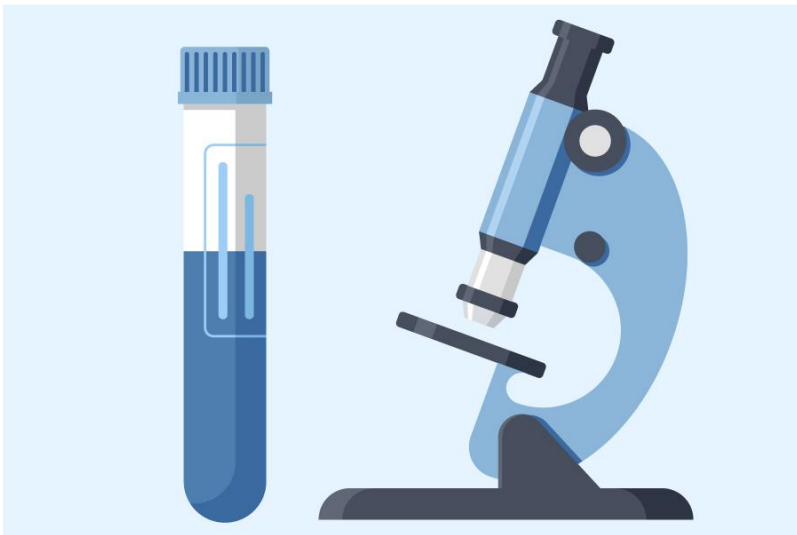


REFERENCE STANDARD



- Tutti fanno entrambi i test?
- I ricercatori sono in cieco?

REFERENCE STANDARD



Popolazione



Test

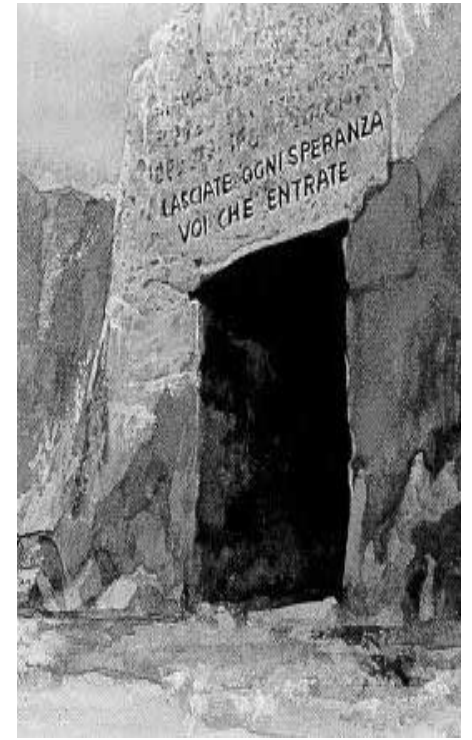


Standard



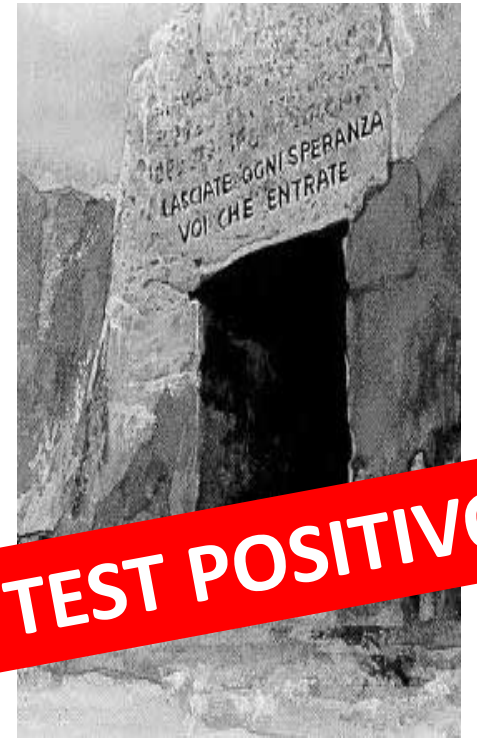
Accuratezza





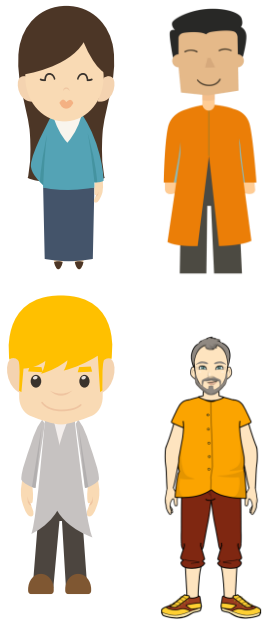


TEST NEGATIVO

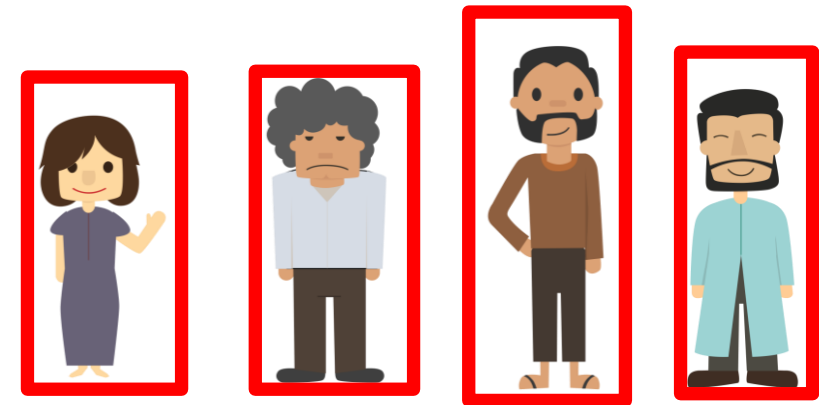
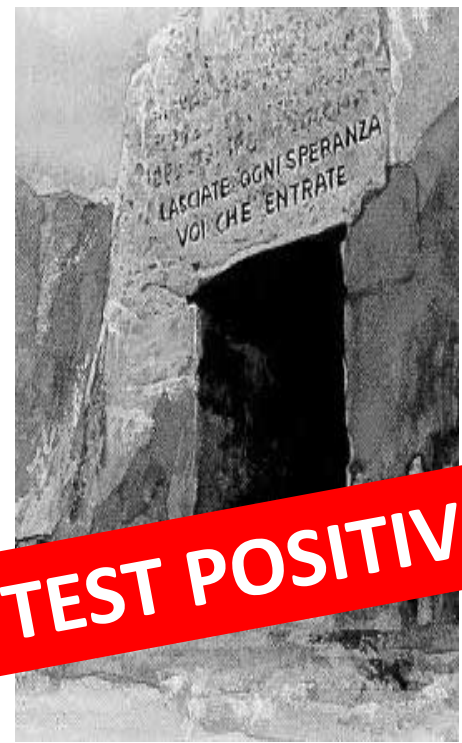


