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If they had instead used a lower cutoff as indicated by the dashed vertical line, which of the following would most likely be seen?

- A. Higher number of false negatives (8%)
- B. Higher positive predictive value (9%)
- C. Higher sensitivity (66%)
- D. Lower number of false positives (5%)
- E. Lower number of true positives (9%)

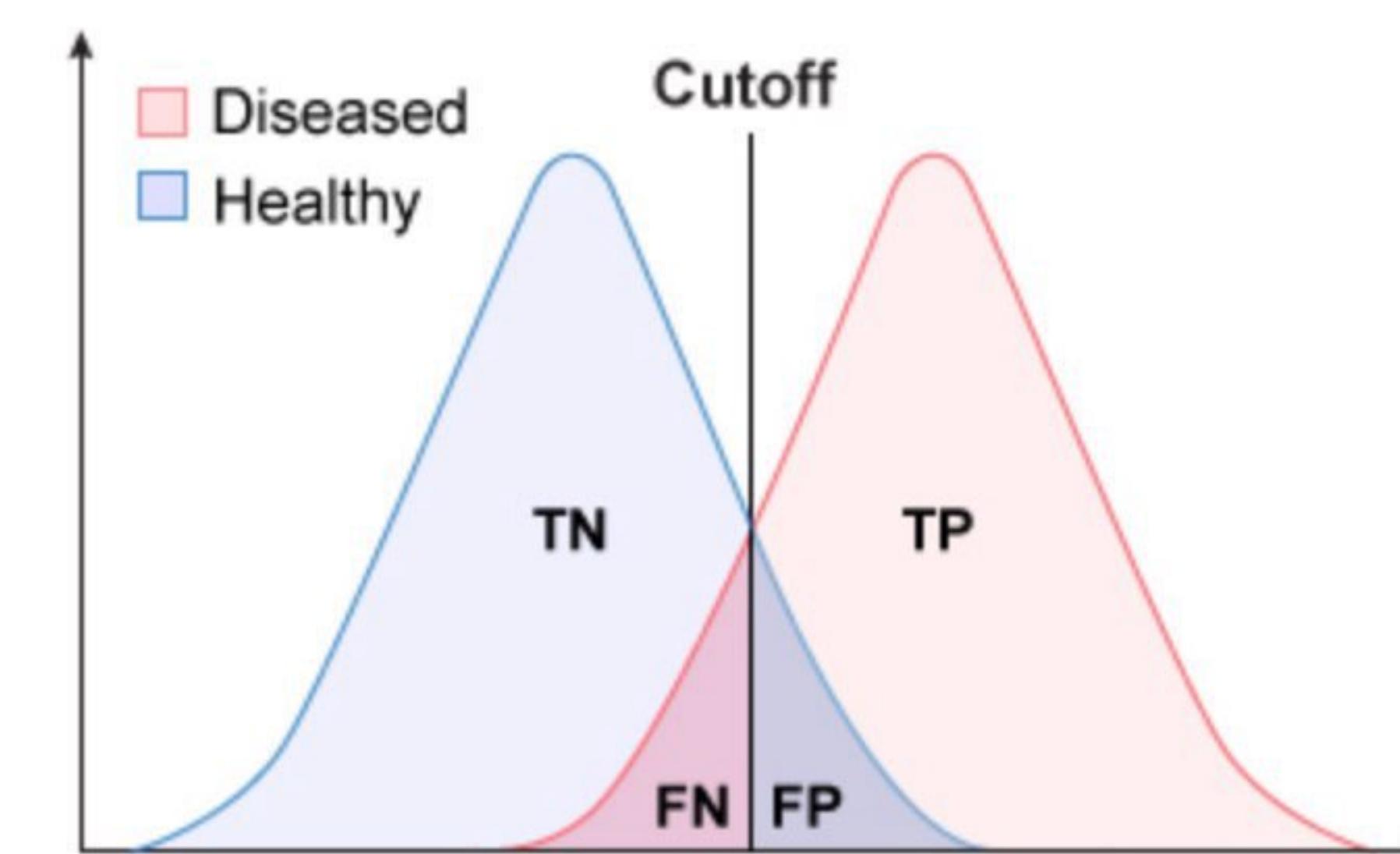
Omitted
Correct answer
C

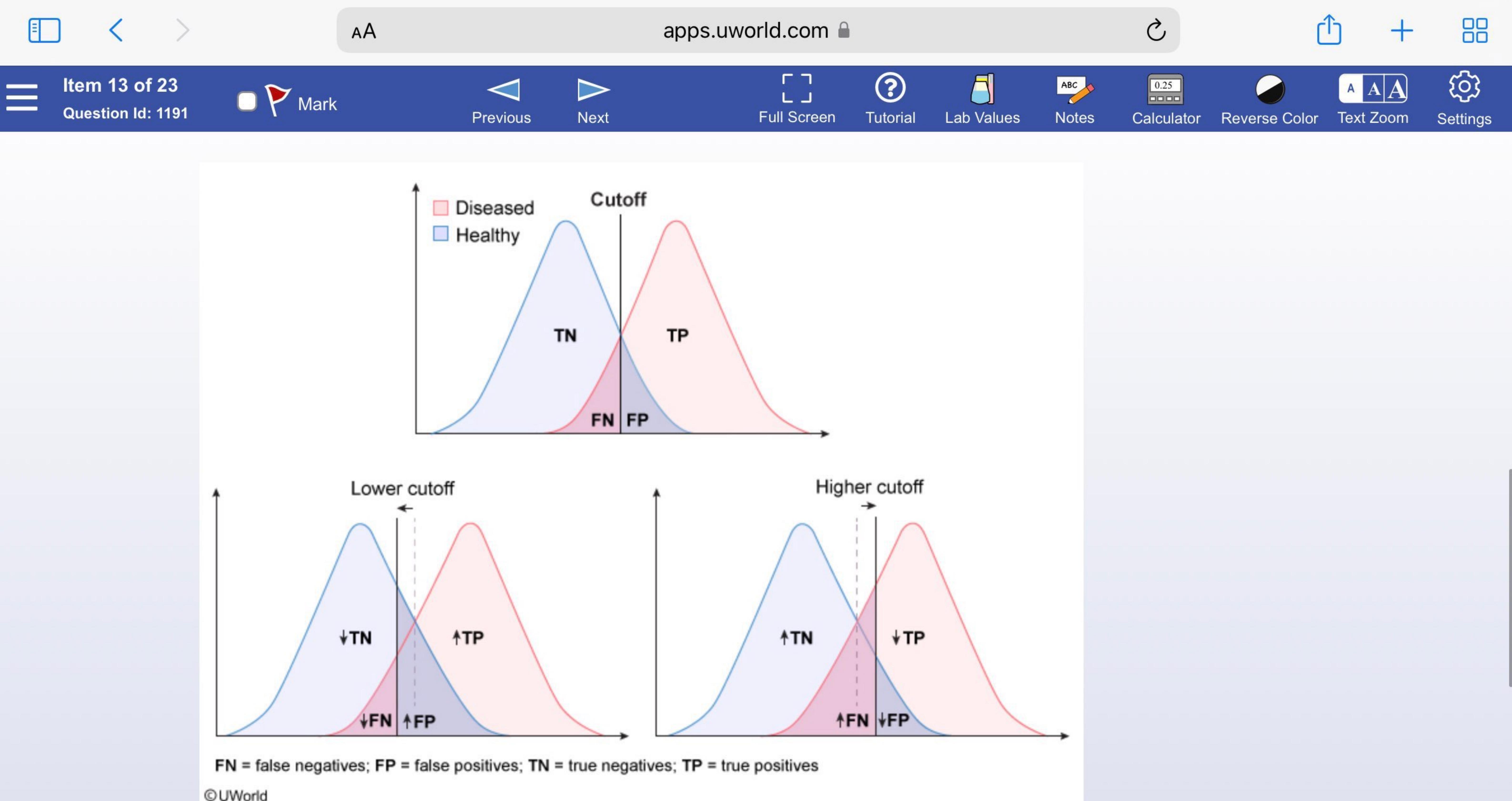
66%
Answered correctly

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Explanation





Important parameters of diagnostic tests include the following:

- True positives (TP) represent diseased individuals with positive test results.
- True negatives (TN) represent healthy individuals with negative test results.
- False positives (FP) represent healthy individuals with positive test results.
- False negatives (FN) represent diseased individuals with negative test results.

