USMLE

Step 1 lecture Notes

Psychiatry

SMASHUSMLE REVIEWS
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SMASH USMLE Step 1 High Yield Review

(First Edition)

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SMASH USMLE Step 1 High Yield Review

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-This book is dedicated to the Almighty God, the Master physician, entrepreneur, author and finisher of my faith.

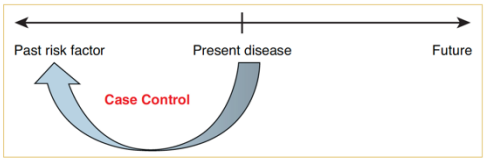
-To my lovely wife and children, Olufunmilayo, Olamide and Oluwadamola, and my parents, for your love and encouragement.

Chapter 4

Behavioral Sciences step 1 notes

Clinical Studies

Case Control Studies

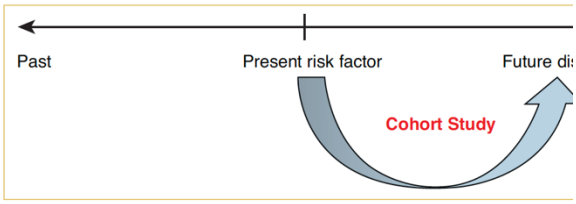


- Study that compare 2 groups of people, those with a disease or condition under the study against a suitable comparison group without the disease or condition
- Considered as retrospective study
- Very useful for studying conditions with very low incidence or prevalence

Examples

- Compares cases of treatment-resistant TB with those of nonresistant TB
- Patients with COPD had higher odds of a smoking history than those without COPD.
- A study trying to show that people who smoke (the attribute) are more likely to be diagnosed with lung cancer (the outcome), the cases would be persons with lung cancer, the controls would be persons without lung cancer (not necessarily healthy), and some of each group would be smokers. If a larger proportion of the cases smoke than the controls, that suggests, but does not conclusively show, that the hypothesis is valid.

Cohort Studies



- Population group of those who have been exposed to risk factor is identified and followed over time and compared with a group not exposed to the risk factor.
- Cohort studies can be retrospective (looking back in time, thus using existing data such as medical records or claims database) and ask who develop the disease or prospective (requiring the collection of new data) and ask who will develop the disease
- Can determine incidence and causal relationships and must follow population long enough for incidence to appear.

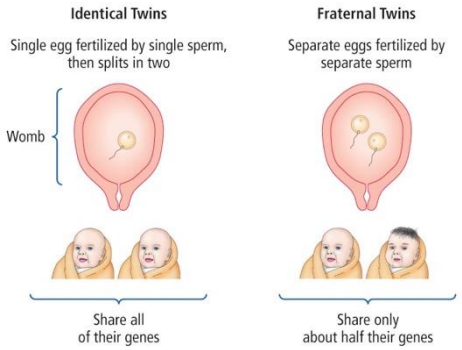
$$RR = \frac{\text{Incidence in exposed group (risk factor)}}{\text{Incidence in unexposed group (no risk factor)}}$$

Relative risk

- Comparative probability asking, “How much more likely?
- Done by calculating the IR of the exposed group divided by the IR of the unexposed group.
- How much greater chance does one group have of contracting the disease compared with the other group?

Cross sectional studies

- The presence or absence of disease (and other variables such as the frequency of the disease and frequency of risk factors) are determined in each member of the study population or representative sample at a particular time
- Disease prevalence, not incidence, is recorded
- Can used to describe the absolute and relative risk
- The effect of hyperlipidemia (Risk factor) on coronary artery disease



Twin concordance study

- Compares the frequency with which both monozygotic twins vs both dizygotic twins develop the same disease.
- Study the importance of genetic and environmental factors on individuals Used to describes behavioral genetics and psychology.
- Measures heritability and influence of environmental factors (“nature vs nurture”).

Adoption Study

- Adoption studies are meant to evaluate genetic and environmental influences on phenotype.
- Typically used in combination with twin studies when making habitability estimates
- Compares siblings raised by biological vs adoptive parents.

Randomized controlled clinical trial

- Used to test the effectiveness of new treatment
- subjects are randomly allocated into "intervention" and "control" groups to receive or not receive an
an experimental/preventive/therapeutic procedure or intervention.
- The randomness in the assignment of subjects to groups reduces selection bias and allocation bias, balancing both known and unknown prognostic factors, in the assignment of treatments

Cross over study

- A cross-over study is one in which, for ethical reasons, no group involved can remain untreated.
- Crossover designs are common for experiments in psychology, pharmaceutical science, and medicine.
- All subjects receive the intervention but at different times

Example:

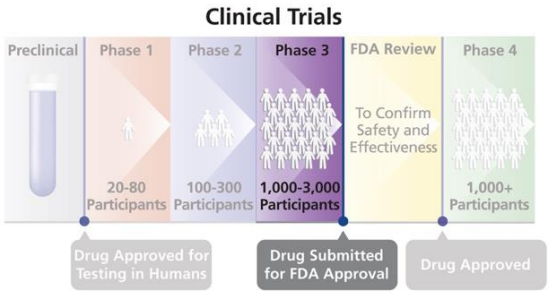
- Group A receives X treatment for 3 months while group B is the control.
- For the second 3 months, group B receives X treatment and group A is the control.