TEST POSITIVO

TEST NEGATIVO

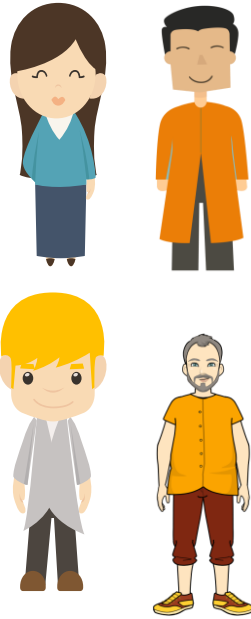


TEST POSITIVO

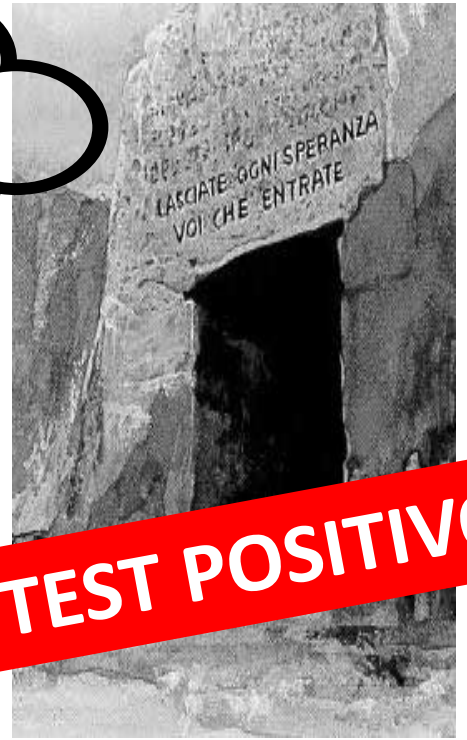
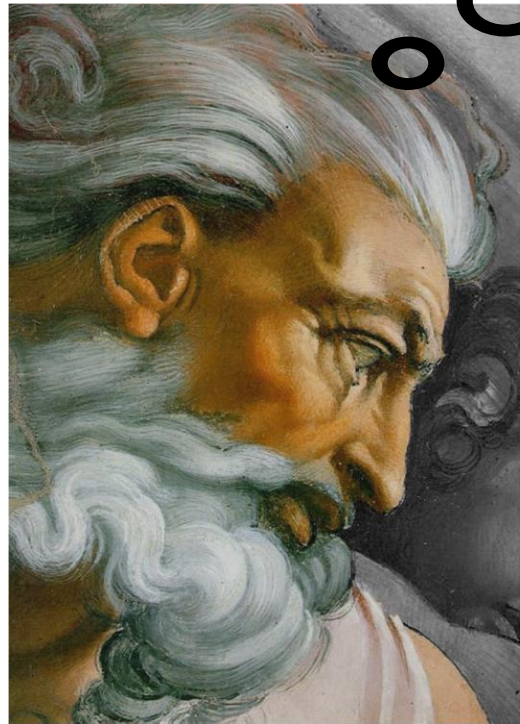




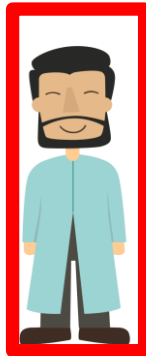
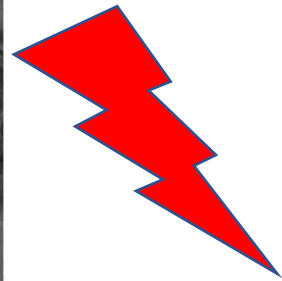
TEST NEGATIVO