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Important parameters of diagnostic tests include the following:

- True positives (TP) represent diseased individuals with positive test results.
- True negatives (TN) represent healthy individuals with negative test results.
- False positives (FP) represent healthy individuals with positive test results.
- False negatives (FN) represent diseased individuals with negative test results.
- **Sensitivity** ($TP / [TP + FN]$) represents a test's ability to correctly identify diseased individuals from among all individuals. A test with high sensitivity has a low FN rate (important for screening purposes). With a highly sensitive test, most diseased patients will have a positive test result (and a **negative** test result would help rule **out** the disease [**SnNOut**]).
- **Specificity** ($TN / [TN + FP]$) represents the ability of a test to exclude those without the disease. A very specific test has a low FP rate (important for confirmatory tests). With a highly specific test, most healthy patients will have a negative test result (and a **positive** test result would help rule **in** the disease [**SpPIn**]).

The **cutoff value** of a quantitative diagnostic test determines whether a given result is interpreted as **positive or negative**. Depending on the disease or condition being tested for, sensitivity or specificity may be preferred and the cutoff value adjusted accordingly. A cutoff value just outside the overlapping region of the curves can maximize the sensitivity or specificity at 100% by correctly classifying all diseased or healthy individuals, respectively.

In the above example, changing the cutoff point to a **lower value** (shift to the left) would cause more patients with the disease to test positive ($\uparrow TP, \downarrow FN$), **increasing the sensitivity** of the test. However, as a consequence, more patients without the disease would also test positive ($\downarrow TN, \uparrow FP$), resulting in **decreased specificity**.

(Choices A, D, and E) Raising the cutoff value (shift to the right) would cause fewer individuals with the disease to have a positive test result ($\downarrow TP, \uparrow FN$), so sensitivity would decrease. Fewer individuals without the disease

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negative. Depending on the disease or condition being tested for, sensitivity or specificity may be preferred and the cutoff value adjusted accordingly. A cutoff value just outside the overlapping region of the curves can maximize the sensitivity or specificity at 100% by correctly classifying all diseased or healthy individuals, respectively.

In the above example, changing the cutoff point to a **lower value** (shift to the left) would cause more patients with the disease to test positive ($\uparrow TP, \downarrow FN$), **increasing the sensitivity** of the test. However, as a consequence, more patients without the disease would also test positive ($\downarrow TN, \uparrow FP$), resulting in **decreased specificity**.

(Choices A, D, and E) Raising the cutoff value (shift to the right) would cause fewer individuals with the disease to have a positive test result ($\downarrow TP, \uparrow FN$), so sensitivity would decrease. Fewer individuals without the disease would also test positive ($\uparrow TN, \downarrow FP$), so specificity would increase.

(Choice B) Positive predictive value ($PPV = TP / [TP + FP]$) represents the probability that a patient with a positive test result actually has the disease. In this case, the lower cutoff value would increase both TP and FP; how this affects the PPV depends on **disease prevalence**, which is not provided. In a population with very low disease prevalence, the number of FP would be expected to increase proportionately more than the number of TP, which would lower the PPV.

Educational objective:

The cutoff value of a quantitative diagnostic test determines whether a given result is interpreted as positive or negative. Lowering the cutoff point typically causes more patients with the disease to test positive, decreasing the number of false negatives and increasing test sensitivity. Consequently, more patients without the disease will also test positive, resulting in an increased number of false positives and decreased specificity.

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A study was conducted to assess the age at menarche among young female gymnasts. Based on commitment to the sport, gymnasts were divided into two groups: competitive gymnasts and recreational gymnasts.

Age at menarche

	Sample size (n)	Mean, y	Standard deviation, y
Competitive	16	13.4	1.3
Recreational	22	12.3	0.8

Assuming that age at menarche is normally distributed, which of the following is closest to the probability that a randomly chosen competitive gymnast will have onset of menarche at age ≥ 16 ?

- A. 0.997 (3%)
- B. 0.950 (7%)
- C. 0.680 (3%)
- D. 0.160 (4%)
- E. 0.025 (72%)
- F. 0.0015 (9%)

Omitted

Correct answer

E



72%

Answered correctly



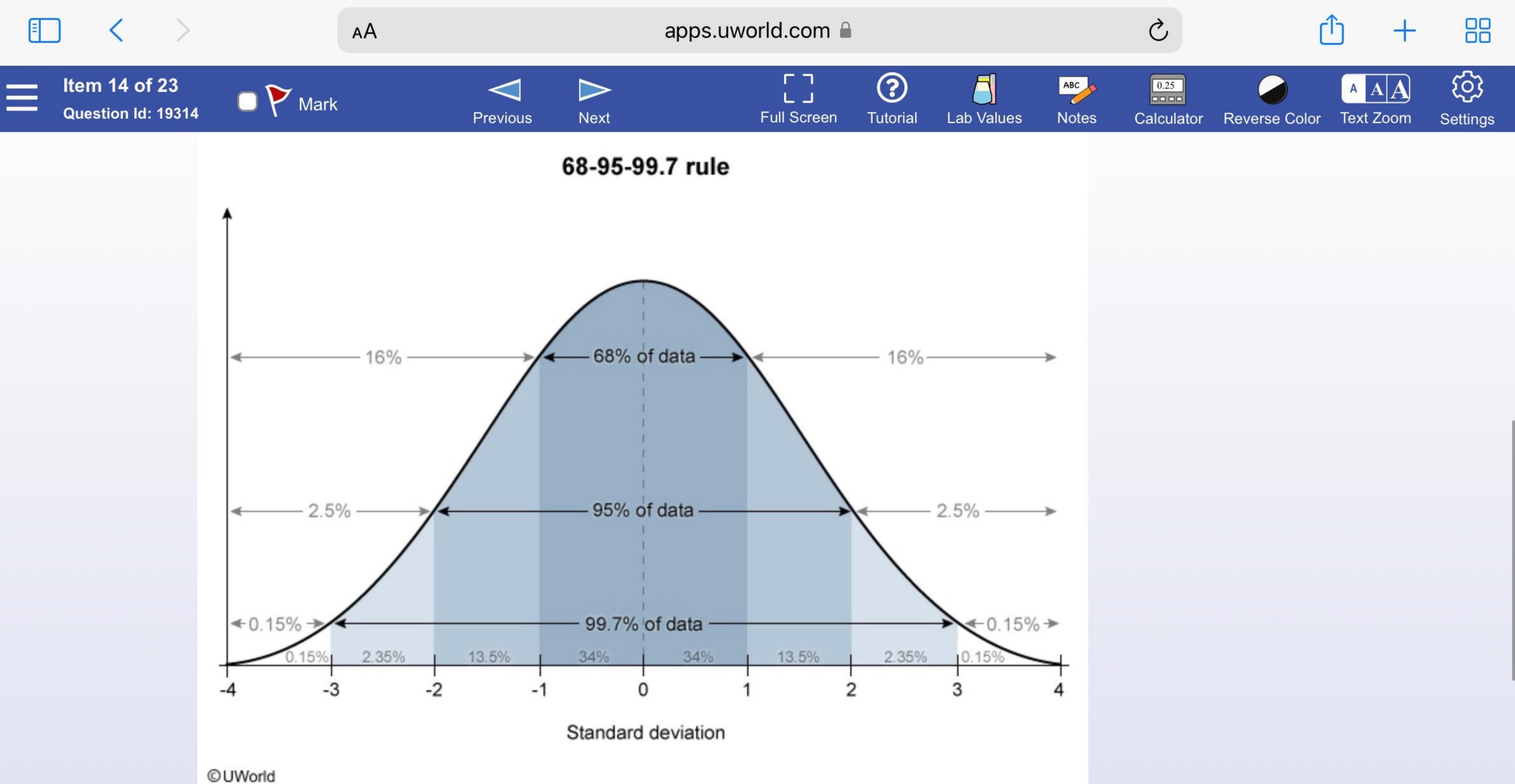
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A normal (Gaussian) distribution is a symmetrical, bell-shaped distribution with a fixed percentage of observations lying within a certain distance of the mean. This distance is called the standard deviation (SD) and represents the degree of dispersion from the mean. The **68-95-99.7** rule for normal distributions states that 68% of all observations lie within 1 SD of the mean, 95% of all observations lie within 2 SDs of the mean, and 99.7% of all observations lie within 3 SDs of the mean.

