

HIGH-YIELD PRINCIPLES IN

Public Health Sciences

“Medicine is a science of uncertainty and an art of probability.”
 —Sir William Osler

“People will forget what you said, people will forget what you did, but people will never forget how you made them feel.”
 —Maya Angelou

“On a long enough timeline, the survival rate for everyone drops to zero.”
 —Chuck Palahniuk, *Fight Club*

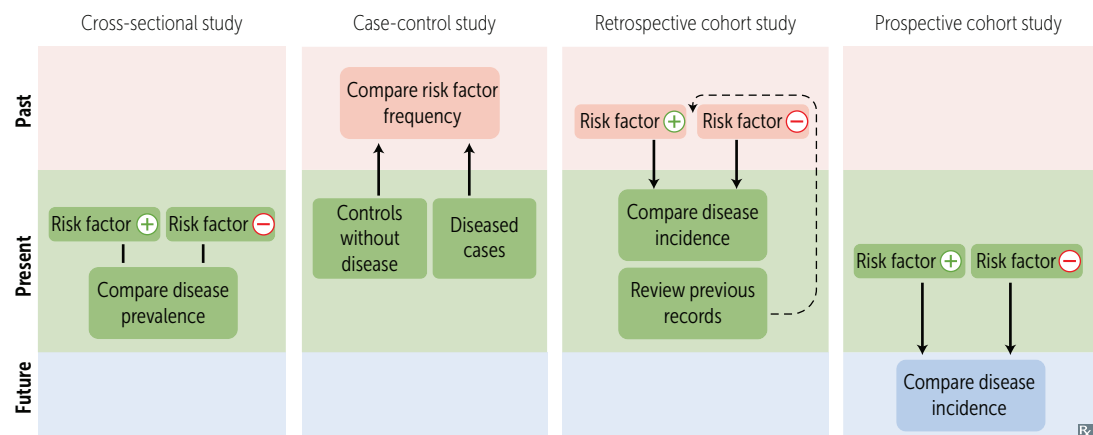
A heterogenous mix of epidemiology, biostatistics, ethics, law, healthcare delivery, patient safety, quality improvement, and more falls under the heading of public health sciences. Biostatistics and epidemiology are the foundations of evidence-based medicine and are very high yield. Make sure you can quickly apply biostatistical equations such as sensitivity, specificity, and predictive values in a problem-solving format. Also, know how to set up your own 2 × 2 tables, and look out for questions that switch the rows and columns. Quality improvement and patient safety topics were introduced a few years ago on the exam and represent trends in health system science. Medical ethics questions often require application of principles. Typically, you are presented with a patient scenario and then asked how you would respond. In this edition, we provide further details on communication skills and patient care given their growing emphasis on the exam. Effective communication is essential to the physician-patient partnership. Physicians must seek opportunities to connect with patients, understand their perspectives, express empathy, and form shared decisions and realistic goals.

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► PUBLIC HEALTH SCIENCES—EPIDEMIOLOGY AND BIOSTATISTICS

Observational studies

STUDY TYPE	DESIGN	MEASURES/EXAMPLE
Case series	Describes several individual patients with the same diagnosis, treatment, or outcome.	Description of clinical findings and symptoms. Has no comparison group, thus cannot show risk factor association with disease.
Cross-sectional study	Frequency of disease and frequency of risk-related factors are assessed in the present. Asks, “What is happening?”	Disease prevalence. Can show risk factor association with disease, but does not establish causality.
Case-control study	Retrospectively compares a group of people with disease to a group without disease. Looks to see if odds of prior exposure or risk factor differ by disease state. Asks, “What happened?”	Odds ratio (OR). Control the case in the OR . Patients with COPD had higher odds of a smoking history than those without COPD.
Cohort study	Compares a group with a given exposure or risk factor to a group without such exposure. Looks to see if exposure or risk factor is associated with later development of disease. Can be prospective or retrospective, but risk factor has to be present prior to disease development.	Disease incidence. Relative risk (RR). People who smoke had a higher risk of developing COPD than people who do not. Cohort = relative risk .
Twin concordance study	Compares the frequency with which both monozygotic twins vs both dizygotic twins develop the same disease.	Measures heritability and influence of environmental factors (“nature vs nurture”).
Adoption study	Compares behavioral traits/genetics in siblings raised by biological vs adoptive parents.	Measures heritability and influence of environmental factors.
Ecological study	Compares frequency of disease and frequency of risk-related factors across populations. Measures population data not necessarily applicable to individuals (ecological fallacy).	Used to monitor population health. COPD prevalence was higher in more polluted cities.



Clinical therapeutic trial

Experimental study involving humans. Compares therapeutic benefits of ≥ 2 interventions (eg, treatment vs placebo, treatment vs treatment). Study quality improves when clinical trial is randomized, controlled, and double-blinded (ie, neither subject nor researcher knows whether the subject is in the treatment or control group). Triple-blind refers to additional blinding of the researchers analyzing the data.

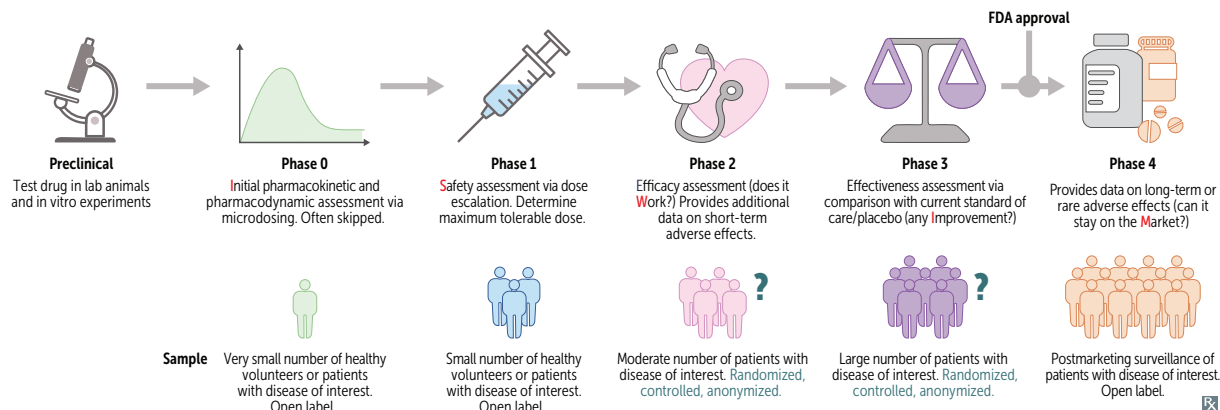
Crossover clinical trial—compares the effect of a series of ≥ 2 treatments on a subject. Order in which subjects receive treatments is randomized. Washout period occurs between treatments. Allows subjects to serve as their own controls.

Intention-to-treat analysis—all subjects are analyzed according to their original, randomly assigned treatment. No one is excluded, ie, once randomized, always analyzed. Attempts to avoid bias from attrition, crossover, and nonrandom noncompliance, but may dilute the true effects of intervention.

As-treated analysis—all subjects are analyzed according to the treatment they actually received. ↑ risk of bias.

Per-protocol analysis—subjects who fail to complete treatment as originally, randomly assigned are excluded. ↑ risk of bias.

Clinical trials occur after preclinical studies and consist of five phases (“Can I SWIM?”).



Off-label drug use

Use of a drug to treat a disease in a form, population group, or dosage that is not specifically approved by the FDA. Reasons for off-label use include treatment of an illness with no approved pharmacologic treatment or exploring alternative treatments after failure of approved options. Example: use of tricyclic antidepressants for treating neuropathic/chronic pain.

Bradford Hill criteria

A group of principles that provide limited support (ie, necessary but not sufficient criteria) for establishing evidence of a causal relationship between presumed cause and effect.