Io sono il GOD
STANDARD

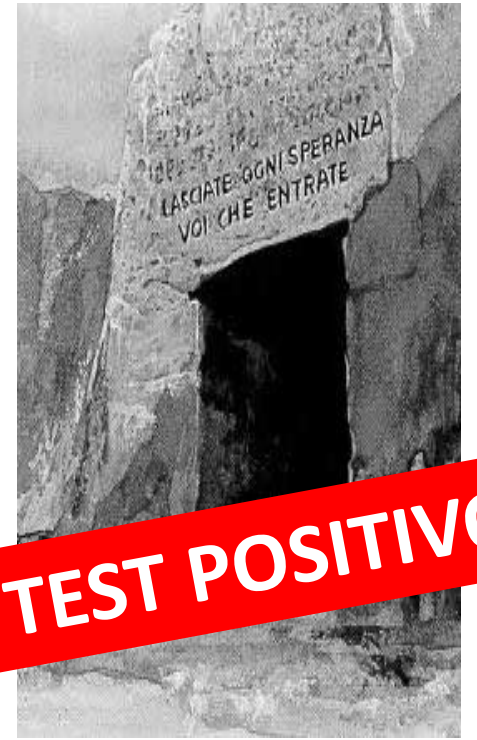
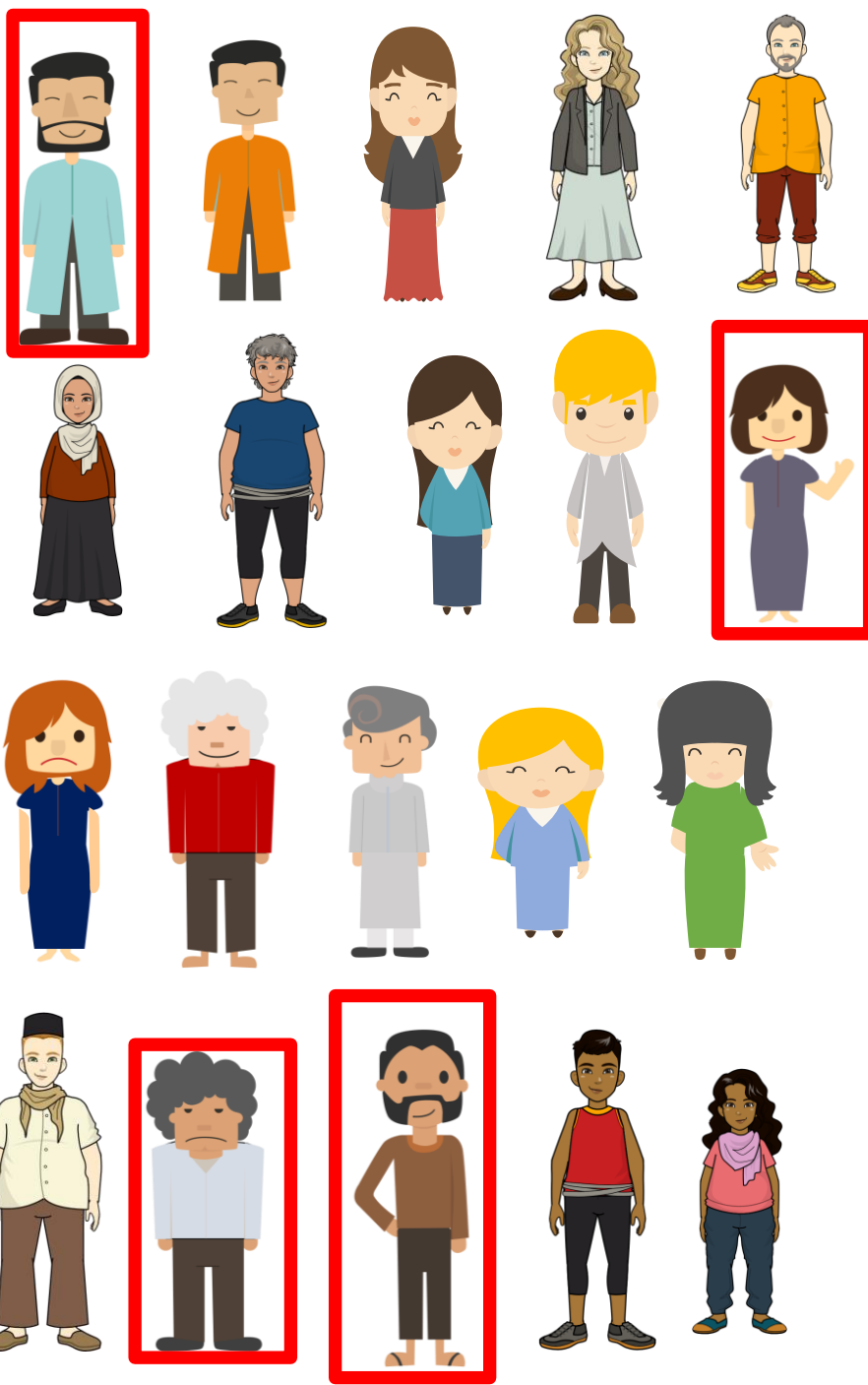


TEST POSITIVO

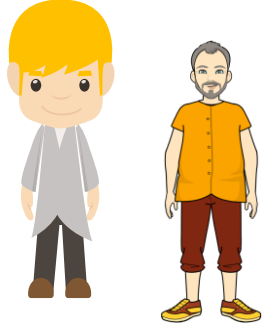




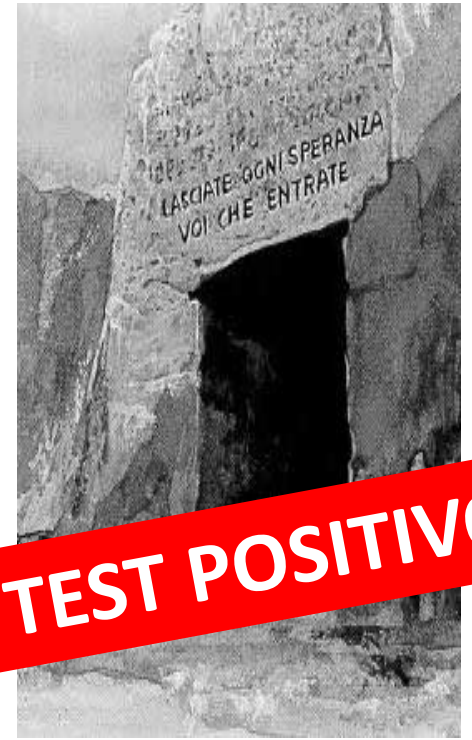
TEST NEGATIVO



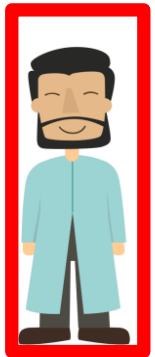
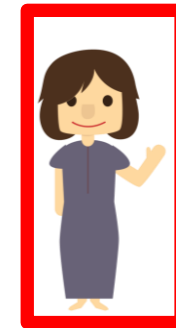
TEST POSITIVO