Meta-analysis studies

- Meta-analysis is the statistical procedure for combining data from multiple studies.
- When the treatment effect (or effect size) is consistent from one study to the next, meta-analysis can be used to identify this common effect.
- Compensate for poor research

Clinical Trial
Definition

- Researchers design clinical trials to answer specific research questions related to a medical product including drug safety and efficacy
- Clinical trials often conducted when bringing new drug into the market
- Clinical trials follow randomized controlled clinical trial (RCT) and it usually double blinded studies
- In this case the subjects are randomized into 2 groups "intervention or control group"
- Being double blinded to decrease any possible bias
- A control group (often the placebo group) will includes subjects who do not receive the drug under investigation
- The control group is used as a source of comparison to be certain the experiment group is being affected by the intervention and not by other factors.
- For a medical product to receive approval by the Food and Drug Administration (FDA)



Phases of Clinical Trials.

1. Preclinical trials
2. Request for new drug application to be tested in human
3. Phase 1 Studies
4. Phase 2 Studies
5. Phase 3 Studies
6. Submission of new drug application (Asking FDA to consider the drug for marketing approval
7. Phase 4 studies

Preclinical studies

- Studies are done on experimental animals or human cells to test for a prove of concept of a new target
- These studies tended to evaluate:

1. Drug pharmacodynamics in vivo and In vitro
2. Pharmacokinetics (Absorption, distribution and elimination)
3. Toxicity profile
4. Therapeutic index (Safety and efficacy evaluation)

- If the screening is successful, the agency will send a request for FDA asking for approval to start testing in humans (Investigational New Drug Application IND)

Phase I

- The first trial to be conducted in human
- Used to test drug pharmacokinetics, dynamics and safety
- Performed in a small subject number (healthy volunteers)
- Used to test the maximum tolerated dose (MTD) of the new treatment
- Note: In some case Phase 0 might exit to perform micro dosing studies before starting phase I trial in healthy subjects in order to get a preliminary data regarding pharmacokinetics

Phase II

- Named as Therapeutic exploratory trials
- Testing with a larger group of people (typically 100–300) to determine efficacy and to further evaluate its safety
- Usually performed against a placebo
- Aim to establish dose efficacy relationship, duration of therapy, frequency of administration and therapeutic window
- Phase II clinical trials can de divided into

Phase IIa	Phase IIb
• Early phase	• Late phase
• 20-200 patients	• 50-300 patients
• Comparison with standard drug	• Comparison with a placebo or standard drug

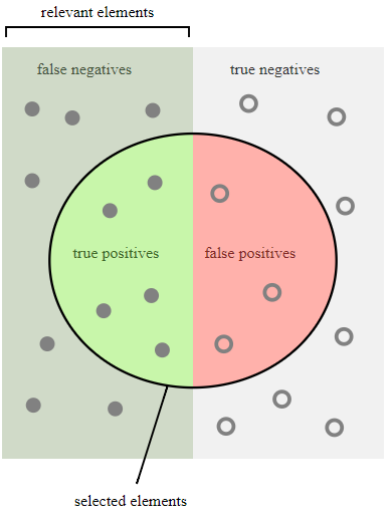
Phase III

- Named as therapeutic confirmatory trial
- Performed on large groups of people 1000-3000 to confirm drug efficacy and monitor side effects
- To determine efficacy of the drug against already proved therapy
- Takes a long time up to 5 years
- If the drug shows efficacy in comparison of the already approved drugs the sponsor will send a request for FDA to approve a new drug application

Phase IV

- Post-marketing studies delineate risks, benefits, and optimal use.
- Help to understand possible adverse effects and drug-drug interaction
- The objective of these studies to provide more assurance regarding safety and efficacy on a large population during practice
- Figure out over dosing and the possibility of identifying new indications

Evaluation of diagnostic test (sensitivity)



Definition

- Diagnostic test: Medical test that provides some evidence for presence or absence of a pathology
- Four outcomes of a diagnostic test:

1. True positive (TP) If you order a test and comes positive for the disease
2. False positive (FP) The patient does not have the disease, but the test comes back positive
3. True negative (TN) If you order a test for a disease and comes negative for the disease (patient does not have the disease)
4. False negative (FN) The patient has the disease, but the test comes negative.

- Uses data of 2X2 table

	Have the disease	Don´t have the disease
+	TP	FP
-	FN	TN

Sensitivity (True positive rate) definition:

The proportion of people who test positive and have the disease

OR

The proportion of truly diseased persons in the screened population who are identified as diseased by the screening test

OR

The probability that the test detects a disease actually when the disease is there

- Named as rule out test because it rule out the disease
- Sensitivity = TP/ (TP+FN)

- True positives/ (True positives false negatives)
- High sensitivity means in case of a negative result indicates the absence of the disease

Problem based learning

200 patients are enrolled in a study to evaluate the accuracy of a new ELISA based test for influenza. 100 patients were diagnosed with influenza by the reference standard culture of respiratory secretion. 80 of those patients with Influenza had a positive ELISA based test as did 5 patients without Influenza. Calculate sensitivity?