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For competitive gymnasts in this sample, the **mean age at menarche is 13.4 years**, with a **SD of 1.3 years**.

Based on the 68-95-99.7 rule:

- 68% of observations lie within 1 SD: $13.4 \pm 1.3 = 12.1-14.7$.
- **95% of observations lie within 2 SDs: $13.4 \pm 2.6 = 10.8-16.0$.**
- 99.7% of observations lie within 3 SDs: $13.4 \pm 3.9 = 9.5-17.3$.

An onset of menarche at **age ≥ 16 years is 2 SDs** from the mean; therefore, **2.5%** of the observations must lie **above 16 years** (with 2.5% of observations below 10.8 years). The probability that a random competitive gymnast will have an onset of menarche at age ≥ 16 years is 0.025.

(Choices A, B, and C) The 68-95-99.7 rule states that 99.7% of observations lie within 3 SDs; therefore, 0.997 is the probability that a random competitive gymnast will have an onset of menarche between age 9.5 and 17.3 years. Similarly, 0.95 is the probability that a random competitive gymnast will have an onset of menarche between age 10.8 and 16.0 years (ie, within ± 2 SDs from the mean), and 0.68 is the probability that a random competitive gymnast will have an onset of menarche between age 12.1 and 14.7 years (ie, within ± 1 SD from the mean).

(Choices D and F) Based on the 68-95-99.7 rule, 32% (ie, $100\% - 68\%$) of observations lie outside 1 SD from the mean, with half (ie, $32/2 = 16\%$) above and half (16%) below 1 SD from the mean. Therefore, 0.160 is the probability that a random competitive gymnast will have an onset of menarche at either age ≤ 12.1 years (ie, ≥ 1 SD below the mean) or at age ≥ 14.7 years (ie, ≥ 1 SD above the mean). Similarly, 0.0015 is the probability that a random competitive gymnast will have an onset of menarche at either age ≤ 9.5 years (ie, ≥ 3 SDs below the mean) or at age ≥ 17.3 years (ie, ≥ 3 SDs above the mean).

Educational objective:

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An onset of menarche at **age ≥ 16 years is 2 SDs** from the mean; therefore, **2.5%** of the observations must lie **above 16 years** (with 2.5% of observations below 10.8 years). The probability that a random competitive gymnast will have an onset of menarche at age ≥ 16 years is 0.025.

(Choices A, B, and C) The 68-95-99.7 rule states that 99.7% of observations lie within 3 SDs; therefore, 0.997 is the probability that a random competitive gymnast will have an onset of menarche between age 9.5 and 17.3 years. Similarly, 0.95 is the probability that a random competitive gymnast will have an onset of menarche between age 10.8 and 16.0 years (ie, within ± 2 SDs from the mean), and 0.68 is the probability that a random competitive gymnast will have an onset of menarche between age 12.1 and 14.7 years (ie, within ± 1 SD from the mean).

(Choices D and F) Based on the 68-95-99.7 rule, 32% (ie, $100\% - 68\%$) of observations lie outside 1 SD from the mean, with half (ie, $32/2 = 16\%$) above and half (16%) below 1 SD from the mean. Therefore, 0.160 is the probability that a random competitive gymnast will have an onset of menarche at either age ≤ 12.1 years (ie, ≥ 1 SD below the mean) or at age ≥ 14.7 years (ie, ≥ 1 SD above the mean). Similarly, 0.0015 is the probability that a random competitive gymnast will have an onset of menarche at either age ≤ 9.5 years (ie, ≥ 3 SDs below the mean) or at age ≥ 17.3 years (ie, ≥ 3 SDs above the mean).

Educational objective:

In a normal (bell-shaped) distribution, 68% of all values are within 1 standard deviation (SD) of the mean; 95% are within 2 SDs of the mean; and 99.7% are within 3 SDs of the mean.

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Carbamoyl phosphate synthetase I deficiency is an inherited disorder characterized by accumulation of ammonia in the blood. The most severe form occurs in the first 24-72 hours following birth, after feeding begins and milk proteins start to be broken down in the liver. If left untreated, affected neonates often die due to severe metabolic derangements; survivors often develop permanent neurologic injury. The estimated incidence of carbamoyl phosphate synthetase I deficiency is about 1 in 800,000 newborns. If a decision is made to test all newborns for this disease, then this initial test should be designed to have a high:

- A. Cutoff value (0%)
- B. Number of true negatives (2%)
- C. Positive predictive value (7%)
- D. Sensitivity (77%)
- E. Specificity (12%)

Omitted
Correct answer
D

 77%
Answered correctly

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Time Spent

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Explanation

Carbamoyl phosphate synthetase I deficiency is a rare disorder (incidence 1 in 800,000 newborns) with serious and possible irreversible consequences if not detected and treated early. Therefore, it is important to identify all individuals who potentially have the disease using a **screening test** that can be performed on a large number of

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Carbamoyl phosphate synthetase I deficiency is a rare disorder (incidence 1 in 800,000 newborns) with serious and possible irreversible consequences if not detected and treated early. Therefore, it is important to identify all individuals who potentially have the disease using a **screening test** that can be performed on a large number of newborns.

Although an ideal screening test would be highly sensitive and specific, developing a test that has both of these properties is often not possible, and so a compromise must be made. The sensitivity of a test refers to its ability to correctly identify those with the disease: it is the probability of the test returning a positive result in a person with the disease. A **highly sensitive test** will ensure that most patients with the disease will have a positive test result (leading to few false negative results); therefore, **fewer cases of disease are missed**. Given a test with high sensitivity, a negative result would help to rule out a diagnosis (SnNout). This is important during screening for **life-threatening diseases**, even if obtaining a high sensitivity causes an increased numbers of false positives (ie, reduced specificity).

(Choice A) Setting a high cutoff value typically (but not always) produces higher specificity and lower sensitivity.

(Choices B and E) Specificity represents the ability of a test to correctly identify those without the disease. A very specific test has a low rate of false positives, so most healthy patients will have a negative test result (true negative). Given a test with high specificity, a positive result would help to rule in a diagnosis (SpPin).

Confirmatory tests with high specificity are often used on patients who test positive on a screening test to ensure that a patient actually has the disease.

(Choice C) Positive predictive value refers to the probability that a disease is present given a positive test result. Positive predictive value depends on disease prevalence. When screening patients for a rare disorder, positive predictive value will often be low due to a high number of false positives.