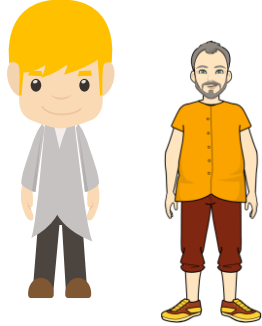


TEST NEGATIVO



TEST POSITIVO

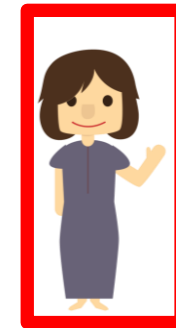
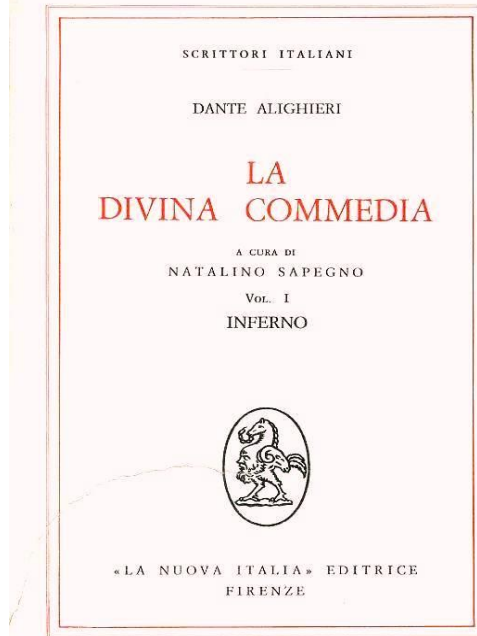




TEST NEGATIVO



TEST POSITIVO

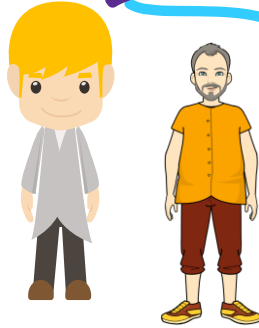




TEST NEGATIVO

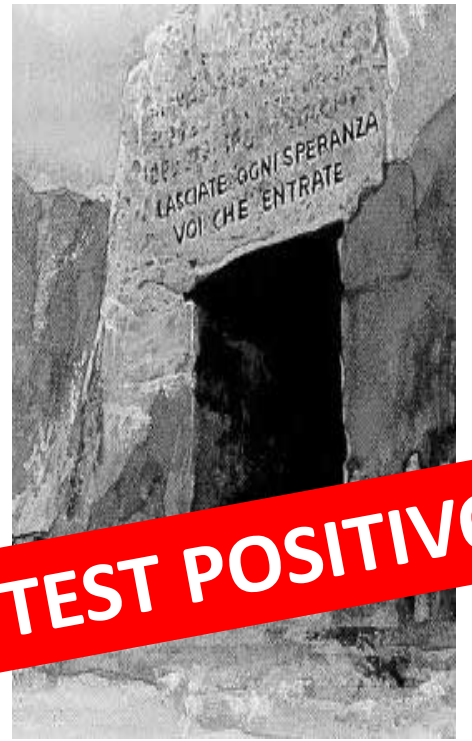


FN

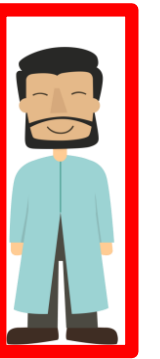


VN

FP



TEST POSITIVO



VP

SENSIBILITA'

- Quanto è bravo un test a rilevare la malattia quando è presente.
- Alta sensibilità = pochi falsi negativi.

SPECIFICITA'

- Quanto è bravo un test a NON rilevare la malattia quando questa è assente.
- Alta specificità = pochi falsi positivi.

Problema...

Sensibilità e Specificità rispondono a domande come

«Se io sono malato, qual è la probabilità che il test risulti positivo?»

MA.... a noi interessa di più sapere:

«Se il test risulta positivo, qual è la probabilità che io sia malato?»