- Total number of patients 200

	Have influenza	Don´t have influenza
+	80	5
-	20	95
Total	100	100

- SN= 80/ 80+20= 80/100= 80%
- These values mean that from 100 patient have the disease the test was able to diagnose about 80 people with the disease
- SN= 1-FN (0) = 1-0 =1
- Sensitivity test for low prevalence diseases
- A mnemonic for the clinical use of sensitivity is SN-N-OUT (sensitive test-negative-rules out disease).

Example adapted from Clinical tests: sensitivity and specificity. BJA education 2008

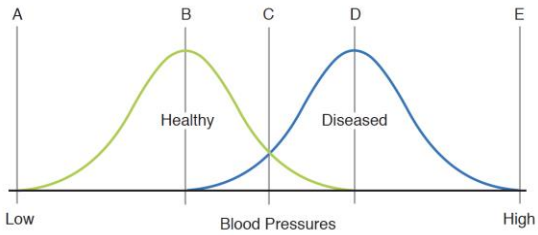
A test with 100% sensitivity correctly identifies all patients with the disease. A test with 80% sensitivity detects 80% of patients with the disease (true positives) but 20% with the disease go undetected (false negatives). A high sensitivity is clearly important where the test is used to identify a serious but treatable disease (e.g. cervical cancer). Screening the female population by cervical smear testing is a sensitive test. However, it is not very specific and a high proportion of women with a positive cervical smear who go on to have a colposcopy are ultimately found to have no underlying pathology.

Sensitivity and Specificity Graph Overview

Gold standard

	Have disease	Don´t have disease	
+	TP (True Positive)	FP (False Positive)	Positive predictive value →
-	FN (False Negative)	TN (True Negative)	Negative predictive value →
	↓ Sensitivity	↓ Specificity	

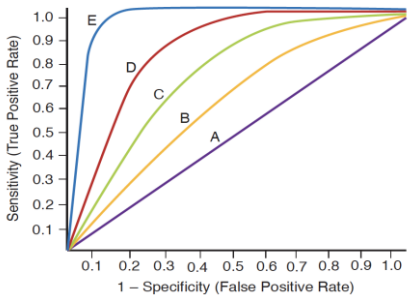
Double Hump graph



- Cutoff point B has the highest sensitivity which correctly identifies all the sick patients
- Cutoff D would be the most specific test (it identifies only sick people).
- Cutoff C where the 2 curves intersect is the most accurate.

How to determine the best screening test

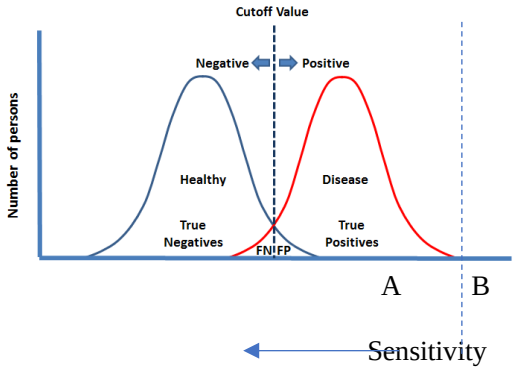
- Curve E achieves the highest sensitivity (y-axis) without including too many false-positives (x-axis).



Validity of screening test

- Sensitivity: The ability of a test to identify correctly those who have the disease or true positives.

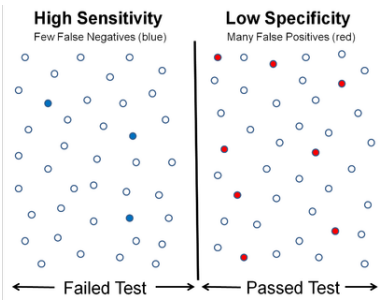
- Specificity: the ability of a test to identify correctly those who do not have a disease or true negatives



Specificity

- A= 100% sensitivity cutoff vale
- B= Practical compromise between specificity and sensitivity
- C= 100% specificity cutoff value

Specificity



Specificity (True negative rate) definition:

- The proportion of all people without disease who test negative

OR

- The probability of correctly identifying disease-free persons.
- Used as a confirmatory test after a positive screening test
- SP= TN/(TN+FP)
- Measures only the distribution of persons who are disease-free
- If a test has a high specificity, then a positive result indicates the existence of the disease

Problem based learning

200 patients are enrolled in a study to evaluate the accuracy of a new ELISA based test for influenza. 100 patients were diagnosed with influenza by the reference standard culture of respiratory secretion. 80 of those patients with Influenza had a positive ELISA based test as did 5 patients without Influenza. Calculate sensitivity?