Strength	Association does not necessarily imply causation, but the stronger the association, the more evidence for causation.
Consistency	Repeated observations of the findings in multiple distinct samples.
Specificity	The more specific the presumed cause is to the effect, the stronger the evidence for causation.
Temporality	The presumed cause precedes the effect by an expected amount of time.
Biological gradient	Greater effect observed with greater exposure to the presumed cause (dose-response relationship).
Plausibility	A conceivable mechanism exists by which the cause may lead to the effect.
Coherence	The presumed cause and effect do not conflict with existing scientific consensus.
Experiment	Empirical evidence supporting the presumed cause and effect (eg, animal studies, in vitro studies).
Analogy	The presumed cause and effect are comparable to a similar, established cause and effect.

Quantifying risk

Definitions and formulas are based on the classic 2×2 or contingency table.

		Disease or outcome	
		⊕	⊖
Exposure or intervention	⊕	a	b
	⊖	c	d

TERM	DEFINITION	EXAMPLE	FORMULA								
Odds ratio	Typically used in case-control studies. Represents the odds of exposure among cases (a/c) vs odds of exposure among controls (b/d). OR = 1 → odds of exposure are equal in cases and controls. OR > 1 → odds of exposure are greater in cases. OR < 1 → odds of exposure are greater in controls.	If in a case -control study, 20/30 patients with lung cancer and 5/25 healthy individuals report smoking, the OR is 8; so the patients with lung cancer are 8 times more likely to have a history of smoking. You take a case to the OR .	$OR = \frac{a/c}{b/d} = \frac{ad}{bc}$ <table border="1"><tr><td>a</td><td>b</td></tr><tr><td>20</td><td>5</td></tr><tr><td>c</td><td>d</td></tr><tr><td>10</td><td>20</td></tr></table>	a	b	20	5	c	d	10	20
a	b										
20	5										
c	d										
10	20										
Relative risk	Typically used in cohort studies. Risk of developing disease in the exposed group divided by risk in the unexposed group. RR = 1 → no association between exposure and disease. RR > 1 → exposure associated with ↑ disease occurrence. RR < 1 → exposure associated with ↓ disease occurrence.	If 5/10 people exposed to radiation are diagnosed with cancer, and 1/10 people not exposed to radiation are diagnosed with cancer, the RR is 5; so people exposed to radiation have a 5 times greater risk of developing cancer. For rare diseases (low prevalence), OR approximates RR.	$RR = \frac{a/(a + b)}{c/(c + d)}$ <table border="1"><tr><td>a</td><td>b</td></tr><tr><td>5</td><td>5</td></tr><tr><td>c</td><td>d</td></tr><tr><td>1</td><td>9</td></tr></table>	a	b	5	5	c	d	1	9
a	b										
5	5										
c	d										
1	9										
Relative risk reduction	The proportion of risk reduction attributable to the intervention/ treatment (ART) as compared to a control (ARC).	If 2% of patients who receive a flu shot develop the flu, while 8% of unvaccinated patients develop the flu, then RR = 2/8 = 0.25, and RRR = 0.75.	$RRR = 1 - RR$ $RRR = \frac{(ARC - ART)}{ARC}$								
Attributable risk	The difference in risk between exposed and unexposed groups.	If risk of lung cancer in people who smoke is 21% and risk in people who don't smoke is 1%, then the attributable risk is 20%.	$AR = \frac{a}{a + b} - \frac{c}{c + d}$ $AR\% = \frac{RR - 1}{RR} \times 100$								
Absolute risk reduction	The difference in risk (not the proportion) attributable to the intervention as compared to a control.	If 8% of people who receive a placebo vaccine develop the flu vs 2% of people who receive a flu vaccine, then ARR = 8%–2% = 6% = 0.06.	$ARR = \frac{c}{c + d} - \frac{a}{a + b}$								
Number needed to treat	Number of patients who need to be treated for 1 patient to benefit. Lower number = better treatment.		$NNT = 1/ARR$								
Number needed to harm	Number of patients who need to be exposed to a risk factor for 1 patient to be har med. Higher number = safer exposure.		$NNH = 1/AR$								
Case fatality rate	Percentage of deaths occurring among those with disease.	If 4 patients die among 10 cases of meningitis, case fatality rate is 40%.	$CFR\% = \frac{\text{deaths}}{\text{cases}} \times 100$								

Quantifying risk (continued)

TERM	DEFINITION	EXAMPLE	FORMULA
Mortality rate	Number of deaths (in general or due to specific cause) within a population over a defined period.	If 80 people in a town of 10,000 die over 2 years, mortality rate is 4 per 1000 per year.	Deaths/1000 people per year.
Attack rate	Proportion of exposed people who become ill.	If 80 people in a town are exposed and 60 people become ill, attack rate is 75%.	$\frac{\text{People who become ill}}{\text{Total people exposed}}$

Demographic transition

As a country proceeds to higher levels of development, birth and mortality rates decline to varying degrees, changing the age composition of the population.

Population pyramid			
Birth rate	↑↑	↓	↓↓
Mortality rate	↑	↓	↓
Life expectancy	Short	Long	Long
Population	Growing	Stable	Declining

Likelihood ratio

$$LR^+ = \frac{\text{probability of positive result in patient with disorder}}{\text{probability of positive result in patient without disorder}} = \frac{\text{sensitivity}}{1 - \text{specificity}} = \frac{\text{TP rate}}{\text{FP rate}}$$

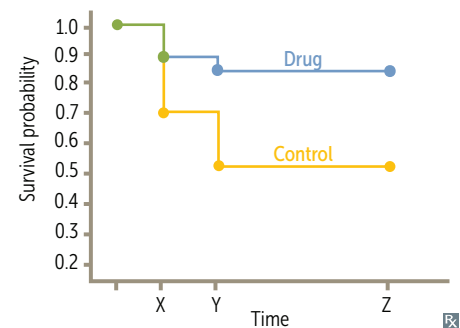
$$LR^- = \frac{\text{probability of negative result in patient with disorder}}{\text{probability of negative result in patient without disorder}} = \frac{1 - \text{sensitivity}}{\text{specificity}} = \frac{\text{FN rate}}{\text{TN rate}}$$

$LR^+ > 10$ indicates a highly specific test, while $LR^- < 0.1$ indicates a highly sensitive test.
 Pretest odds \times LR = posttest odds. Posttest probability = posttest odds / (posttest odds + 1).

Kaplan-Meier curve

Used to estimate probability of survival over time. Graphic representation shows the survival probabilities (y-axis) vs length of time (x-axis). Useful for displaying “time-to-event” data.

Outcomes examined may include any event, but frequently include mortality.
 Survival probability = 1 – (event probability).
 P value for the survival difference can be calculated using log rank test or Cox regression.



Evaluation of diagnostic tests

Sensitivity and specificity are fixed properties of a test. PPV and NPV vary depending on disease prevalence in population being tested.
Test efficiency =
 $(TP + TN) / (TP + FN + FP + TN)$

	Disease			
	⊕	⊖		
Test	⊕	TP	FP	PPV = TP/(TP + FP)
	⊖	FN	TN	NPV = TN/(TN + FN)
		Sensitivity = TP/(TP + FN)	Specificity = TN/(TN + FP)	Prevalence $\frac{TP + FN}{(TP + FN + FP + TN)}$

Sensitivity (true-positive rate)

Proportion of all people with disease who test positive, or the ability of a test to correctly identify those with the disease.
Value approaching 100% is desirable for **ruling out** disease and indicates a **low false-negative rate**.

$= TP / (TP + FN)$
 $= 1 - FN \text{ rate}$
SN-N-OUT = highly **Se**nsitive test, when **N**egative, rules **OUT** disease
High sensitivity test used for screening

Specificity (true-negative rate)

Proportion of all people without disease who test negative, or the ability of a test to correctly identify those without the disease.
Value approaching 100% is desirable for **ruling in** disease and indicates a **low false-positive rate**.