Accuratezza

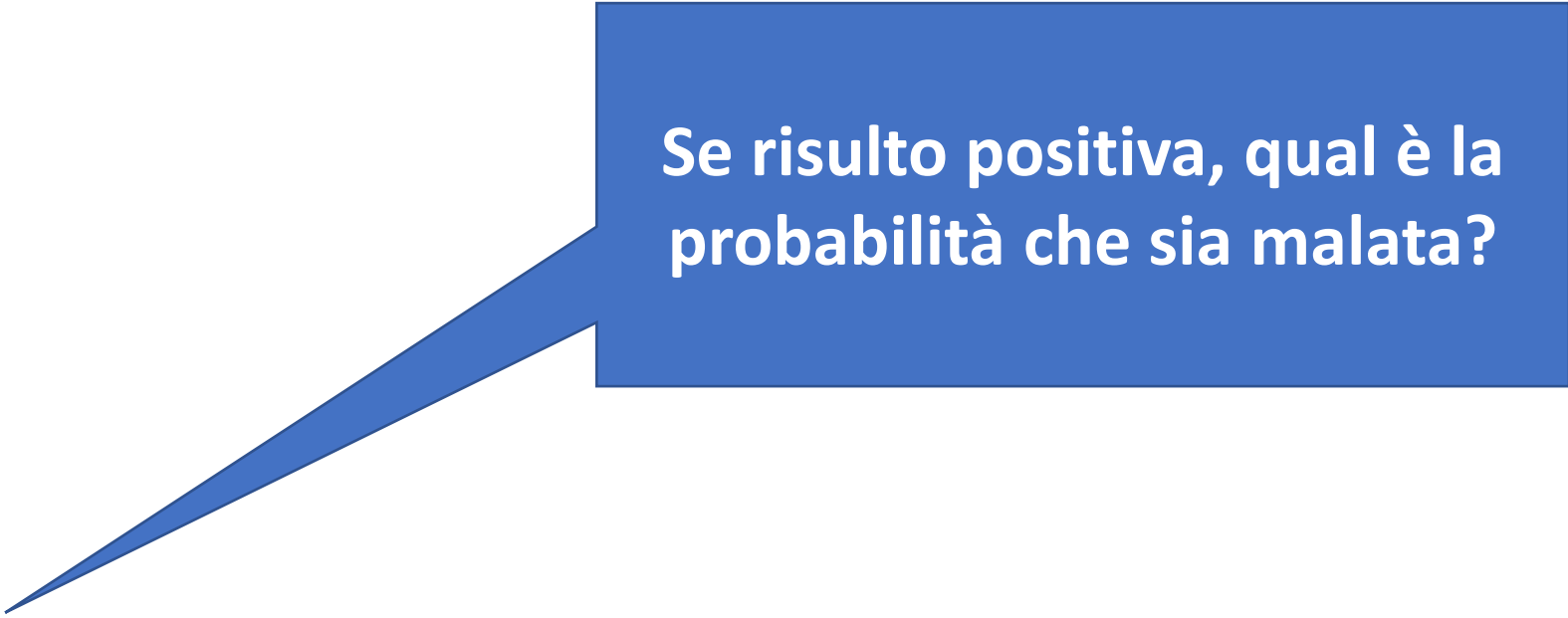
Utilità Clinica



Studi su test diagnostici

VALORE PREDITTIVO POSITIVO

La probabilità che una persona con un test positivo abbia la malattia.

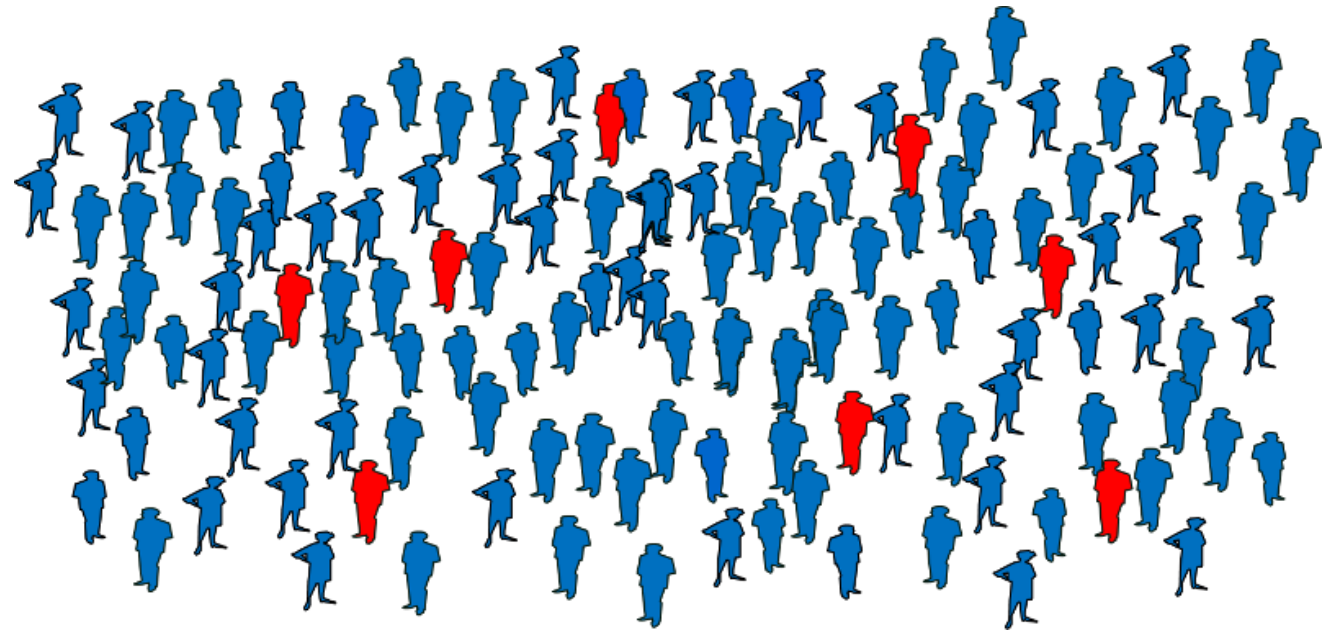


Se risultato positiva, qual è la probabilità che sia malata?

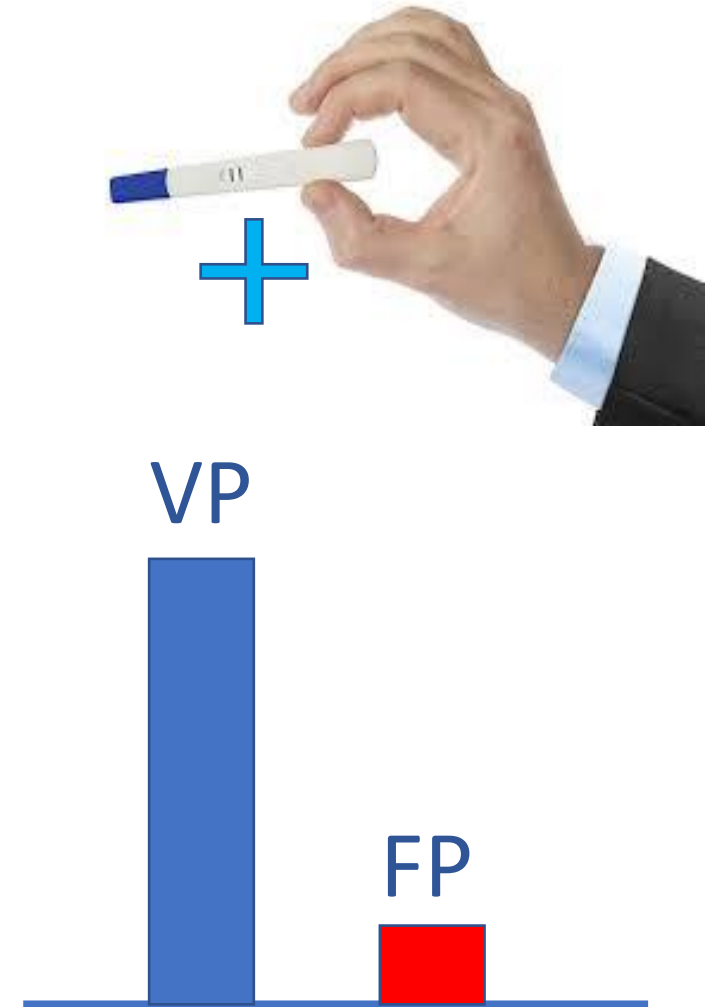
Problema...