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Although an ideal screening test would be highly sensitive and specific, developing a test that has both of these properties is often not possible, and so a compromise must be made. The sensitivity of a test refers to its ability to correctly identify those with the disease: it is the probability of the test returning a positive result in a person with the disease. A **highly sensitive test** will ensure that most patients with the disease will have a positive test result (leading to few false negative results); therefore, **fewer cases of disease are missed**. Given a test with high sensitivity, a negative result would help to rule out a diagnosis (SnNout). This is important during screening for **life-threatening diseases**, even if obtaining a high sensitivity causes an increased numbers of false positives (ie, reduced specificity).

(Choice A) Setting a high cutoff value typically (but not always) produces higher specificity and lower sensitivity.

(Choices B and E) Specificity represents the ability of a test to correctly identify those without the disease. A very specific test has a low rate of false positives, so most healthy patients will have a negative test result (true negative). Given a test with high specificity, a positive result would help to rule in a diagnosis (SpPin).

Confirmatory tests with high specificity are often used on patients who test positive on a screening test to ensure that a patient actually has the disease.

(Choice C) Positive predictive value refers to the probability that a disease is present given a positive test result. Positive predictive value depends on disease prevalence. When screening patients for a rare disorder, positive predictive value will often be low due to a high number of false positives.

Educational objective:

The sensitivity of a test refers to its ability to correctly identify those with the disease. A highly sensitive test should always be considered over a highly specific test when screening for life-threatening diseases, where identification of every person with the disease is important.

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A research laboratory is evaluating a new dipstick test for diagnosing urinary tract infections (UTIs). The new test is compared to urinalysis of a midstream urine specimen (considered the diagnostic gold standard) to establish diagnostic test parameters. The study enrolls 300 patients, of which 100 have a UTI as determined by urinalysis. The new dipstick test is determined to be 70% sensitive and 90% specific for the diagnosis of UTIs. How many false positives are present in the study?

- A. 20 (63%)
- B. 30 (25%)
- C. 70 (4%)
- D. 120 (2%)
- E. 180 (3%)

Omitted
Correct answer
A

63%
Answered correctly

03 secs
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Explanation

	Disease positive	Disease negative	
Test	a	b	$a + b$

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	Disease positive	Disease negative	
Test positive	a True positive	b False positive	a + b
Test negative	c False negative	d True negative	c + d
	a + c	b + d	

Sensitivity = $a/(a + c)$; Specificity = $d/(b + d)$

False positives describe people who **test positive** for a disease but **do not actually have it**.

The number of false positives can be calculated using the test's specificity and total number of patients without urinary tract infections (UTIs). The **specificity** of a test refers to the number of true negatives (d) divided by the total number of patients without the disease (b + d). In this case, the specificity is 90% (ie, 0.9) and the total number of patients without UTIs (b + d) equals $300 - 100 = 200$. Using this information, the number of **true negatives** (d) can be calculated:

$$\text{Specificity} = d/(b + d)$$

$$0.9 = d/200$$

$$d = 180$$

The total number of patients without the disease (b + d) equals 200, and the number of true negatives (d) equals 180. Using this information, the number of false positives (b) can be calculated:

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The total number of patients without the disease ($b + d$) equals 200, and the number of true negatives (d) equals 180. Using this information, the number of false positives (b) can be calculated:

$$\text{False positives} = (b + d) - d = 200 - 180 = 20$$

For the sake of thoroughness, the 2×2 table can be completed as follows. **Sensitivity** refers to the number of true positives (a) divided by all people with the disease ($a + c$). Repeating the same exercise as above gives the completed table:

$$\text{Sensitivity} = a/(a + c)$$

$$0.7 = a/100$$

$$a = 70$$

$$c = (a + c) - a = 100 - 70 = 30$$

	+ UTI	- UTI	
Test positive	70	20	90
Test negative	30	180	210
	100	200	

The number of true negatives and false positives can be more quickly calculated using the following equations:

$$\text{True negatives} = (\text{Specificity}) * (\text{Number of patients confirmed without the disease})$$

$$\text{False positives} = (1 - \text{Specificity}) * (\text{Number of patients confirmed without the disease})$$

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$$0.7 = a/100$$

$$a = 70$$

$$c = (a + c) - a = 100 - 70 = 30$$

	+ UTI	- UTI	
Test positive	70	20	90
Test negative	30	180	210
	100	200	

The number of true negatives and false positives can be more quickly calculated using the following equations:

True negatives = (Specificity) * (Number of patients confirmed without the disease)

False positives = (1 – Specificity) * (Number of patients confirmed without the disease)

Educational objective:

Specificity is the number of true negatives divided by the total number of subjects confirmed as not having the disease.

True negatives = (Specificity) * (Number of patients confirmed without the disease)

False positives = (1 – Specificity) * (Number of patients confirmed without the disease)

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A study is conducted examining the effect of a low-carbohydrate diet compared to a low-fat diet on body weight. Researchers enroll 150 overweight but otherwise healthy adults from a large city in the study and randomly assign them in a 1:1 ratio to either the low-carbohydrate (40 g/d) or the low-fat (<7% saturated fat) diet. At 12 months, a greater body weight change was reported in the low-carbohydrate diet group compared to the low-fat diet group, with a mean difference in body weight change of -3.5 kg ($p = 0.01$, predetermined significance level = 0.05). Which of the following is the most accurate interpretation of the results of this study?

- A. The observed mean difference in body weight change of -3.5 kg is not statistically significant (3%)
- B. The probability of observing a mean difference in body weight change of -3.5 kg is 0.01 (5%)
- C. There is a 1% chance of observing a mean difference in body weight change of at least -3.5 kg when no difference between groups is assumed (57%)
- D. There is a 1% chance that an adult on a low-carbohydrate diet will have a body weight change of at least -3.5 kg at 12 months after starting the diet (9%)
- E. There is a 1% chance that the mean difference in body weight change is biased in favor of the low-carbohydrate diet group (24%)

Omitted
Correct answer
C

57%
Answered correctly

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Explanation

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Statistical tests contrast a null hypothesis (H_0) and an alternative hypothesis (H_a), in this case:

- H_0 is a claim of **no difference** between populations (eg, no difference in mean body weight between the low-carbohydrate population and the low-fat population).
- H_a is a claim of a **difference** between populations (eg, difference in mean body weight between the 2 populations).

Statistical inference uses data from **samples** (eg, 75 adults in the low-carbohydrate sample, 75 adults in the low-fat sample) to draw conclusions about underlying **populations**. Sample estimates or differences (eg, sample mean, difference in mean between 2 samples) generally vary with distinct samples (eg, if a different sample of 75 adults was chosen for each group) and may be close but not equal to the underlying population value.

One way to account for **sampling variation** is to calculate the **p-value**, which is the **probability of obtaining a sample value at least as large as the one observed** when the population value claimed in H_0 is assumed to be true. The magnitude of the p-value compared to a predetermined significance level (eg, 0.05 [or 5%] commonly used as the threshold) determines whether there is convincing evidence against H_0 .

- A low p-value (eg, <0.05) occurs when the sample value significantly disagrees with the population value claimed in H_0 and provides convincing evidence against H_0 (ie, H_0 is probably wrong). Results are considered statistically significant.
- A high p-value (eg, ≥ 0.05) occurs when the sample value is close to the population value claimed in H_0 and provides convincing evidence in favor of H_0 (ie, H_0 might be correct). Results are considered not statistically significant.

In this case, the given **p-value = 0.01**; therefore, there is a **1% chance** (ie, 0.01) of observing a mean difference

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be true. The magnitude of the *p*-value compared to a predetermined significance level (eg, 0.05 [or 5%] commonly used as the threshold) determines whether there is convincing evidence against H_0 .