$= TN / (TN + FP)$
 $= 1 - FP \text{ rate}$
SP-P-IN = highly **SP**ecific test, when **P**ositive, rules **IN** disease
High specificity test used for confirmation after a positive screening test

Positive predictive value

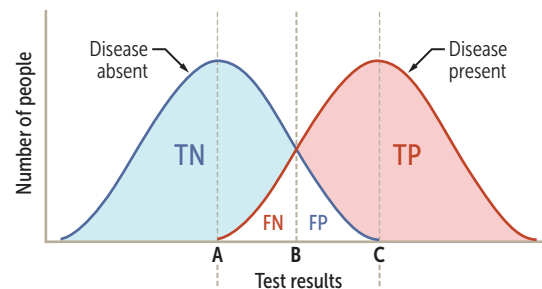
Probability that a person who has a positive test result actually has the disease.

$PPV = TP / (TP + FP)$
PPV varies directly with pretest probability (baseline risk, such as prevalence of disease):
high pretest probability → high PPV

Negative predictive value

Probability that a person with a negative test result actually does not have the disease.

$NPV = TN / (TN + FN)$
NPV varies inversely with prevalence or pretest probability



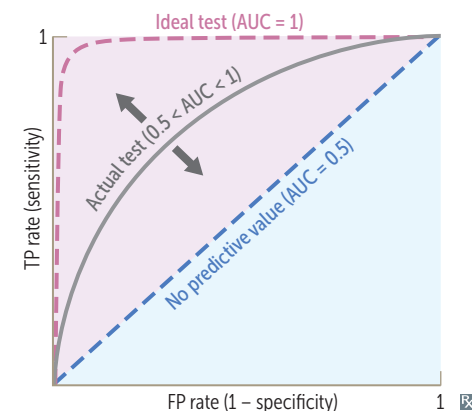
Possible cutoff values for ⊕ vs ⊖ test result
A = 100% sensitivity cutoff value
B = practical compromise between specificity and sensitivity
C = 100% specificity cutoff value

Lowering the cutoff value:	↑ Sensitivity ↑ NPV
B → A (↑ FP ↓ FN)	↓ Specificity ↓ PPV
Raising the cutoff value:	↑ Specificity ↑ PPV
B → C (↑ FN ↓ FP)	↓ Sensitivity ↓ NPV

Note: In diseases where diagnosis is based on lower values (eg, anemia), the TP and TN are switched in the graph, ie, ↓ sensitivity and ↓ NPV, and vice-versa.

Receiver operating characteristic curve

ROC curve demonstrates how well a diagnostic test can distinguish between 2 groups (eg, disease vs healthy). Plots the true-positive rate (sensitivity) against the false-positive rate ($1 - \text{specificity}$).
The better performing test will have a higher area under the curve (AUC), with the curve closer to the upper left corner.



Precision vs accuracy

Precision (reliability)

The consistency and reproducibility of a test.
The absence of random variation in a test.

Random error ↓ precision in a test.

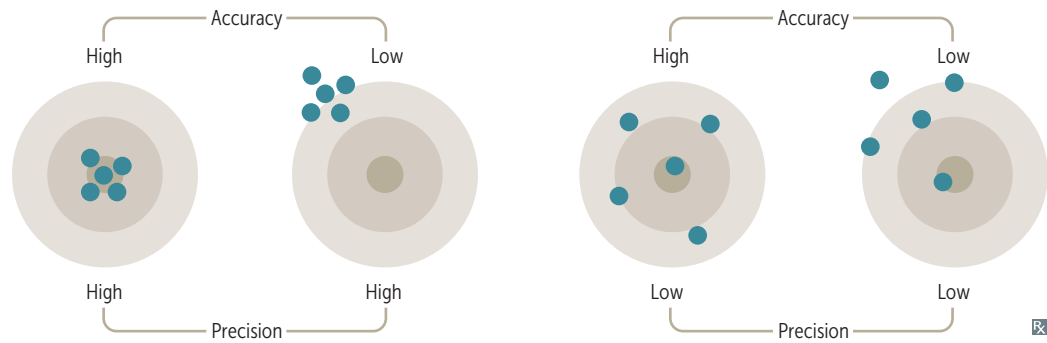
↑ precision → ↓ standard deviation.

↑ precision → ↑ statistical power ($1 - \beta$).

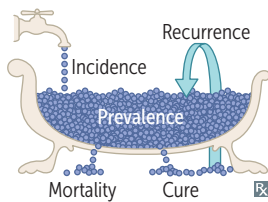
Accuracy (validity)

The closeness of test results to the true values.
The absence of systematic error or bias in a test.

Systematic error ↓ accuracy in a test.



Incidence vs prevalence



$$\text{Incidence} = \frac{\# \text{ of new cases}}{\# \text{ of people at risk}} \quad (\text{per unit of time})$$

$$\text{Prevalence} = \frac{\# \text{ of existing cases}}{\text{Total \# of people in a population}} \quad (\text{at a point in time})$$

$$\frac{\text{Prevalence}}{1 - \text{prevalence}} = \text{Incidence rate} \times \text{average duration of disease}$$

$$\text{Prevalence} = \text{incidence} \times \text{duration of the disease.}$$

Prevalence > incidence for chronic diseases, due to large # of existing cases (eg, diabetes).

Incidence looks at new cases (**incidents**).

Prevalence looks at **all** current cases.

Prevalence ~ pretest probability.

↑ prevalence → ↑ PPV and ↓ NPV.

Prevalence ≈ incidence for short duration disease (eg, common cold).

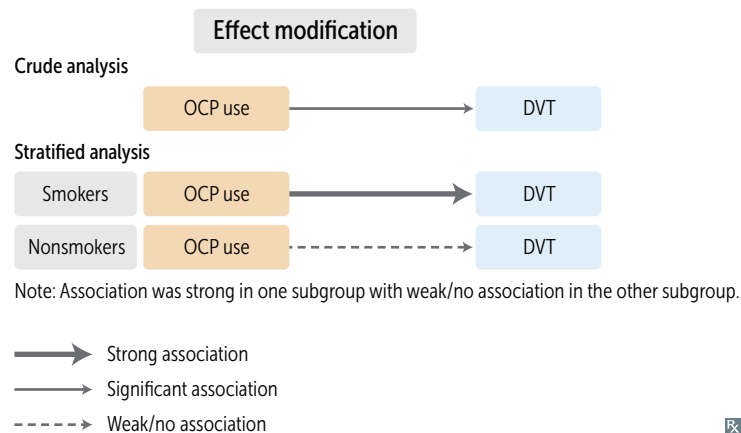
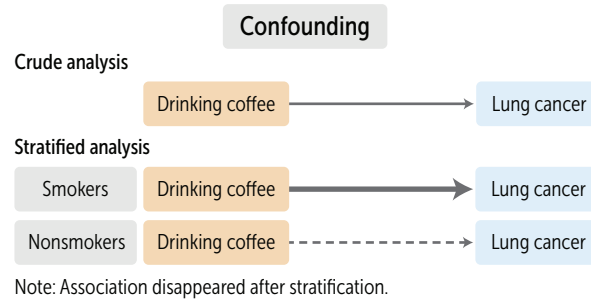
SITUATION	INCIDENCE	PREVALENCE
↑ survival time	—	↑
↑ mortality rate	—	↓
Faster recovery time	—	↓
Extensive vaccine administration	↓	↓
↓ risk factors	↓	↓
↑ diagnostic sensitivity	↑	↑
New effective treatment started	—	↓
↓ contact between infected and noninfected patients with airborne infectious disease	↓	↓