I valori predittivi dipendono dalla prevalenza della malattia.

Prevalenza di malattia =
quanto è diffusa la malattia nella
popolazione



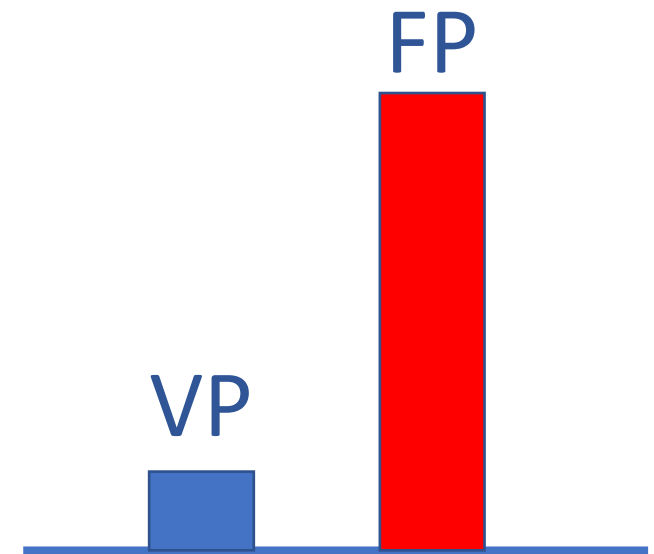
Ad esempio, il valore predittivo positivo aumenta all'aumentare della prevalenza di malattia...



... e diminuisce al diminuire della prevalenza di malattia



+



Accuratezza

Utilità Clinica



Studi su test diagnostici

“Alzheimer’s disease can be predicted with up to 99 per cent accuracy years before its onset using biomarkers found in spinal fluids, a study says”

“Our results make a strong case for clinical use of this diagnostic technology.”





"Let Us make living creatures out of mud, so the mud can see what We have done."

Man blinked. "What is the purpose of all this?" he asked politely.

"Everything must have a purpose?" asked God.

"Certainly," said man.

"Then I leave it to you to think of one for all this," said God.

And He went away."

Kurt Vonnegut-Cat's Cradle



Accuracy

≠

Clinical benefit



140 diagnostic test studies with accuracy & outcomes evaluation

The effect of testing on patients **outcome did not correlate with** the diagnostic **accuracy** of the test.



Accuracy

≠

Clinical benefit



Stress radionuclide myocardial perfusion imaging for the detection of coronary artery disease in asymptomatic diabetics

High accuracy

But

No reduction in incidence of cardiac death

Sigmoidoscopy for the detection of colon cancer

Medium accuracy

But

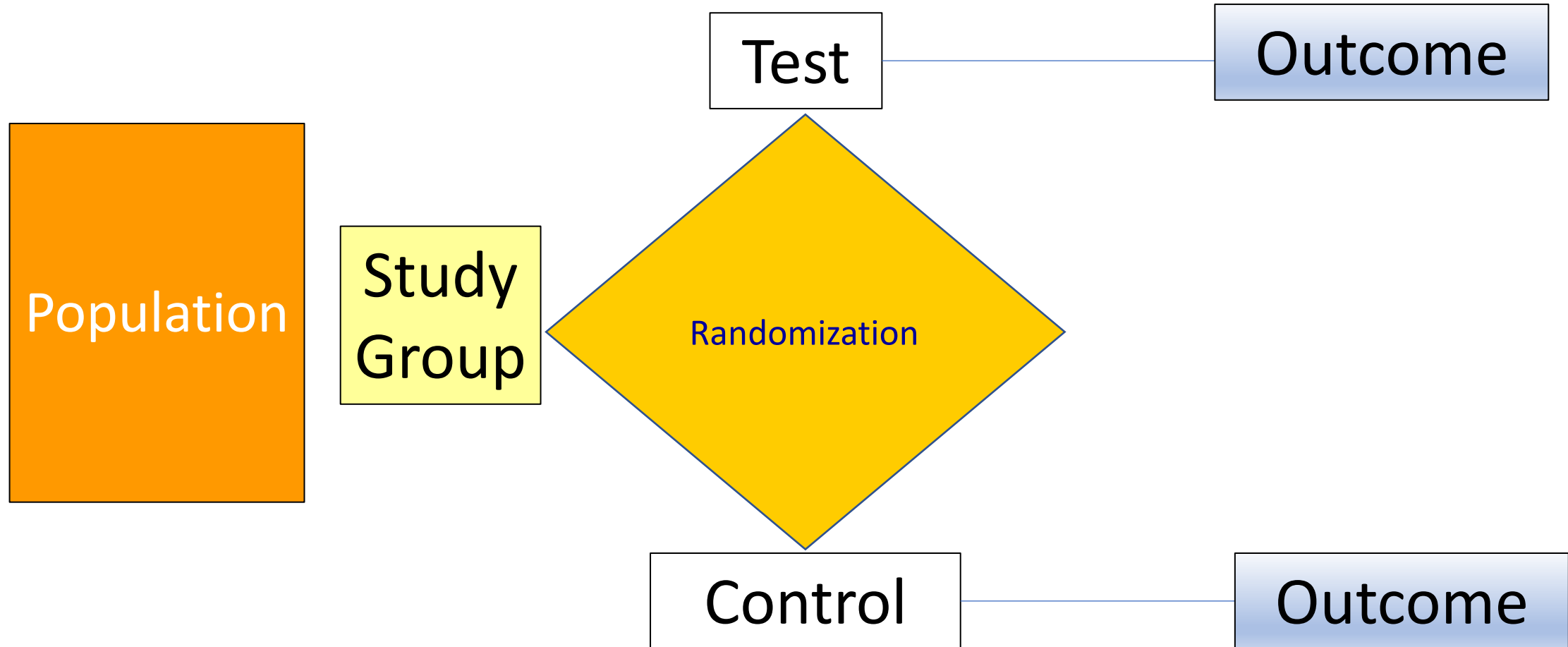
Was shown to significantly reduced colorectal cancer death in a trial.