- Total number of patients 200

	Have influenza	Don´t have influenza
+	80	5
-	20	95
Total	100	100

- SP= 95/ 95+5= 95/100= 95% specific
- SP= 1-FP rate
- A test with a high sensitivity but low specificity results in many patients who are disease free being told of the possibility that they have the disease and are then subject to further investigation
  so If FP=0 the SP becomes 100 % that reduces the rate of false positive

Sensitivity VS Specificity

	Sensitivity	Specificity
Definition	Proportion of patients with a disease who test positive	Proportion of patients without the disease who test negative
100% (1.0) Means	The test correctly identify every person who has the target disorder	The test correctly identify every person who does not have the target disorder
Statistical Outcome	True Positive	True Negative
Ideal Test Result	Negative Test Result	Positive Test Result
Test Interpretation	They are definitely not positive → They DON'T have it	They are definitely not negative → They DO have it
The Rule	Rule Out (SnOut)	Rule In (SpIn)

Positive and Negative Predictive values Overview

- Predictive value reflects the diagnostic power of a test
- High PV+ indicates a strong chance that a person with a positive test has the disease
- High PV- means that a negative test in effect rules out the disease

Positive Predictive Value (PPV).

- What is the chance or the given the probability that given a positive test, the patient has the disease
- The probability of disease in a person who receives a positive test result.
- PPV measures only the distribution of persons who receive a positive test result.

	Have disease	Don´t have disease
+	TP	FP
-	FN	TN

PVD= TP/(TP+FP)

- Positive predictive value focuses on subjects with a positive screening test in order to ask the probability of disease for those subjects.

Problem based learning

200 patients are enrolled in a study to evaluate the accuracy of a new ELISA based test for influenza. 100 patients were diagnosed with influenza by the reference standard culture of respiratory secretion. 80 of those patients with Influenza had a positive ELISA based test as did 5 patients without Influenza

	Influenza	No Influenza
+	80	5
-	20	95

PVD= 80/ (80+5) = 80/85= 94%

- Among those who had a positive screening test, the probability of disease was 94%

Negative Predictive Value (PPV).

- What is the chance or probability that a patient does not have the disease given a negative test
- NPV= TN/ (TN+FN) (True negative)/(True negative+ false negative)

	Have disease	Don´t have disease
+	TP	FP
-	FN	TN

- Based on the previous example:
- Negative predictive value focuses on subjects with a negative screening test in order to ask the probability that subjects with a negative test are truly not diseased.

	Influenza	No Influenza
+	80	5
-	20	95

- NPV= 95/ (20+95) = 95/115=83%
- False negative rate= 20/ (20+95) =17%= 1-NPV
- Among those who had a negative screening test, the probability of being disease-free was 83%.

Calculating odds and risks

Definitions.

- "Risk" refers to the probability of occurrence of an event or outcome. Statistically, risk = chance of the outcome of interest/all possible outcomes.
- The term "odds" is often used instead of risk. "Odds" refers to the probability of occurrence of an event/probability of the event not occurring

Exposure /risk factor	Yes	NO
Yes	a	b
NO	c	d

- Exposure to risk factor might be:

1. Advantageous in case of treatment
2. Or Not: in case of carcinogens

- (A) means you got exposed so you get the disease
- Outcome> Exposure
- Risk (exposed group) = a/(a+b)
- Risk (unexposed group) = c/(c+d)

Risk difference

Absolute Risk Reduction (ARR):

- when the risk of an outcome is decreased by the exposure OR reduction in incidence of associated with treatment compared to the control group.
- ARR= Risk in the control group - Risk in the Treatment group.
- Example:
- In a study case, 5% of patients on statin had MI. 9% of those on placebo develop MI.
- One got exposed to statin and another to placebo and the outcome remains same- MI
- ARR = 9% - 5% = 4%
- Risk of MI is reduced by 4% in those who take statins.
- The incidence of MI is reduced by 4%.

Attributable risk (AR):

- is the difference between the risk of an outcome in the exposed group and the unexposed group.
- AR = risk in exposed- risk in unexposed= a/(a+b) - c/(c+d)

Example:
9% exposed to asbestos- bronchogenic carcinoma
2% without exposure- bronchogenic carcinoma
AR = 9% - 2% = 7%

Number needed to treat (NNT):

- The Number Needed to Treat (NNT) is the number of patients you need to treat to prevent one additional bad outcome (death, stroke, etc.).

- To calculate the NNT, you need to know the Absolute Risk Reduction (ARR); the NNT is the inverse of the ARR: NNT= (1/ARR)

Example:

- Example if ARR of statin therapy is 4% so NNT = ¼% = 25
- We need to treat 25 people with statin to prevent MI in one patient.
- The smaller the number to treat the better the medication.

Number needed to harm (NNH):

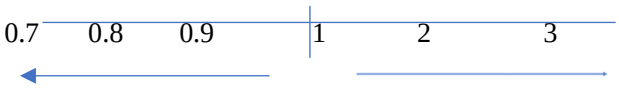
- How many persons on average need to be exposed to a risk factor over a specific period to cause harm in an average of one person who would not otherwise have been harmed.
- 1/Attributable risk = 1/0.02 = 50

Relative risk used in cohort studies

- The ratio of the probability of an outcome in an exposed group to the probability of an outcome in an unexposed group.