Bias and study errors

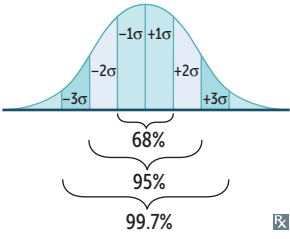
TYPE	DEFINITION	EXAMPLES	STRATEGIES TO REDUCE BIAS
Recruiting participants			
Selection bias	Nonrandom sampling or treatment allocation of subjects such that study population is not representative of target population Most commonly a sampling bias Convenience sampling —patients are enrolled on basis of ease of contact	Berkson bias —cases and/or controls selected from hospitals (bedside bias) are less healthy and have different exposures Attrition bias —participants lost to follow up have a different prognosis than those who complete the study	Randomization (creates groups with similar distributions of known and unknown variables) Ensure the choice of the right comparison/reference group
Performing study			
Recall bias	Awareness of disorder alters recall by subjects; common in retrospective studies	Patients with disease recall exposure after learning of similar cases	Decrease time from exposure to follow-up; use medical records as sources
Measurement bias	Information is gathered in a systemically distorted manner	Using a faulty automatic sphygmomanometer Hawthorne effect —participants change behavior upon awareness of being observed (Hawthorne watches you like a hawk).	Use objective, standardized, and previously tested methods of data collection that are planned ahead of time Use placebo group
Procedure bias	Subjects in different groups are not treated the same	Patients in treatment group spend more time in highly specialized hospital units	Blinding (masking) and use of placebo reduce influence of participants and researchers on procedures and interpretation of outcomes as neither are aware of group assignments
Observer-expectancy bias	Researcher's belief in the efficacy of a treatment changes the outcome of that treatment (also called Pygmalion effect)	An observer expecting treatment group to show signs of recovery is more likely to document positive outcomes	
Interpreting results			
Lead-time bias	E arly d etection interpreted as ↑ survival, but the disease course has not changed	Breast cancer diagnosed early by mammography may appear to exaggerate survival time because patients are known to have the cancer for longer	Measure “back-end” survival (adjust survival according to the severity of disease at the time of diagnosis); a caveat of adjusting for severity is the potential masking of causality
Length-time bias	Screening test detects diseases with long latency period, while those with shorter latency period become symptomatic earlier	A slowly progressive cancer is more likely detected by a screening test than a rapidly progressive cancer	A randomized controlled trial assigning subjects to the screening program or to no screening

Confounding vs effect modification


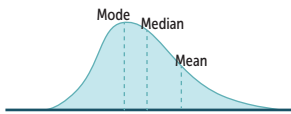
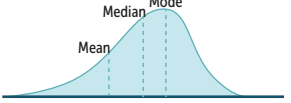
TYPE	DEFINITION	EXAMPLES	STRATEGIES TO REDUCE BIAS
Confounding	Factor related to both exposure and outcome (not on a causal pathway) distorts the effect on the outcome No association after stratification	Coffee appears to be linked to lung cancer, but smoking is the true cause, as coffee drinkers tend to smoke more	Crossover studies (subject serves as self-control) Matching (patients with similar characteristics in both treatment and control groups) Analytic techniques (eg, regression analysis when confounding variables are known and were measured)
Effect modification	Exposure leads to different outcomes in subgroups stratified by factor True association exists	A study among women using OCPs showed significant risk of DVT, but when these data were stratified by smoking habits, there was a very strong association between OCP use and DVT among smokers, but there was no such association in people who do not smoke	Stratified analysis (eg, after testing for interaction between OCP and smoking, analyze risk among smokers and nonsmokers)



Statistical distribution

Measures of central tendency	Mean = (sum of values)/(total number of values).	Most affected by outliers (extreme values).
	Median = middle value of a list of data sorted from least to greatest.	If there is an even number of values, the median will be the average of the middle two values.
	Mode = most common value.	Least affected by outliers.
Measures of dispersion	Standard deviation = how much variability exists in a set of values, around the mean of these values.	σ = SD; n = sample size.
	Standard error = an estimate of how much variability exists in a (theoretical) set of sample means around the true population mean.	Variance = $(SD)^2$. SE = σ/\sqrt{n} . SE ↓ as n ↑.
Normal distribution	Gaussian, also called bell-shaped.	
	Mean = median = mode.	
	For normal distribution, mean is the best measure of central tendency.	
	For skewed data, median is a better measure of central tendency than mean.	

Nonnormal distributions

Bimodal distribution	Suggests two different populations (eg, metabolic polymorphism such as fast vs slow acetylators; age at onset of Hodgkin lymphoma; suicide rate by age).	
Positive skew	Typically, mean > median > mode. Asymmetry with longer tail on right; mean falls closer to tail.	
Negative skew	Typically, mean < median < mode. Asymmetry with longer tail on left; mean falls closer to tail.	

Statistical hypothesis testing

Null hypothesis	Also called H_0 . Hypothesis with no difference or association (eg, there is zero association between disease and risk factor in the population).
Alternative hypothesis	Also called H_1 . Hypothesis with at least one difference or relationship (eg, there is some association between disease and risk factor in the population).
P value	Probability of obtaining test results at least as extreme as those observed in the sample, assuming that H_0 is correct. Commonly accepted as 0.05 (< 5% of such repeated tests would show results that extreme just by chance alone).

Outcomes of statistical hypothesis testing

Correct result

Stating that there is an effect or difference when one exists (H_0 rejected in favor of H_1).
Stating that there is no effect or difference when none exists (H_0 not rejected).

		Reality	
		H_1	H_0
Study rejects H_0	Study does not reject H_0	Power ($1 - \beta$)	α Type I error
		β Type II error	

Blue shading = correct result.

Testing errors

Type I error (α)

Stating that there is an effect or difference when none exists (H_0 incorrectly rejected in favor of H_1).
 α is the probability of making a type I error (usually 0.05 is chosen). If $P < \alpha$, then assuming H_0 is true, the probability of obtaining the test results would be less than the probability of making a type I error. H_0 is therefore rejected as false.
Statistical significance \neq clinical significance.

Also called false-positive error.

1st time boy cries wolf, the town believes there is a wolf, but there is not (false positive).
You can never “prove” H_1 , but you can reject the H_0 as being very unlikely.

Type II error (β)

Stating that there is not an effect or difference when one exists (H_0 is not rejected when it is in fact false).
 β is the probability of making a type II error. β is related to statistical power ($1 - \beta$), which is the probability of rejecting H_0 when it is false.
↑ power and ↓ β by:

- ↑ sample size
- ↑ expected effect size
- ↑ precision of measurement
- ↑ α level (↑ statistical significance level).

Also called false-negative error.

2nd time boy cries wolf, the town believes there is no wolf, but there is one.
If you ↑ sample size, you ↑ power. There is **power in numbers**.
Generally, when type I error increases, type II error decreases.

Statistical vs clinical significance

Statistical significance—defined by the likelihood of study results being due to chance. If there is a high statistical significance, then there is a low probability that the results are due to chance.
Clinical significance—measure of effect on treatment outcomes. An intervention with high clinical significance is likely to have a large impact on patient outcomes/measures.
Some studies have a very high statistical significance, but the proposed intervention may have limited clinical impact/significance, eg, a study might show a statistical significance of lowered blood sugar levels by 1 mg/dL correlated with better outcomes, but this may not be clinically as important.

Confidence interval

Range of values within which the true mean of the population is expected to fall, with a specified probability.

CI = $1 - \alpha$. The 95% CI (corresponding to $\alpha = 0.05$) is often used. As sample size increases, CI narrows.

CI for sample mean = $\bar{x} \pm Z(SE)$

For the 95% CI, $Z = 1.96$.

For the 99% CI, $Z = 2.58$.

H_0 is rejected (and results are significant) when:

- 95% CI for mean difference excludes 0
- 95% CI OR or RR excludes 1
- CIs between two groups do not overlap

H_0 is not rejected (and results are not significant) when:

- 95% CI for mean difference includes 0
- 95% CI OR or RR includes 1
- CIs between two groups do overlap

Meta-analysis

A method of statistical analysis that pools summary data (eg, means, RRs) from multiple studies for a more precise estimate of the size of an effect. Also estimates heterogeneity of effect sizes between studies.

Improves power, strength of evidence, and generalizability (external validity) of study findings.

Limited by quality of individual studies and bias in study selection.

Common statistical tests

t-test

Checks differences between **means** of **2** groups.