Sometimes benefit is self evident...

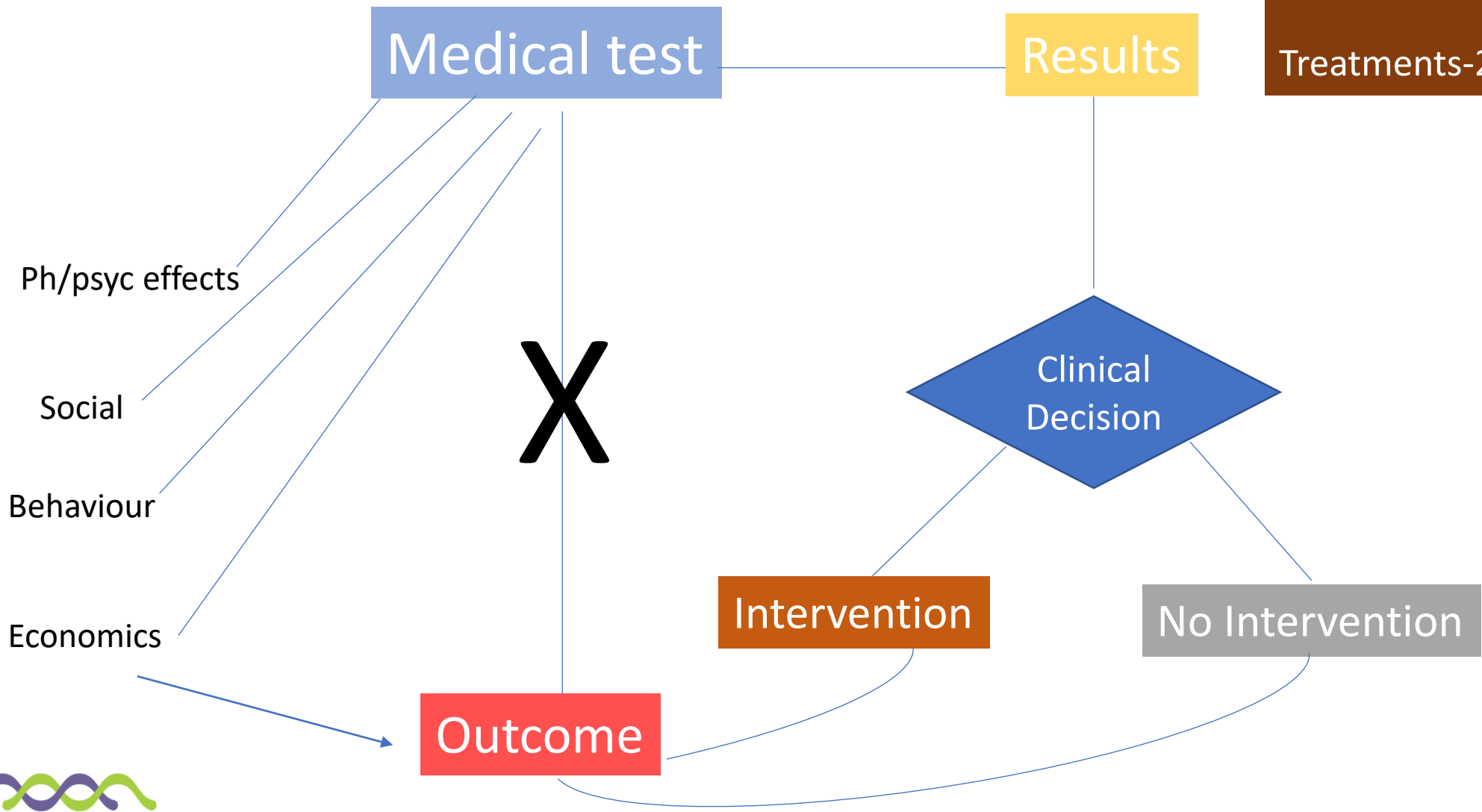
**Haemorrhagic shock- Blood group test-
transfusion-better life**



Randomized controlled trials of diagnostic tests



RCTs of diagnostic tests are rare
2021-2022: 437
Treatments-2021-2022: 47913



Health technology assessment of diagnostic tests: a state of the art review of methods guidance from international organizations

International Journal of Technology Assessment in Health Care, 2023



AHQR

CADTH

IQWiG

MSAC

NICE DAP

SBU

ZIN

Accuracy



QUADAS-2

No specific method

QUADAS-2

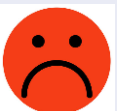
QUADAS-2, STARD

QUADAS-2, STARD

QUADAS-2

QUADAS-2

Outcome prioritization



yes

Not reported

Not reported

yes

No comprehensive approach

Not reported

yes

“There is often a **hiatus** in methods guidance between evaluating diagnostic accuracy and assessing the end clinical effectiveness of diagnostic interventions.»