- Risk ratio measures the association between the exposure and the outcome.

$$RR = \frac{\text{Incidence in exposed group (risk factor)}}{\text{Incidence in unexposed group (no risk factor)}} = \frac{a/(a+b)}{c/(c+d)}$$



Beneficial treatment or exposure (Negative outcome)

Harmful treatment

Examples

- 21% of smokers- lung cancer
- 1% non-smokers – lung cancer
- RR = 21%/ 1% =21
- Smokers are 21 times more likely to develop lung cancer than non-smokers.

- 50% of diabetic pts develop CVD
- 10% of control develop CVD
- RR= 50%/10% = 5

- Diabetics are 5 more times likely to develop CVD than the rest of the population.

Relative Risk Reduction (RRR)

- Is the relative decrease in the risk of an adverse event in the exposed group compared to an unexposed group

$$\frac{\text{Risk in unexposed-Risk in the exposed population}}{\text{Risk of unexposed}} = \frac{c/(c+d) - a/(a+b)}{c/(c+d)}$$

Example

- 5% of pts on statins develop MI
- 9% pts on placebo develop MI
- RRR = 9 – 5/9= 4/9 = 0.44 or 44%

Odds ratio

- Used in case control studies
- Measure of association between an exposure and an outcome.
- Definition: the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure.

OR

- Odds that group with diseases (cases) was exposed to a risk factor divided by the odss that the group w/o the disease (control) was exposed.

$$OR = \frac{a/c}{b/d} = \frac{ad}{bc}$$

$$OR = \frac{(n)\text{ exposed cases}/(n)\text{ unexposed cases}}{(n)\text{ exposed non-cases}/(n)\text{ unexposed non-cases}} = \frac{(n)\text{ exposed cases} \times (n)\text{ unexposed non-cases}}{(n)\text{ exposed non-cases} \times (n)\text{ unexposed cases}}$$

- a = Number of exposed cases
- b = Number of exposed non-cases
- c = Number of unexposed cases
- d = Number of unexposed non-case

- OR > 1 = Increase likelihood of an event in exposed group
- OR <1 = Decrease likelihood
- OR = No difference between the exposed group & control group

Example:

- Researcher conducts a case-control study to determine risk of lymphoma due to CT scans. 100 people were selected with Lymphoma, 180 people W/O lymphoma were selected as control. 5 patients with lymphoma had received a CT scan at some point their life. 2 pts without lymphoma had received a CT scan. Calculate CT scan-

	Lymphoma	
CT scan	a 5	b 2
	C 95	d 98

$\frac{5 \times 98}{2 \times 95} = 490/180 = 2.6$

- Those who had CT scans are 2.6 more likely to develop lymphoma than those who were not exposed to CT scans.

Incidence and Prevalence

Incidence

- Measurement of the number of new individuals who contract a disease during a particular period of time.

Incidence rate= $\frac{\text{Number of new cases in specific time period}}{\text{Population at risk at this time period}}$

- Used when working with infectious diseases such as TB and malaria

- Example: In a population of 5000 that is studied over 10 years 500 news cases of Ebola are reported. Hence incidence rate = 500/5000= 10%

Prevalence

- Measurement of all individuals (new and old) affected by the disease at a particular time

Prevalence rate= $\frac{\text{Number of existing cases}}{\text{Population at risk}}$

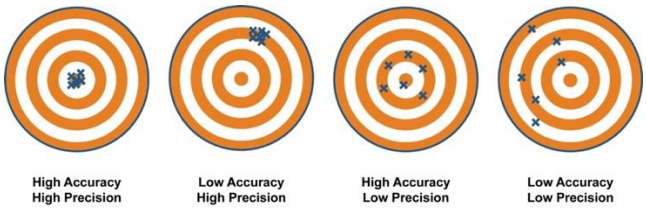
- 5000/50000= 10%

- Incidence rate is higher in acute diseases, while prevalence rate is greater than incidence rate in chronic infectious diseases

Precision and accuracy

Precision VS Accuracy

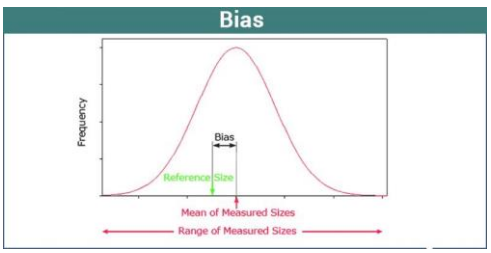
- precision is the ability of a test to measure something consistently. Think of the clustering of rifle hots at a target (reliability).
- Accuracy is the degree to which a test measures that which was intended known also as Validity



- Precision measures how close measurements are to each other
- Accuracy measures how close result is to the truth
- Random error ↓ precision in a test.
- ↑ precision lead to ↓ standard deviation.
- ↑ precision ↑ statistical power $(1 - \beta)$.
- Systematic error ↓accuracy in a test.