Tea is **meant** for **2**.

Example: comparing the mean blood pressure between men and women.

ANOVA

Checks differences between means of **3** or more groups.

3 words: **AN**alysis **Of** **V**ariance.

Example: comparing the mean blood pressure between members of 3 different ethnic groups.

Chi-square (χ^2)

Checks differences between 2 or more percentages or proportions of **categorical** outcomes (not mean values).

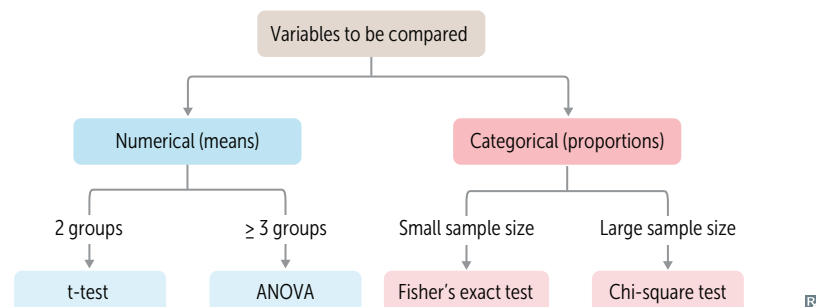
Pronounce **chi-tegorical**.

Example: comparing the proportion of members of 3 age groups who have essential hypertension.

Fisher's exact test

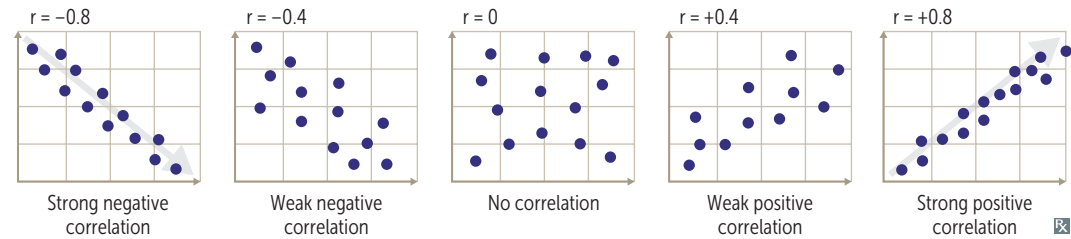
Checks differences between 2 percentages or proportions of categorical, nominal outcomes. Use instead of chi-square test with small samples.

Example: comparing the percentage of 20 men and 20 women with hypertension.



Pearson correlation coefficient

A measure of the linear correlation between two variables. r is always between -1 and $+1$. The closer the absolute value of r is to 1 , the stronger the linear correlation between the 2 variables. Variance is how much the measured values differ from the average value in a data set. Positive r value \rightarrow positive correlation (as one variable \uparrow , the other variable \uparrow). Negative r value \rightarrow negative correlation (as one variable \uparrow , the other variable \downarrow). Coefficient of determination = r^2 (proportion of variance in one variable that can be explained by variance in the other variable). Correlation does not necessarily imply causation.



► PUBLIC HEALTH SCIENCES—ETHICS

Core ethical principles

Autonomy

Obligation to respect patients as individuals (truth-telling, confidentiality), to create conditions necessary for autonomous choice (informed consent), and to honor their preference in accepting or not accepting medical care.

Beneficence

“Do good.” Physicians have a special ethical (fiduciary) duty to act in the patient’s best interest. May conflict with autonomy (an informed patient has the right to decide) or what is best for society (eg, mandatory TB treatment). Traditionally, patient interest supersedes. **Principle of double effect**—facilitating comfort is prioritized over potential side effects (eg, respiratory depression with opioid use) for patients receiving end-of-life care.

Nonmaleficence

“Do no harm.” Must be balanced against beneficence; if the benefits outweigh the risks, a patient may make an informed decision to proceed (most surgeries and medications fall into this category).

Justice

To treat persons fairly and equitably. This does not always imply equally (eg, triage).

Decision-making capacity

Physician must determine whether the patient is psychologically and legally capable of making a particular healthcare decision.

Note that decisions made with capacity cannot be revoked simply if the patient later loses capacity. Intellectual disabilities and mental illnesses are not exclusion criteria unless the patient’s condition presently impairs their ability to make healthcare decisions.

Capacity is determined by a physician for a specific healthcare-related decision (eg, to refuse medical care).

Competency is determined by a judge and usually refers to more global categories of decision-making (eg, legally unable to make any healthcare-related decision).

Four major components of decision-making:

- Understanding (what do you know about your condition/proposed procedure/treatment?)
- Appreciation (what does your condition mean to you? why do you think your doctor is recommending this course of treatment?)
- Reasoning (how are you weighing your options?)
- Expressing a choice (what would you like to do?)

Informed consent

A process (not just a document/signature) that requires:

- Disclosure: discussion of pertinent information, including risks/benefits (using medical interpreter, if needed)
- Understanding: ability to comprehend
- Capacity: ability to reason and make one's own decisions (distinct from competence, a legal determination)
- Voluntariness: freedom from coercion and manipulation

Patients must have a comprehensive understanding of their diagnosis and the risks/benefits of proposed treatment and alternative options, including no treatment.

Patients must be informed of their right to revoke written consent at any time, even orally.

Exceptions to informed consent (**WIPE** it away):

- **Waiver**—patient explicitly relinquishes the right of informed consent
- Legally **Incompetent**—patient lacks decision-making capacity (obtain consent from legal surrogate)
- Therapeutic **Privilege**—withholding information when disclosure would severely harm the patient or undermine informed decision-making capacity
- **Emergency situation**—implied consent may apply

Consent for minors

A minor is generally any person < 18 years old. Parental consent laws in relation to healthcare vary by state. In general, parental consent should be obtained, but exceptions exist for emergency treatment (eg, blood transfusions) or if minor is legally emancipated (eg, married, self-supporting, or in the military).

Situations in which parental consent is usually not required:

- **Sex** (contraception, STIs, prenatal care—usually not abortion)
- **Drugs** (substance use disorder treatment)
- **Rock and roll** (emergency/trauma)

Physicians should always encourage healthy minor-guardian communication.

Physician should seek a minor's assent (agreement of someone unable to legally consent) even if their consent is not required.

Advance directives

Instructions given by a patient in anticipation of the need for a medical decision. Details vary per state law.

Oral advance directive

Incapacitated patient's prior oral statements commonly used as guide. Problems arise from variance in interpretation. If patient was informed, directive was specific, patient made a choice, and decision was repeated over time to multiple people, then the oral directive is more valid.

Written advance directive

Delineates specific healthcare interventions that patient anticipates accepting or rejecting during treatment for a critical or life-threatening illness. A living will is an example.

Medical power of attorney

Patient designates an agent to make medical decisions in the event that the patient loses decision-making capacity. Patient may also specify decisions in clinical situations. Can be revoked by patient if decision-making capacity is intact. More flexible than a living will.

Do not resuscitate order

DNR order prohibits cardiopulmonary resuscitation (CPR). Patient may still consider other life-sustaining measures (eg, intubation, feeding tube, chemotherapy).

Ventilator-assisted life support

Ideally, discussions with patients occur before ventilator support is necessary. However, information about patient preferences may be absent at the time patients require this intervention to survive. Medical decision-making frequently relies on surrogate decision-makers (patient identified or legally appointed) when discussing the continuation or withdrawal of ventilatory support, focusing on both the prognosis of the condition and the believed wishes of the patient. If surrogates indicate patient would not have wanted to receive life support with ventilation → withhold or withdraw life support regardless of what the surrogate prefers. If the decision is made to withhold or withdraw life support, involve palliative care, chaplain services, and the primary care physician in medical discussions with the family and provide emotional support.

Surrogate decision-maker

If a patient loses decision-making capacity and has not prepared an advance directive, individuals (surrogates) who know the patient must determine what the patient would have done. Priority of surrogates: **spouse** → adult **children** → **parents** → adult **siblings** → other relatives (the **spouse chips** in).