- A low *p*-value (eg, <0.05) occurs when the sample value significantly disagrees with the population value claimed in H_0 and provides convincing evidence against H_0 (ie, H_0 is probably wrong). Results are considered statistically significant.
- A high *p*-value (eg, ≥ 0.05) occurs when the sample value is close to the population value claimed in H_0 and provides convincing evidence in favor of H_0 (ie, H_0 might be correct). Results are considered not statistically significant.

In this case, the given ***p*-value = 0.01**; therefore, there is a **1% chance** (ie, 0.01) of observing a mean difference in body weight change (ie, sample estimate) of **at least –3.5 kg** between the low-fat and the low-carbohydrate samples when **no difference between the populations is assumed** (ie, H_0 is assumed to be true) (**Choice B**).

(Choices A, D, and E) The *p*-value of 0.01 is less than 0.05; therefore, the observed mean difference is statistically significant at the 5% level. The *p*-value is not associated with individual observations in a sample. It accounts for sampling variation (ie, random variation) not bias (ie, systematic variation).

Educational objective:

The *p*-value is the probability of obtaining a result (ie, sample estimate) at least as large as the one observed when the population value claimed in the null hypothesis is assumed to be true. A *p*-value <0.05 typically indicates that results are statistically significant.

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Researchers want to study the effects of labyrinthectomy with cochlear implantation on hearing, vertigo, and tinnitus. A random sample of medical charts is selected from a cohort of patients who had undergone labyrinthectomy with cochlear implantation in the same ear for intractable vertigo and hearing loss and who had documentation of both preoperative and postoperative audiotmetric evaluations. Tinnitus is quantified using the Tinnitus Handicap Inventory (THI) before and after the interventions. The THI score ranges from 0 to 100, with higher values indicating greater tinnitus severity. Which of the following statistical tests is most appropriate for comparing preoperative and postoperative THI scores?

- A. Analysis of variance (4%)
- B. Chi-square test (11%)
- C. Correlation analysis (13%)
- D. Meta-analysis (1%)
- E. Paired *t*-test (69%)

Omitted
Correct answer
E

 69%
Answered correctly

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Explanation

Dependent variable

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		Dependent variable	
		Qualitative (categorical)	Quantitative
Independent variable	Qualitative (categorical)	Chi-square, logistic regression*	t test, ANOVA, linear regression
	Quantitative	Logistic regression*	Correlation, linear regression

*Dependent variable must be dichotomous.

ANOVA = analysis of variance.

Variables are broadly classified as qualitative (ie, categorical) or quantitative (ie, continuous) based on their scale of measurement. **Qualitative variables** (eg, type of treatment, blood type) represent categories or groups, whereas **quantitative variables** (eg, temperature, glucose levels) represent numerical values. The scale of measurement of the dependent (eg, outcome) and independent (eg, exposures, risk factors) variables in a study determines the correct statistical test for any given situation.

A **t-test** compares the **mean of 2 groups**. It requires that a quantitative dependent variable (ie, outcome) be evaluated in 2 groups that are classified based upon a categorical independent variable (ie, exposure).

In this study:

- The quantitative dependent variable was the **Tinnitus Handicap Inventory (THI) score**.
- The categorical independent variable was the **audiometric evaluation** (with categories "preoperative" and "postoperative").

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A *t*-test will determine whether there is a statistically significant difference in mean THI scores between the preoperative and postoperative audiometric evaluations. A large, statistically significant difference in mean scores indicates that labyrinthectomy with cochlear implantation is associated with changes in tinnitus (ie, the null hypothesis is rejected).

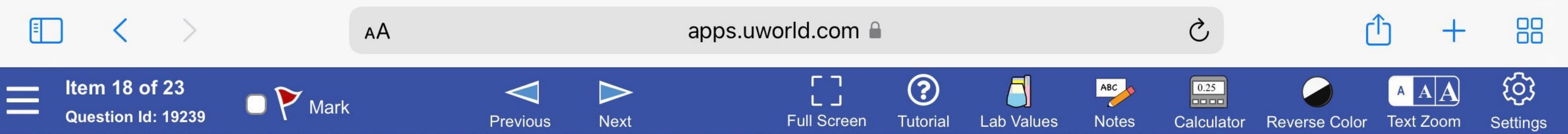
There are 2 types of *t*-tests: the independent samples *t*-test (used when 2 groups are independent) and the **paired *t*-test** (used with 2 related groups with matched pairs). Matched groups are formed when each observation in one group is paired with an observation from the other group. Examples include a study in which individuals have been assessed twice (eg, before and after an intervention) and one in which 2 groups of individuals have been matched based on certain attributes (eg, age, severity of disease). In this case, THI scores are assessed twice for each patient (preoperative and postoperative audiometric evaluations); therefore, a paired *t*-test is used.

(Choice A) The analysis of variance (ANOVA) test compares the mean of ≥ 3 independent groups, as in a study comparing serum ferritin concentrations (ie, quantitative variable) in children (age 0-17), adults (age 18-59), and seniors (age ≥ 60).

(Choice B) The chi-square test evaluates the association between 2 categorical variables, as in a study evaluating the association between sex (ie, "male" and "female") and myocardial infarction (ie, presence or absence).

(Choice C) A correlation analysis uses the [correlation coefficient](#) to describe the linear relationship between 2 quantitative variables, as in a study evaluating the [linear relationship](#) between hours of sleep and irritability score.

(Choice D) Meta-analysis is a statistical technique used to combine and analyze data from several studies to conduct an analysis with a greater statistical power than that of the individual studies.



Individuals have been matched based on certain attributes (eg, age, severity of disease). In this case, THI scores are assessed twice for each patient (preoperative and postoperative audiotmetric evaluations); therefore, a paired *t*-test is used.

(Choice A) The analysis of variance (ANOVA) test compares the mean of ≥ 3 independent groups, as in a study comparing serum ferritin concentrations (ie, quantitative variable) in children (age 0-17), adults (age 18-59), and seniors (age ≥ 60).

(Choice B) The chi-square test evaluates the association between 2 categorical variables, as in a study evaluating the association between sex (ie, "male" and "female") and myocardial infarction (ie, presence or absence).

(Choice C) A correlation analysis uses the [correlation coefficient](#) to describe the linear relationship between 2 quantitative variables, as in a study evaluating the [linear relationship](#) between hours of sleep and irritability score.

(Choice D) Meta-analysis is a statistical technique used to combine and analyze data from several studies to conduct an analysis with a greater statistical power than that of the individual studies.

Educational objective:

The paired *t*-test compares the mean of 2 related groups. The test requires that a quantitative dependent variable (ie, outcome) be evaluated in 2 related (ie, matched, paired) groups.

References

- [The differences and similarities between two-sample *t*-test and paired *t*-test.](#)

Biostatistics

Subject

Biostatistics & Epidemiology

System

Statistical tests

Topic

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An 89-year-old man is brought to a geriatric clinic by family members who are concerned that he is developing dementia due to recent worsening of his memory. The attending physician uses a new cognitive test (test X) to help rule out the possibility of dementia. The patient's test result is negative. A study evaluating the efficacy of test X in a sample of 200 individuals age ≥ 85 , in which the prevalence of dementia is 50%, has determined that the test has a specificity of 80% and a sensitivity of 90%. Assuming that this patient's pretest probability of having dementia is equivalent to the disease prevalence in the study population, what is the probability that this patient truly does not have dementia?