Bias

Outline:



Bias

- Deviation from the truth of inferred results Due to systematic error or favor particular direction
- Bias is a statistical term which means a systematic deviation from the true value.
- It is a sampling procedure that may show some serious problems for the researcher as it cannot be reduced by mere increase in sample size.
- Bias is the difference between the expected value and real value of the parameter.

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Types of Bias

Selection bias (Sampling bias)- Berkson bias

- Type of bias caused by choosing non-random data for statistical analysis
- Case-control studies are susceptible to selection bias, as both the exposure and disease/outcome have occurred by the time the patient is recruited into the study
- In case control studies, selection bias can occur in the selection cases if they are not representative of all cases within the population, or in the selection of controls if they are not representative of the population that produced the cases
- They lack external validity.

Examples:

- Like you pay money to people who are low in their socioeconomic status and enroll them for study and then collect data and try to generalize it on the rest of the population
- Heart disease being studied in a population that does not subjects above 65 years of age.
- Predicting rates of heart disease by gathering subjects from a local health club
- Using only hospital records to estimate population prevalence (Berkson bias)
- Including people in a study who are different from those who are not included (nonrespondent bias)

Solution:

- Random sampling should be done to eliminate sampling bias.
- Independent sample; weight data

Recall bias

- Subjects fail to accurately recall events in the past, that is going to influence the course of your study.
- Recall bias is a problem in studies that have self-reporting, such as case-control study and retrospective cohort studies

Example

- Non-smokers with lung cancer report significant exposure to second-hand smoke as a child

Solution

- Conduct a prospective study or confirm objective sources of information.

Sampling bias

- Sampling bias occurs when a sample statistic does not accurately reflect the true value of the parameter in the target population
- Sampling bias can also occur if sample is too small to represent the target population
- To ensure that a sample is representative of a population, sampling should be random, i.e. every subject needs to have equal probability to be included in the study.
- In sampling bias, results in a biased sample, a non-random sample of a population (or non-human factors) in which all individuals, or instances, were not equally likely to have been selected
- Medical sources sometimes refer to sampling bias as ascertainment bias.
- Ascertainment bias has basically the same definition, but is still sometimes classified as a separate type of bias

Late-look bias

- When there is late-look bias, individuals with severe disease are less likely to be uncovered in a survey because they die fir it.
- Information that was gathered too late to make useful conclusions.
- Patients are severely incapable or dying during the study.

Example:

- Survey of patients with pancreatic cancer shows patients with minimal symptoms as they are too sick to respond, or they die during the survey.

Solution

- Stratify by disease severity

Procedure bias (Experimental bias)

- A process where the scientists performing the research influence the results, in order to portray a certain outcome
- When patients or investigators decide on treatment assignment, can lead to extremely large biases.
- The investigator may consciously or subconsciously assign particular treatments to specific types of patients.

For example:

- One group of patients receives surgical intervention, however, the other group didn´t get any surgical intervention
- Randomization is the primary design feature that removes this bias.

Attrition bias

- Systematic error caused by unequal loss of participants from a randomized controlled trial (RCT).
- Patients start to drop off during the study

Example 1:

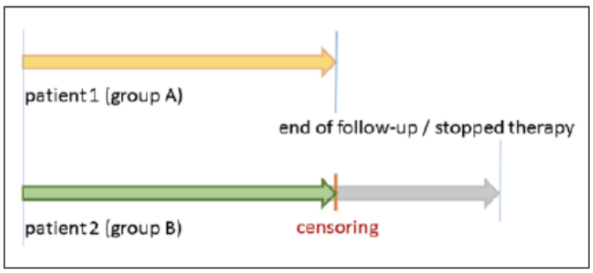
- Study group for a drug to reduce acne, from 200, 120 pts drop off because the drug was not working.
- Remaining 80 of them find that the Drug is working in reducing their acne.

Example 2:

- in an intervention study of diet in people with depression, those with more severe depression might find it harder to adhere to the diet regimen and therefore more likely to leave the study.

Solution

- Gather as much data from the patients who have dropped out.



Confounding bias

- A situation in which the effect or association between an exposure and outcome is distorted by the presence of another variable
- Confounder: an extraneous variable that wholly or partially accounts for the observed effect of a risk factor on disease status. The presence of a confounder can lead to inaccurate results.

Example 1

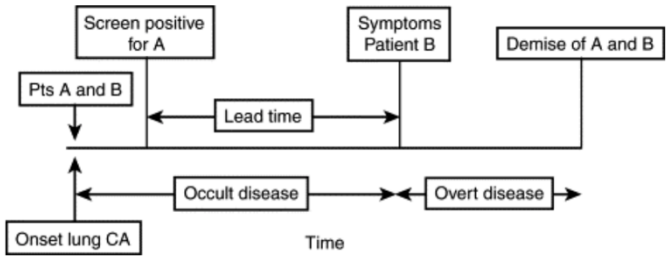
- Study done to find the link between the drinking coffee and lung cancer
- Usually drinking coffee is associated with heavy smokers, so smoking is considered a confounding variable

Example 2

- Compare the relationship between exercise and heart disease in 2 populations when one population is younger and the other is older. Are differences in heart disease due to exercise or to age?