Confidentiality

Confidentiality respects patient privacy and autonomy. If the patient is incapacitated or the situation is emergent, disclosing information to family and friends should be guided by professional judgment of patient's best interest. The patient may voluntarily waive the right to confidentiality (eg, insurance company request).

General principles for exceptions to confidentiality:

- Potential physical harm to self or others is serious and imminent
- Alternative means to warn or protect those at risk is not possible
- Steps can be taken to prevent harm

Examples of exceptions to patient confidentiality (many are state specific) include the following ("The physician's good judgment **SAVED** the day"):

- Patients with active **Suicidal**/homicidal ideation
- **Abuse** (children, older adults, and/or prisoners)
- Duty to protect—state-specific laws that sometimes allow physician to inform or somehow protect potential **Victim** from harm
- Patients with **Epilepsy** and other impaired automobile drivers
- Reportable **Diseases** (eg, STIs, hepatitis, food poisoning); physicians may have a duty to warn public officials, who will then notify people at risk. Dangerous communicable diseases, such as TB or Ebola, may require involuntary treatment.

Accepting gifts from patients

A complex subject without definitive regulations. Some argue that the patient-physician relationship is strengthened through accepting a gift from a patient, while others argue that negative consequences outweigh the benefits of accepting any gift.

In practice, patients often present items such as cards, baked goods, and inexpensive gifts to physicians. The physician's decision to accept or decline is based on an individual assessment of whether or not the risk of harm outweighs the potential benefit.

- Physicians should not accept gifts that are inappropriately large or valuable.
- Gifts should not be accepted if the physician identifies that the gift could detrimentally affect patient care.
- Gifts that may cause emotional or financial stress for the patient should not be accepted.

If a gift violates any of the guidelines above, the best practice is to thank the patient for offering a kind gift, but politely indicate that it must be declined. During this conversation it should be emphasized that the incident does not influence the physician-patient relationship in any way.

► PUBLIC HEALTH SCIENCES—COMMUNICATION SKILLS

Patient-centered interviewing techniques

Introduction	Introduce yourself and ask the patient their name and how they would like to be addressed. Address the patient by the name and pronouns given. Avoid making gender assumptions. Sit at eye level, near the patient, while facing them directly.
Agenda setting	Identify concerns and set goals by developing joint agenda between the physician and the patient.
Reflection	Actively listen and synthesize information offered by the patient, particularly with respect to primary concern(s).
Validation	Legitimize or affirm the patient's perspectives.
Recapitulation	Summarize what the patient has said so far to ensure correct interpretation.
Facilitation	Encourage the patient to speak freely without guiding responses or leading questions. Allow the patient to ask questions throughout the encounter.

Establishing rapport

PEARLS

Partnership	Work together with patient to identify primary concerns and develop preferred solutions.
Empathy	Acknowledge the emotions displayed and demonstrate understanding of why the patient is feeling that way.
Apology	Take personal responsibility when appropriate.
Respect	Commend the patient for coming in to discuss a problem, pushing through challenging circumstances, keeping a positive attitude, or other constructive behaviors.
Legitimization	Assure patient that emotional responses are understandable or common.
Support	Reassure patient that you will work together through difficult times and offer appropriate resources.

Delivering bad news

SPIKES

Setting	Offer in advance for the patient to bring support. Eliminate distractions, ensure privacy, and sit down with the patient to talk.
Perception	Determine the patient's understanding and expectations of the situation.
Invitation	Obtain the patient's permission to disclose the news and what level of detail is desired.
Knowledge	Share the information in small pieces without medical jargon, allowing time to process. Assess the patient's understanding.
Emotions	Acknowledge the patient's emotions, and provide opportunity to express them. Listen and offer empathetic responses.
Strategy	If the patient feels ready, discuss treatment options and goals of care. Offer an agenda for the next appointment. Giving control to the patient may be empowering. Ask how they feel a problem might be solved and what they would like to do about the plan of action.

Gender- and sexuality-inclusive history taking

Avoid making assumptions about sexual orientation, gender identity, gender expression, and behavior (eg, a patient who identifies as heterosexual may engage in same-sex sexual activity). Use gender-neutral terms when referring to the patient or the patient's family (eg, "partner" rather than "husband" or "wife") upon first meeting the patient until the patient instructs otherwise or uses specific pronouns. A patient's assigned sex at birth and gender identity may differ. Do not bring up gender or sexuality if it is not relevant to the visit (eg, a gender-nonconforming patient seeking care for a hand laceration). Consider stating what pronouns you use when you introduce yourself (eg, "I'm Dr. Smith, and I use she/her pronouns") and asking patients how they would like to be addressed. Also consider ways of being inclusive (eg, ensuring correct name and pronouns are in the electronic medical record). Reassure them about the confidentiality of their visits and be sensitive to the fact that patients may not be open about their sexual orientation or gender identity to others in their life. Remember: trust is built over time, and listening to and learning from patients about how they would like to approach the topics discussed above is key.

Cultural formulation interview

Identify the problem through the patient's perspective. Ask the patient to describe the problem in their own words, or how the patient would describe the problem to their family and friends. Identify cultural perceptions of factors leading to a problem. Ask the patient to explain why they think they are experiencing their problem. Identify how the patient's background influences their problem. Ask the patient about what makes their problem better or worse. Investigate roles of family, community, and spirituality. Identify how culture may impact current and future interventions. Ask the patient if they have any concerns or suggestions about the current plan of treatment. If they do not want to follow medical advice, investigate if there is a way to combine their plans with the standard medical regimen. Identify possible barriers to care based on culture. Ask the patient if there is anything that would prevent them from seeking care in a standard medical institution. Probe for explanations and what may increase the chance of maintaining a good patient-physician relationship.

Motivational interviewing

Counseling technique to facilitate behavior modification by helping patients resolve ambivalence about change. Useful for many conditions (eg, nicotine dependence, obesity). Helpful when patient has some desire to change, but it does not require that the patient be committed to making the change. May involve asking patients to examine how their behavior interferes with their life or why they might want to change it. Assess barriers (eg, food access, untreated trauma) that may make behavior change difficult. Assessing a patient's readiness for change is also important for guiding physician-suggested goals. These goals should be **S**pecific, **M**easurable, **A**chievable, **R**elevant, and **T**ime bound (**SMART**).

Trauma-informed care

Patients with history of psychological trauma should receive thorough behavioral health screenings. Regularly assess mood, substance use, social supports, and suicide risk. Focus assessments on trauma-related symptoms that interfere with social and occupational function. Always be empathetic. Do not ask invasive questions requiring the patient to describe trauma in detail. Ask permission prior to discussion. Before the physical exam, reassure patients that they may signal to end it immediately if they experience too much physical or emotional discomfort. Offer the presence of additional staff for support. Psychological counseling may be indicated. Follow-up counseling is offered (or advised) as appropriate. Remember **4 R**'s: **R**ealize, **R**ecognize, **R**espond, **R**esist retraumatization.

Challenging patient and ethical scenarios

The most appropriate response is usually one that is **patient-centered**, open-ended, and empathetic; acknowledges the **obstacles** in care; and **validates** emotions. It often honors one or more of the principles of autonomy, beneficence, nonmaleficence, and justice. Appropriate responses are respectful of patients and other members of the healthcare team. Consider the patient's **point of view**.