E' accurato l'Apple watch per il rilievo delle aritmie cardiache?

Mi farà vivere meglio o più a lungo?

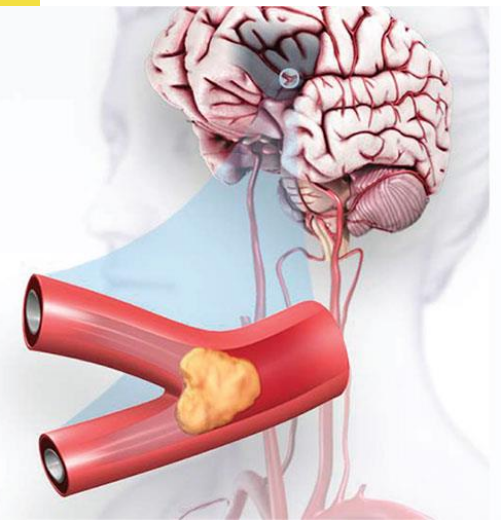
AF screening makes sense...



✓ AF increase the risk of stroke, especially in people aged 65 ys and above.

✓ We have anticoagulants

Apple watch can reveal AF in an early stage



Apple Watch segnala la Fibrillazione Atriale: Eugenio Finardi salvato in extremis dallo smartwatch



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Tech > Mobile

My Apple Watch saved my life: 5 people share their stories

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L'Apple Watch Series 8 ha già salvato la vita di una donna

Una donna aveva contattato il figlio dicendogli di sentirsi poco bene, un ECG effettuato con l'Apple Watch Series 8 le ha salvato la vita. È successo nel Regno Unito

DI [UMBERTO STENTELLA](#) 21–Set–2022 / 2:30 PM



Inc.

The Apple Watch Saved This Young Man's Life. Tim Cook's Response Is a Powerful Lesson If you're passionate about your

Apple Watch salva la vita di un trentaseienne

L'autore Adam Croft, 36 anni, di Flitwick nel Bedfordshire, si è svegliato scoprendo che il suo dispositivo Apple lo aveva avvisato per tutta la notte che il suo cuore era in fibrillazione atriale.



By Francesco Santagati — 13 Marzo 2023

0 Commenti

2 Mins Read

Condividi [f](#) [t](#)

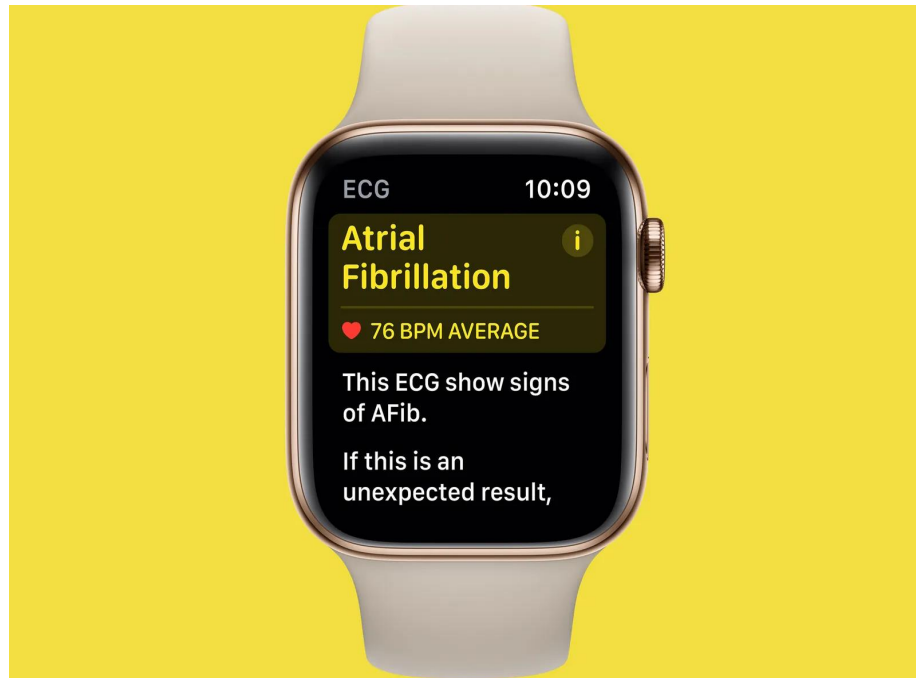
Advertising



Prevalence AF in general population: 2%

Specificity: 99%

False positive rate: $100 - 99 = 1\%$



1.000.000 people

20.000 with AF

980.000 without AF

1% of 980.000 = **9800 FP**

PPV 66%

An  a day **doesn't** keep the doctor away

Anticoagulants*

Life quality

Additional treatments

Additional tests

**9800
False Positives**

Social limitations

Physical effect

Psychological effects

* Absolute risk of 1 major bleeding: 1%/y, that is 98 people with unnecessary iatrogenic bleeding

Loop recorder

Randomization

Standard care

75-90Y without
AF & 1 risk
factor for stroke

Accuracy

3-fold more AF detection
and OAC in the screening group

Clinical outcomes

- ❖ No considerable difference in ischemic stroke
- ❖ Higher rate of major bleeding
- ❖ 3-fold more bradyarrhythmia notifications, more PM, same outcomes



Non sappiamo ancora se/quante fibrillazioni atriali sub cliniche (o digitali) necessitano di anticoagulanti

If God (standard) couldn't make it happen,
it will be difficult for an apple to succeed



STAT

FIRST OPINION

Beware the hype over the Apple Watch heart app. The device could do more harm than good