- A. 18% (4%)
- B. 53% (4%)
- C. 66% (8%)
- D. 82% (25%)
- E. 89% (56%)

Omitted
Correct answer
E

56%
Answered correctly

02 secs
Time Spent

2023
Version

Explanation

The **negative predictive value (NPV)** of a diagnostic test is the probability that a patient truly **does not have the disease** when the patient receives a **negative test result**. It can be calculated from study data as follows:

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The **negative predictive value** (NPV) of a diagnostic test is the probability that a patient truly **does not have the disease** when the patient receives a **negative test** result. It can be calculated from study data as follows:

$$\text{NPV} = \frac{\text{number of true negatives}}{\text{total number of negative tests}}$$

To determine the NPV in this case, it helps to summarize the results of the efficacy study in a 2×2 table. The study evaluated 200 individuals in a population with a 50% prevalence of dementia (ie, 100 patients had dementia while 100 did not). Knowing that specificity (ie, true negatives/total disease negatives) and sensitivity (ie, true positives/total disease positives) are 80% and 90%, respectively, the following 2×2 table can be created:

Standard 2×2 contingency table

		Disease present	Disease absent	
Test positive	Disease present	a (true positive)	b (false positive)	a + b
	Disease absent	c (false negative)	d (true negative)	c + d
a + c	b + d			

Test X

		Dementia present	Dementia absent	
Test X positive	Dementia present	90	20	110
	Dementia absent	10	80	90
100	100			

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The NPV can now be estimated as follows:

$$\text{NPV} = \frac{\text{number of true negatives (d)}}{\text{total number of negative tests (c + d)}}$$

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a + c	b + d
100	100

The NPV can now be estimated as follows:

$$\text{NPV} = \text{number of true negatives (d)} / \text{total number of negative tests (c + d)}$$

$$\text{NPV} = d / (c + d) = 80 / (10 + 80) = 0.889 = \sim 89\%$$

Unlike sensitivity and specificity, positive and negative predictive values vary based on the prevalence of the disease. In fact, the NPV is inversely proportional to the prevalence of a disease (eg, NPV ↓ as disease prevalence ↑). For the NPV to be applicable to an individual patient, that patient's **pretest probability** (eg, probability of having the disease before testing) must be **similar** to the **prevalence of disease** in the population where the study was conducted. The question says to assume that the patient's pretest probability is equivalent to the disease prevalence in the study population, so the NPV calculated in the study is generalizable to this patient.

Educational objective:

Negative predictive value (NPV) represents the probability of not having a disease given a negative test result. NPV is inversely proportional to the prevalence of a disease. When a patient has characteristics similar to the overall population (eg, age, sex, risk factor status), the disease prevalence is a valid estimate of the pretest probability of disease.

Biostatistics
Subject

Biostatistics & Epidemiology
System

Sensitivity, specificity, NPV, PPV
Topic

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Item 20 of 23 Question Id: 1192

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A new serologic test has been developed for the detection of active pulmonary tuberculosis and is compared to the gold standard of sputum mycobacterial culture. A total of 1000 subjects are randomly selected for testing from a population with a high prevalence of tuberculosis. Results of the study are given below:

	Sputum culture positive	Sputum culture negative	
Serologic test positive	130	60	190
Serologic test negative	50	760	810
	180	820	1000

Which of the following is the positive predictive value of the test under study?

- A. $130/180 (11\%)$
- B. $130/190 (86\%)$
- C. $180/1000 (1\%)$
- D. $760/810 (0\%)$
- E. $760/820 (0\%)$

Omitted
Correct answer

86%

02 secs

2023

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The **positive predictive value (PPV)** of a test answers the question: If the test result is positive, what is the probability that a patient has the disease? PPV is calculated as the proportion of subjects who truly have the disease among all those with a positive test result. In contrast, the **negative predictive value (NPV)** of a test answers the question: If the test result is negative, what is the probability that a patient does not have the disease? It is calculated as the proportion of subjects who are truly free of disease among all those with a negative test result. Predictive values are of prime importance to physicians because, in clinical practice, patients will present more often with a positive or negative test than with a defined diseased or disease-free state.

Consider the following 2×2 (contingency) table:

	Positive condition	Negative condition	
Positive test result	TP	FP	$PPV = \frac{TP}{TP + FP}$
Negative test result	FN	TN	$NPV = \frac{TN}{TN + FN}$
Sensitivity = $TP / (TP + FN)$		Specificity = $TN / (TN + FP)$	
FN = false negative; FP = false positive; NPV = negative predictive value; PPV = positive predictive value; TN = true negative; TP = true positive.			

$PPV = TP / (TP + FP)$, where TP is true positives and FP is false positives.

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			$TN / (TN + FN)$
	Sensitivity = $TP / (TP + FN)$	Specificity = $TN / (TN + FP)$	
FN = false negative; FP = false positive; NPV = negative predictive value; PPV = positive predictive value; TN = true negative; TP = true positive.			

PPV = $TP / (TP + FP)$, where TP is true positives and FP is false positives.

NPV = $TN / (TN + FN)$, where TN is true negatives and FN is false negatives.

In this case, PPV = $130 / (130 + 60) = 130/190$.

(Choices A and E) Sensitivity is a test's ability to correctly identify individuals with the disease. Sensitivity = $TP / (TP + FN) = 130 / (130 + 50) = 130/180$. Specificity is a test's ability to correctly identify individuals without the disease. Specificity = $TN / (TN + FP) = 760 / (760 + 60) = 760/820$.

(Choice C) The total number of individuals who have tuberculosis (based on the gold standard of positive sputum culture) is 180. The total number of individuals in this sample is 1000. Therefore, the prevalence of tuberculosis in this sample is $180/1000$.

(Choice D) NPV = $760 / (760 + 50) = 760/810$.

Educational objective:

The positive predictive value (PPV) of a test answers the question: If the test result is positive, what is the probability that a patient has the disease? $PPV = \text{true positives} / (\text{true positives} + \text{false positives})$.

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Item 21 of 23 Question Id: 1190

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A 45-year-old woman comes to the office with a palpable thyroid node. Medical history reveals that she was diagnosed with medulloblastoma during childhood and treated with chemotherapy and external beam radiation. Fine-needle aspiration of the thyroid shows no malignant cells. As the test results are explained to the patient, she asks, "What are the chances that I really do not have thyroid cancer?" Which of the following diagnostic test parameters would be most useful for answering this patient's question?

- A. Negative predictive value (74%)
- B. Positive predictive value (2%)
- C. Sensitivity (9%)
- D. Specificity (11%)
- E. Validity (0%)

Omitted
Correct answer
A

74%
Answered correctly

03 secs
Time Spent

2023
Version

Explanation

Negative predictive value (NPV) is defined as the probability of not having a disease when the test result is negative. NPV is calculated as the proportion of **true negatives** divided by the total number of **negative tests** (true and false negatives); therefore, it varies with the prevalence of disease in the target population.

The prevalence of a disease in a population may be used as an estimate for the **pretest probability** of having

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Question Id: 1190

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(true and false negatives), therefore, it varies with the prevalence of disease in the target population.

The prevalence of a disease in a population may be used as an estimate for the **pretest probability** of having the disease in patients who **closely resemble** the population. A patient with a high pretest probability will have a low NPV with a negative test, whereas a patient with a low pretest probability will have a high NPV with a negative test.

This patient has a high pretest probability for having thyroid cancer since she most likely received significant radiation exposure to the thyroid during childhood. As such, her negative cytology results would have a lower NPV when compared to another patient with no risk factors for thyroid malignancy who also tests negative.

(Choice B) Positive predictive value also varies according to the pretest probability but applies to positive test results.

(Choices C and D) Sensitivity and specificity of a test are intrinsic characteristics of a test; their values are fixed and do not vary with the pretest probability of a disease. An ideal diagnostic test should be both highly sensitive and highly specific. In this case, fine-needle aspiration has a high sensitivity and specificity; however, the NPV is a better parameter for addressing the patient's question (ie, how likely is she to not have thyroid cancer given her negative test result?); in this case her NPV might be low given her prior radiation exposure.