SITUATION	APPROPRIATE RESPONSE
Patient does not follow the medical plan.	Determine whether there are financial, logistical, or other obstacles preventing the patient's adherence. Do not coerce the patient into adhering or refer the patient to another physician. Schedule regular follow-up visits to track patient progress.
Patient desires an unnecessary procedure.	Attempt to understand why the patient wants the procedure and address underlying concerns. Do not refuse to see the patient or refer to another physician. Avoid performing unnecessary procedures.
Patient has difficulty taking medications.	Determine what factors are involved in the patient's difficulties. If comprehension or memory are issues, use techniques such as providing written instructions, using the teach-back method, or simplifying treatment regimens.
Family members ask for information about patient's prognosis.	Avoid discussing issues with relatives without the patient's permission.
A patient's family member asks you not to disclose the results of a test if the prognosis is poor because the patient will be "unable to handle it."	Explore why the family member believes this would be detrimental, including possible cultural factors. Explain that if the patient would like to know information concerning care, it will not be withheld. However, if you believe the patient might seriously harm self or others if informed, you may invoke therapeutic privilege and withhold the information.
A 17-year-old is pregnant and requests an abortion.	Many states require parental notification or consent for minors for an abortion. Unless there are specific medical risks associated with pregnancy, a physician should not sway the patient's decision for, or against, an elective abortion (regardless of patient's age or fetal condition). Discuss options for terminating the pregnancy and refer to abortion care, if needed.
A 15-year-old is pregnant and wants to raise the child. The patient's parents want you to tell the patient to give the child up for adoption.	The patient retains the right to make decisions regarding the child, even if the patient's parents disagree. Provide information to the teenager about the practical aspects of caring for a baby. Discuss options for terminating the pregnancy, if requested. Encourage discussion between the patient and parents to reach the best decision.
A terminally ill patient requests physician-assisted dying.	The overwhelming majority of states prohibit most forms of physician-assisted dying. Physicians may, however, prescribe medically appropriate analgesics even if they potentially shorten the patient's life.
Patient is suicidal.	Assess the seriousness of the threat. If patient is actively suicidal with a plan, suggest remaining in the hospital voluntarily; patient may be hospitalized involuntarily if needed.
Patient states that you are attractive and asks if you would go on a date.	Use a chaperone if necessary. Romantic relationships with patients are never appropriate. Set firm professional boundaries with direct communication. Transition care to another physician if necessary.
A woman who had a mastectomy says she now feels "ugly."	Find out why the patient feels this way. Do not offer falsely reassuring statements (eg, "You still look good").
Patient is angry about the long time spent in the waiting room.	Acknowledge the patient's anger, but do not take a patient's anger personally. Thank the patient for being patient and apologize for any inconvenience. Stay away from efforts to explain the delay.
Patient is upset with treatment received from another physician.	Suggest that the patient speak directly to that physician regarding the concern. If the problem is with a member of the office staff, reassure the patient you will speak to that person.

Challenging patient and ethical scenarios (continued)

SITUATION	APPROPRIATE RESPONSE
An invasive test is performed on the wrong patient.	Regardless of the outcome, a physician is ethically obligated to inform a patient that a mistake has been made.
A patient requires a treatment not covered by insurance.	Discuss all treatment options with patients, even if some are not covered by their insurance companies. Inform patient of financial assistance programs.
A 7-year-old boy loses a sister to cancer and now feels responsible.	At ages 5–7, children begin to understand that death is permanent, all life functions end completely at death, and everything that is alive eventually dies. Provide a direct, concrete description of his sister's death. Avoid clichés and euphemisms. Reassure the boy that he is not responsible. Identify and normalize fears and feelings. Encourage play and healthy coping behaviors (eg, remembering her in his own way).
Patient is victim of intimate partner violence.	Ask if patient is safe and help devise an emergency plan if there isn't one. Ask patient direct, open-ended questions about exam findings and summarize patient's answers back to them. Ask if patient has any questions. Do not necessarily pressure patient to leave a partner or disclose the incident to the authorities (unless required by state law).
Patient wants to try alternative or holistic medicine.	Explore any underlying reasons with the patient in a supportive, nonjudgmental manner. Advise the patient of known benefits and risks of treatment, including adverse effects, contraindications, and medication interactions. Consider referral to an appropriate complementary or alternative medicine provider.
Physician colleague presents to work impaired.	This presents a potential risk to patient safety. You have an ethical and usually a legal obligation to report impaired colleagues so they can cease patient care and receive appropriate assistance in a timely manner. Seek guidance in reporting as procedures and applicable law vary by institution and state.
Patient's family insists on maintaining life support after brain death has occurred, citing patient's movements when touched.	Gently explain to family that there is no chance of recovery, and that brain death is equivalent to death. Movement is due to spinal arc reflex and is not voluntary. Bring case to appropriate ethics board regarding futility of care and withdrawal of life support.
A pharmaceutical company offers you a sponsorship in exchange for advertising its new drug.	Reject this offer. Generally, decline gifts and sponsorships to avoid any conflict of interest. The AMA Code of Ethics does make exceptions for gifts directly benefitting patients; special funding for medical education of students, residents, fellows; grants whose recipients are chosen by independent institutional criteria; and funds that are distributed without attribution to sponsors.
Patient requests a nonemergent procedure that is against your personal or religious beliefs.	Provide accurate and unbiased information so patients can make an informed decision. In a neutral, nonjudgmental manner, explain to the patient that you do not perform the procedure but offer to refer to another physician.
Mother and 15-year-old daughter are unresponsive and bleeding heavily, but father refuses transfusion because they are Jehovah's Witnesses.	Transfuse daughter, but do not transfuse mother. Emergent care can be refused by the healthcare proxy for an adult, particularly when patient preferences are known or reasonably inferred, but not for a minor based solely on faith.
A dependent patient presents with injuries inconsistent with caretaker's story.	Document detailed history and physical. If possible and appropriate, interview the patient alone. Provide any necessary medical care. If suspicion remains, contact the appropriate agencies or authorities (eg, child or adult protective services) for an evaluation. Inform the caretaker of your obligation to report. Physicians are required by law to report any reasonable suspicion of abuse, neglect, or endangerment.
A pediatrician recommends standard vaccinations for a patient, but the child's parent refuses.	Address any concerns the parent has. Explain the risks and benefits of vaccinations and why they are recommended. Do not administer routine vaccinations without the parent's consent.

Communicating with patients with disabilities

Patients may identify with person-first (ie, “a person with a disability”) or identity-first (ie, “a disabled person”) language. Ask patients what terms they use.

Under most circumstances, talk directly to the patient. Do not assume that nonverbal patients do not understand. Accompanying caregivers can add information to any discussion as needed. Ask if assistance is desired rather than assuming the patient cannot do something alone. Most people, including people with disabilities, value their independence.

For patients with speech difficulties, provide extra time for the interview. If their speech is difficult to understand, consider asking them to write down a few words or ask them to rephrase their sentence. Repeat what they said to ensure you understood it correctly.

For patients with a cognitive impairment, use concrete, specific language. Ask simple, direct questions. Eliminate background noise and distractions. Do not assume the patient can read. Adjust to how the patient understands best (eg, use hand gestures or ask them to demonstrate a task).

Ask patients who are deaf or hard of hearing their preferred mode of communication. Use light touch or waving to get their attention. For patients who prefer to speak and lipread, eliminate background noise, face the patient, and do not change your mode of speaking. Consider using an interpreter when necessary.

As with other parts of a medical history, do not bring up a disability if it is not relevant to a visit (eg, a patient in a wheelchair with an ear infection). Do not skip relevant parts of the physical exam even if the disability makes the exam challenging.

Use of interpreters

Visits with a patient who speaks little English should utilize a professionally trained medical interpreter unless the physician is conversationally fluent in the patient’s preferred language. If an interpreter is unavailable in person, interpretation services may be provided by telephone or video call. If the patient prefers to utilize a family member, this should be recorded in the chart.

Do not assume that a patient is a poor English speaker because of name, skin tone, or accent. Ask the patient what language is preferred.

The physician should make eye contact with the patient and speak to them directly, without use of third-person statements such as “tell him.”