Example 3

- Pulmonary disease is more common in coal workers than the general population; however, people who work in coal mines also smoke more frequently than the general population



Solution

- Multiple studies
- Matching
- Meta-analysis

Lead time bias

- Lead-time bias gives a false estimate of survival rates, e.g., patients seem to live longer with the disease after it is uncovered by a screening test
- False impression of improved survival in a screened population without affecting mortality, because the cancer is diagnosed earlier in the natural history of the disease, but the patient still dies of the cancer

Example

- At the age of 75 years a man came with back pain and was diagnosed of prostate cancer and died after about 5 years at the age of 80.
- If that man at the age of 60 underwent PSA test and found that the level was more than 24 and had undergone treatment and died at the age of 80 after 20 years
- We conclude wrongly that it was because of PSA test the patient survived for another 20 years.

Solution

- Adjust survival based on the severity of the disease
- Use life-expectancy to assess benefit.

Observer expectancy effect

- Researcher's belief in the efficacy of a treatment changes the outcome of that treatment (aka, Pygmalion effect)
- In research, experimenter bias occurs when experimenter expectancies regarding study results bias the research outcome

Solution

- Use double-blind design, where neither the subject nor the investigators know which group receives the intervention.

Hawthorne effect

- The bias that happens when people change their behavior during the study
- Is a type of reactivity in which individuals modify an aspect of their behavior in response to their awareness of being observed.

Example

- You inform the patient that they are being given a drug to reduce BP and being studied for that. The patient modifies his lifestyle so that the BP lowers.

Solution

- Add a placebo group.

Susceptibility bias

- Type of selection bias where treatment regimen is selected for a patient based on the severity of their condition without taking into account other possible confounding variables.

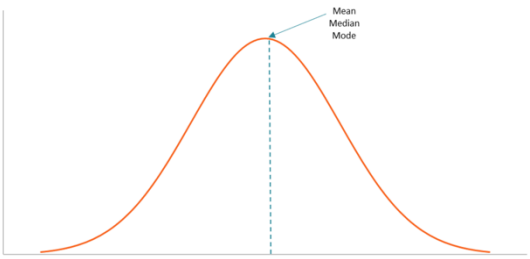
Example

- CAD patients managed surgically compared with the others who receive medical management.

Solution

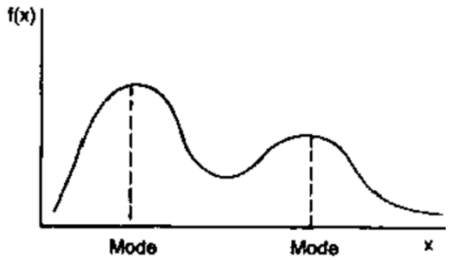
- Randomize patients and place them both in medical and surgical arm of the study.

Statistical distribution



Definitions

- If you have a sample 1,1,2,4,5,7,7,25
- Mean: sum of the values of the observations divided by the numbers of observations, 52/8= 6.5
- Mode: most frequently occurring value in a set of observations 1,7

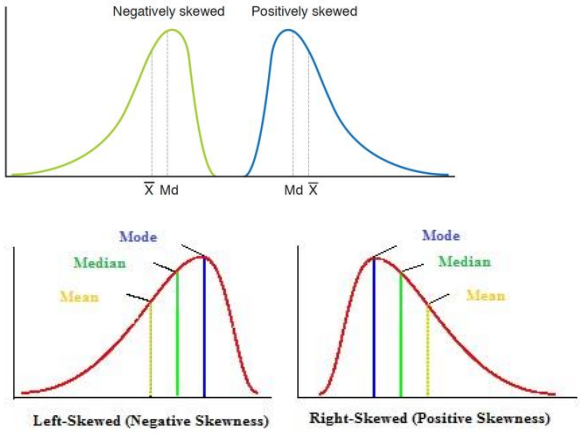


- Median: point on the scale which divides a group into 2 parts (upper and lower half); the measurement below which half the observations fall is 50th percentile (4+5)/2= 9/2= 4.5

Normal bell curve (Gaussian curve)

- The peak of the curve corresponds to the mean of the dataset (note that the mean in the normal probability distribution also equals the median and the mode).

Positive and Negative skew

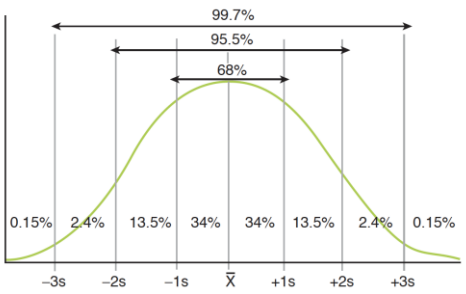


- A positive skew has the tail to the right, and the mean greater than the median - Mean>Median>Mode

A negative skew has the tail to the left, and the median greater than the mean-Mean<Median<Mode.