(Choice E) Validity represents the accuracy of the test (ie, the test measures what it is supposed to measure). It does not depend on the pretest probability of the disease.

Educational objective:

Negative predictive value (NPV) is the probability of not having a disease when the test result is negative. The NPV will vary with the pretest probability of a disease. A patient with a high probability of having a disease will have a low NPV with a negative test, but a patient with a low probability of having a disease will have a high NPV with a negative test.

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Item 22 of 23 Question Id: 19800

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Results of a recent study on the association between levels of glycosylated hemoglobin (HbA1c) and levels of high-sensitivity C-reactive protein (hs-CRP) in patients with type II diabetes mellitus (T2DM) read as follows:

"The results of our study show that levels of HbA1c positively correlated with the levels of hs-CRP ($r = 0.80$). The probability that these results were due to chance alone is 3%, with a 10% chance of concluding no relationship between HbA1c and hs-CRP when one truly exists."

Based on this information, which of the following most likely represents the p -value and the power of the correlation test in the study?

p-value	Power
<input type="radio"/> A. 0.03	0.10 (6%)
<input type="radio"/> B. 0.03	0.80 (6%)
<input checked="" type="radio"/> C. 0.03	0.90 (79%)
<input type="radio"/> D. 0.05	0.10 (2%)
<input type="radio"/> E. 0.05	0.80 (1%)
<input type="radio"/> F. 0.05	0.90 (3%)

Omitted
Correct answer
C

79%
Answered correctly

05 secs
Time Spent

2023
Version

Explanation

Test Id: 303060667

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Mark

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		Truth about the null hypothesis H_0	
		H_0 true	H_0 false
Decision based on test results	Reject H_0	Type I error (α)	Correct conclusion $(1 - \beta) = \text{power}$
	Fail to reject H_0	Correct conclusion $(1 - \alpha)$	Type II error (β)

Power and p -value are related to the process of hypothesis testing. Research studies generally compare a null hypothesis (H_0) (typically of no difference or no association [eg, no correlation between glycosylated hemoglobin and high-sensitivity C-reactive protein levels]) against an alternative hypothesis (H_a) (typically of a difference or an association). Hypothesis testing may result in 1 of 4 possible outcomes:

- 2 correct decisions:
 - Fail to reject a true H_0 (ie, determine there is no correlation when one truly doesn't exist)
 - **Reject a false H_0** (ie, determine there is a correlation when one truly exists)
- 2 incorrect decisions:
 - Type I error: reject a true H_0 (ie, determine there is a correlation when one truly doesn't exist)
 - **Type II error: fail to reject a false H_0** (ie, determine there is no correlation when one truly exists)

The **power of a test** is the probability of making the correct decision of **rejecting a false H_0** . It is the complement of the **probability of a type II error (β)**, which is the probability of failing to reject a false H_0 ; in other words, **power = $(1 - \beta)$** . This study reported a **10% chance** (ie, 0.10 probability) of concluding that there is no relationship (ie, no correlation) between the 2 variables under study when one truly exists: this is the probability of a type II error (β). Therefore, the power of the test (ie, probability of rejecting a false H_0): stating there is a

The screenshot shows a mobile application interface for a statistics test. At the top, there is a header with the URL "apps.uworld.com". Below the header, a blue navigation bar contains various icons and text: "Item 22 of 23", "Question Id: 19800", "Mark" (with a red flag icon), "Previous" and "Next" arrows, "Full Screen", "Tutorial", "Lab Values", "Notes", "Calculator", "Reverse Color", "Text Zoom", and "Settings".

- 2 correct decisions:
 - Fail to reject a true H_0 (ie, determine there is no correlation when one truly doesn't exist)
 - **Reject a false H_0** (ie, determine there is a correlation when one truly exists)
- 2 incorrect decisions:
 - Type I error: reject a true H_0 (ie, determine there is a correlation when one truly doesn't exist)
 - **Type II error: fail to reject a false H_0** (ie, determine there is no correlation when one truly exists)

The **power of a test** is the probability of making the correct decision of **rejecting a false H_0** . It is the complement of the **probability of a type II error (β)**, which is the probability of failing to reject a false H_0 ; in other words, **power = $(1 - \beta)$** . This study reported a **10% chance** (ie, 0.10 probability) of concluding that there is no relationship (ie, no correlation) between the 2 variables under study when one truly exists: this is the probability of a type II error (β). Therefore, the power of the test (ie, probability of rejecting a false H_0 : stating there is a correlation when one truly exists) is **$1 - 0.10 = 0.90$** .

One way to determine whether to reject H_0 is to calculate the **p-value**, the probability of obtaining the observed result (or results more extreme) when H_0 is assumed to be true. The p-value is also informally interpreted as the **probability that the observed results are due to chance** (although this is not technically correct). In this case, researchers concluded that the probability that results were due to chance is 0.03; therefore, the **p-value = 0.03**.

Educational objective:

The power of a test is the probability of making the correct decision of rejecting a false H_0 (ie, determining there is a correlation when one truly exists). The p-value is the probability of obtaining the observed result (or results more extreme) when H_0 is assumed to be true; it is informally interpreted as the probability that the observed results are due to chance.

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Item 23 of 23 Question Id: 1229

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A study investigating a new test for diagnosing acute myocardial infarction (AMI) has just been initiated. The sensitivity of the test is estimated at 75% and the specificity at 80%. The study enrolls 600 patients, of whom 200 are confirmed AMI cases as determined by the diagnostic gold standard. How many false negatives are to be expected in the study?

- A. 50 (53%)
- B. 80 (20%)
- C. 120 (11%)
- D. 150 (11%)
- E. 400 (3%)