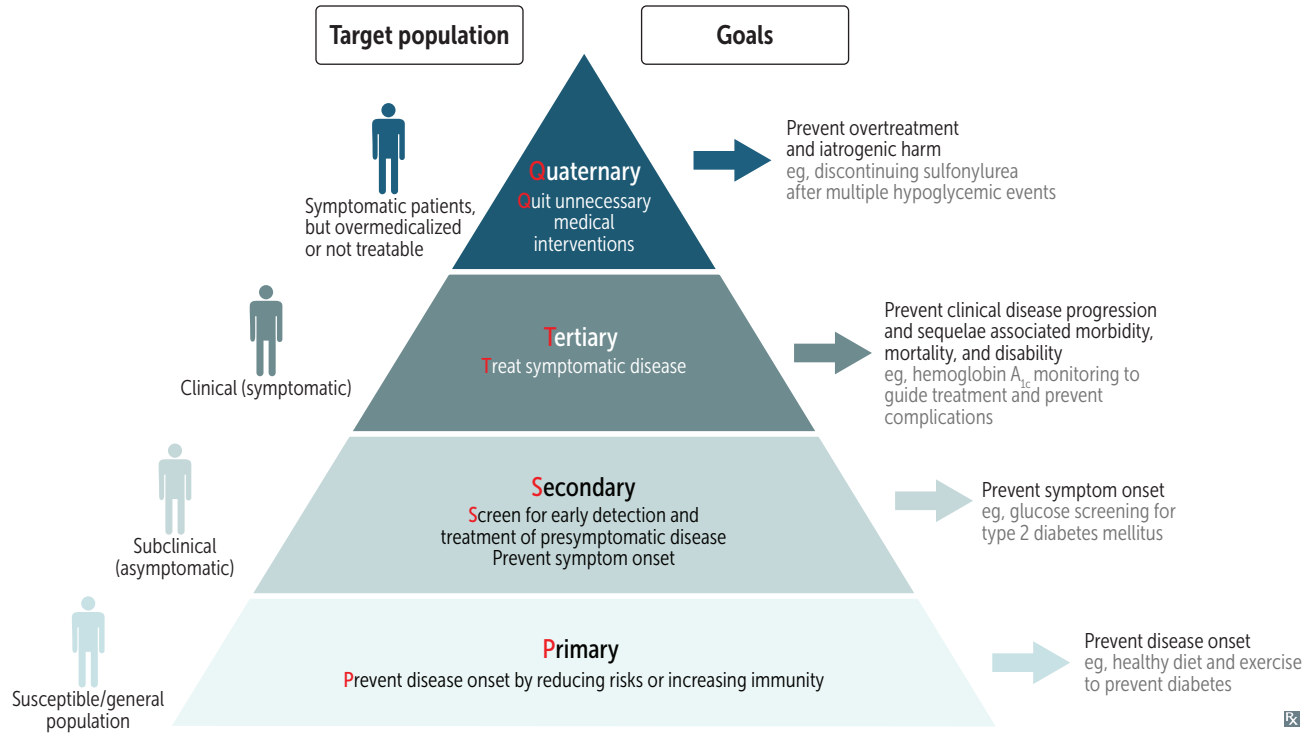
Allow extra time for the interview, and ask one question at a time.

For in-person spoken language interpretation, the interpreter should ideally be next to or slightly behind the patient. For sign language interpretation, the interpreter should be next to or slightly behind the physician.

In cases of emergency, facilitate communication by any tools available (eg, friends, family, sketches, interpreter apps) even though they do not comprise standard procedure otherwise.

► PUBLIC HEALTH SCIENCES—HEALTHCARE DELIVERY

Disease prevention



Major medical insurance plans

Exclusive provider organization (EPO)	Requires in-network care; out-of-network coverage available for emergencies.
Health maintenance organization (HMO)	Lower premiums, limited to in-network providers, requires primary care referral for specialists, lower out-of-pocket cost.
Point of service (PoS)	Combination of HMO and PPO, allows out-of-network care at higher cost, and requires primary care referrals.
Preferred provider organization (PPO)	Flexibility with in-network and out-of-network care, higher cost for out-of-network services, no referral requirement.
Accountable care organization (ACO)	Group of providers who voluntarily coordinate care for Medicare patients.
High deductible health plan (HDHP)	Low premiums, high out-of-pocket cost, compatible with health savings account (HSA).

Healthcare payment models

Bundled payment	Healthcare organization receives a set amount per service, regardless of ultimate cost, to be divided among all providers and facilities involved.
Capitation	Physicians receive a set amount per patient assigned to them per period of time, regardless of how much the patient uses the healthcare system. Used by some HMOs.
Discounted fee-for-service	Insurer and/or patient pays for each individual service at a discounted rate predetermined by providers and payers (eg, PPOs).
Fee-for-service	Insurer and/or patient pays for each individual service.
Global payment	Insurer and/or patient pays for all expenses associated with a single incident of care with a single payment. Most commonly used during elective surgeries, as it covers the cost of surgery as well as the necessary pre- and postoperative visits.

Medicare and Medicaid

Medicare and Medicaid—federal social healthcare programs that originated from amendments to the Social Security Act. Medicare is available to patients ≥ 65 years old, < 65 with certain disabilities, and those with end-stage renal disease. Medicaid is joint federal and state health assistance for people with limited income and/or resources.

Medicar**E** is for **E**lderly.
Medicai**D** is for **D**isadvantaged.

The 4 parts of Medicare:

- Part **A**: hospital **A**dmissions, including hospice, skilled nursing
- Part **B**: **B**asic medical **b**ills (eg, physician fees, diagnostic testing)
- Part **C**: (parts A + B = **C**ombo) delivered by approved private **c**ompanies
- Part **D**: prescription **D**rugs

Palliative care

Medical care aiming to provide comfort, relieve suffering, and improve quality of life in patients with complex or life-threatening illness regardless of their diagnosis or prognosis. Often concurrent with curative or life-prolonging treatment. Delivered by interdisciplinary team (eg, physicians, nurses, social workers) in hospitals, outpatient clinics, or at home. **Hospice care** (end-of-life care)—form of palliative care for patients with prognosis ≤ 6 months when curative or life-prolonging treatment is no longer wanted or beneficial.

Types of medical errors

	May involve patient identification, diagnosis, monitoring, healthcare-associated infection, medications, procedures, devices, documentation, handoffs. Medical errors should be disclosed to patients, independent of immediate outcome (harmful or not).	
Active error	Occurs at level of frontline operator (eg, wrong IV pump dose programmed).	Immediate impact.
Latent error	Occurs in processes indirect from operator but impacts patient care (eg, different types of IV pumps used within same hospital).	Accident waiting to happen.
Never event	Adverse event that is identifiable, serious, and usually preventable (eg, scalpel retained in a surgical patient's abdomen).	Major error that should never occur. Sentinel event —a never event that leads to death, permanent harm, or severe temporary harm.
Near miss	Unplanned event that does not result in harm but has the potential to do so (eg, pharmacist recognizes a medication interaction and cancels the order).	Narrow prevention of harm that exposes dangers.

Medical error analysis

	DESIGN	METHODS
Root cause analysis	Retrospective approach. Applied after failure event to prevent recurrence.	Uses records and participant interviews (eg, 5 whys approach, fishbone/cause-and-effect diagrams, process maps) to identify all the underlying problems (eg, process, people, environment, equipment, materials, management) that led to an error.
Failure mode and effects analysis	Forward-looking approach. Applied before process implementation to prevent failure occurrence.	Uses inductive reasoning to identify all the ways a process might fail and prioritizes them by their probability of occurrence and impact on patients.

Causes of medical errors

Burnout	Prolonged, excessive stress leading to emotional exhaustion, depersonalization, leading to reduced professional efficacy.
Fatigue	Sleep/rest deprivation resulting in cognitive impairment and decreased attention to detail.

SECTION III

High-Yield Organ Systems

“Symptoms, then, are in reality nothing but the cry from suffering organs.”
—Jean-Martin Charcot

“Man is an intelligence in servitude to his organs.”
—Aldous Huxley

“When every part of the machine is correctly adjusted and in perfect harmony, health will hold dominion over the human organism by laws as natural and immutable as the laws of gravity.”
—Andrew T. Still

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