Omitted
Correct answer
A

53%
Answered correctly

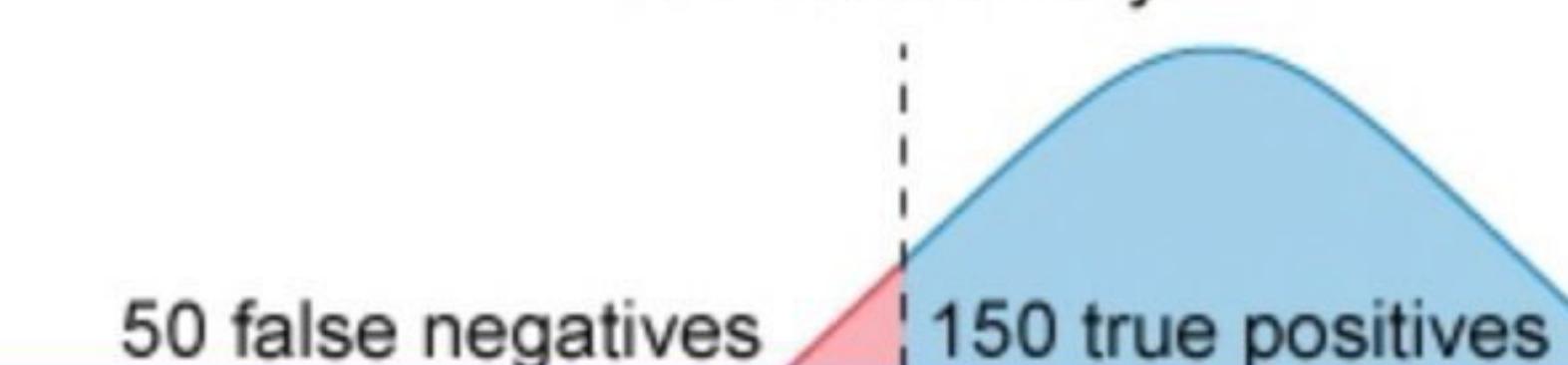
06 secs
Time Spent

2023
Version

Explanation

200 confirmed AMI cases

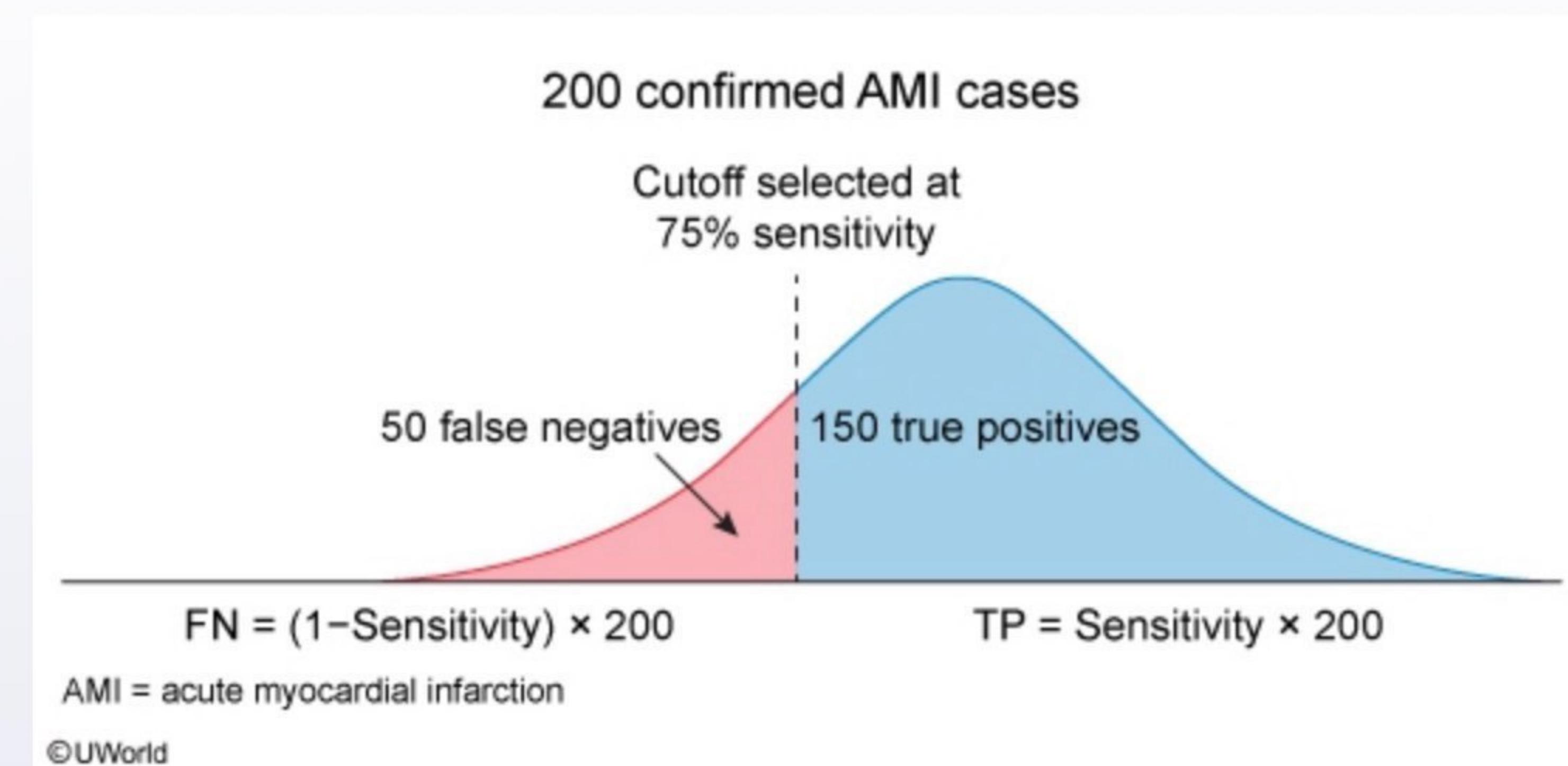
Cutoff selected at
75% sensitivity



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The **sensitivity** of a test determines how well the test categorizes patients who **have the disease** of interest. Tests with higher sensitivity have an increased probability of assigning a positive test result to those patients who truly have the disease; these are considered true positives (rightmost part of the curve). Conversely, patients who **test negative** even though they have the disease are considered **false negatives** (leftmost part of the curve).

True positives (TP) and false negatives (FN) are complementary (ie, an increase in one parameter is exactly offset by a decrease in the other, such that the total is always equal to the number of confirmed patients). As such, the test sensitivity and number of patients with the disease can be used to calculate the number of each:

$$TP = (\text{Sensitivity}) \times (\text{Number of patients with the disease})$$

$$FN = (1 - \text{Sensitivity}) \times (\text{Number of patients with the disease})$$

In this case, the sensitivity of the test is 75% and the total number of patients with confirmed acute myocardial infarction is 200. Therefore, a test that is 75% sensitive will correctly classify 75% of the patients as positive (TP)

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who **test negative** even though they have the disease are considered **false negatives** (leftmost part of the curve).

True positives (TP) and false negatives (FN) are complementary (ie, an increase in one parameter is exactly offset by a decrease in the other, such that the total is always equal to the number of confirmed patients). As such, the test sensitivity and number of patients with the disease can be used to calculate the number of each:

$$TP = (\text{Sensitivity}) \times (\text{Number of patients with the disease})$$

$$FN = (1 - \text{Sensitivity}) \times (\text{Number of patients with the disease})$$

In this case, the sensitivity of the test is 75% and the total number of patients with confirmed acute myocardial infarction is 200. Therefore, a test that is 75% sensitive will correctly classify 75% of the patients as positive (TP) and incorrectly classify 25% of the patients (1 – Sensitivity) as negative (FN).

Using this information, the number of FN can be calculated as follows ([alternate method](#)):

$$FN = (1 - \text{Sensitivity}) \times (\text{Number of patients with the disease}) = (1 - 0.75) \times 200 = 50$$

Educational objective:

When undergoing diagnostic testing, patients with the disease can test positive (true positive, TP) or negative (false negative, FN). The sensitivity of a test determines the proportion of patients that are correctly classified:

$$TP = (\text{Sensitivity}) \times (\text{Number of patients with the disease})$$

$$FN = (1 - \text{Sensitivity}) \times (\text{Number of patients with the disease})$$

Biostatistics

Biostatistics & Epidemiology

Sensitivity and specificity

Subject

System

Topic

Study design and interpretation

A large, multi-country study is conducted to determine the effect of economic development on cancer incidence and mortality. The study uses data obtained from the national cancer registries, along with information regarding per capita gross domestic product as reported by the International Monetary Fund and life expectancy as reported by the World Health Organization. Which of the following best describes the design of this study?

- A. Case-control study
 - B. Cohort study
 - C. Cross-sectional survey
 - D. Ecological study
 - E. Nested case-control study
 - F. Qualitative study
 - G. Randomized controlled trial
 - H. Systematic review

[Proceed To Next Item](#)



A surveillance study is conducted to assess the long-term efficacy and safety of a drug currently being used to treat patients with heart failure. Researchers enroll 8,300 patients with heart failure. The patients receive the drug once daily for 6 months. The results show significant clinical improvement, but severe hypernatremia is observed in 23 patients. The study publication recommends a lower dose of the drug in patients with baseline normonatremia and hypokalemia to prevent hypernatremia. Which of the following best characterizes this type of study?

- A. Phase I clinical trial
- B. Phase II clinical trial
- C. Phase III clinical trial
- D. Phase IV clinical trial
- E. Preclinical study

[Proceed To Next Item](#)