Standard deviation

- Standard deviation: Average distance from the curve
- SD measures the variability within a single sample
- Example: sample set (1,2,3,4,5)
- Number= 5
- Mean= 3
- Standard deviation = (2+1+0+1+2)/5= 1.2



- When you are value 1 SDs from the mean 65%
- When you are value 2 SDs from the mean 95%

- When you are value 3 SDs from the mean 99%

Standard error

- Estimates the variability between samples
- The smaller the standard error, the better and more precise the study.
- The greater the SD, (high variation in the data), the greater the standard error, and the larger the sample size, the smaller the standard error.

Standard error of mean (SEM)

- is a method used to estimate the standard deviation of a sampling distribution.

Standard Error of Sample Mean

$$\sigma_{\bar{x}} = {}^{\sigma}/_{\sqrt{n}}$$

σ is the standard deviation of population.
n is the size of the sample

Statistical Hypothesis

Null Hypothesis

- The hypothesis of No association between two variables. No association between the risk and outcome.
- Null hypothesis justify that the findings are the result of chance or random factors
- The hypothesis says that observed difference is entirely due to sampling error
- Use to establish the basis for calculating the probability that the difference occurred purely of chance.

Alternative Hypothesis (H1)

- alternative hypothesis is one in which a difference (or an effect) between two or more variables is anticipated by the researchers; that is, the observed pattern of the data is not due to a chance occurrence
- It is usually taken to be that the observations are the result of a real effects

H1

H0

H1	Power 1-B	Alpha Type 1 error
H0	B Type 2 error	Correct

Example

- A study to compare the action of metronidazole with a placebo on giardia.
- Null hypothesis says no increased rate of resolution.
- Alternative hypothesis says the contrary.

Steps for testing a hypothesis:

1. A NULL HYPOTHESIS suitable to problem is set up
2. An alternate hypothesis is defined, if necessary.
3. A suitable statistical test, using a relevant formula is calculated.
4. The degree of freedom is determined.

- Then we determine P value:
- The p-value is a standard against which we compare our results.
- The probability value (P value) correspond to the calculated value of test and its degree of freedom
- If $p \leq 0.05$, reject the null hypothesis (reached statistical significance).
- If $p > 0.05$, do not reject the null hypothesis (has not reached statistical significance).

Type I error (α)

- Rejecting the null hypothesis when it's really true
- Known as false alarm, type 1 error, false positive error
- Example: Use of Vitamin C improves the recovery of URT infection patients. Reality- it does not
- The chance of type I error is given by the p-value
- P <0.05 means there is less than 5% of chance that the data will show something that is not really there.
- Alpha = probability of making type 1 error

Type II error (β)

- Failing to reject the null hypothesis when it is really false
- The chance of a type II error cannot be directly estimated from the p-value
- Known as false negative error, type 2 error
- There was a difference which you did not get.
- You missed the difference and you were blinded.
- Beta= Probability of making type 2 error.
- β is related to statistical power ($1 - \beta$), which is the probability of rejecting the null hypothesis when it false
- You can increase the power and decrease β value by:
- ↑ Sample size
- ↑ expected effect size
- ↑ precision of measurement

Note:

- A type I error (error of commission) is generally considered worse than a type II error (error of omission)
- If the null hypothesis is rejected, there is no chance of a type II error.
- If the null hypothesis is not rejected, there is no chance of a type I error.

Core ethical principles

Patient autonomy

- The patient has the right to refuse or choose their treatment. Autonomy can be defined as the ability of the person to make his or her own decisions.
- Autonomy can be defined as the ability of the person to make his or her own decisions
- Also, autonomy refers to obligation to respect patients as individuals (truth-telling, confidentiality)
- Patient autonomy does allow for health care providers to educate the patient but does not allow the health care provider to make the decision for the patient

Beneficence

- Explain how physicians provide positive steps such as prevention, removal of harm to the patient
- Beneficence involves balancing the benefits of treatment against the risks and costs involved

Nonmaleficence

- Non-harming or inflicting the least harm possible to reach a beneficial outcome
- If a surgery or treatment procedure poses more harm than benefit to the patient, then it is better not to be done.

Justice

- The patients should be fairly and equitably treated

Informed consent

Overview:

- The process of communication between a patient and physician that results in the patient's authorization of agreement to undergo a specific medical intervention (American Medical Association)
- Failure to obtain informed consent renders any physician liable for negligence or battery and constitutes medical malpractice.

When informed consent is required

- The patient must be informed in cases of surgery, anesthesia, other invasive or radiological procedure
- The patient should be able to understand and make a decision
- The patient should be able to understands the risk/ benefit for any procedure
- Benefits: Such as recovery time
- Risks: Inform the patient about all possible risks that the patient may have to face- like puncture of neighboring carotid artery in this example. This may lead to increase bleeding. There are chances for pneumothorax.
- The patient should know the diagnosis if possible
- It is necessary to let the patient know the purpose of a proposed treatment or procedures
- The alternatives regardless of cost
- Indication of the procedure- Tell the patient why the procedure is being done.
- Nature of the procedure- the patient should be informed about the procedural steps.

Exceptions

- An emergency in which medical care is needed immediately to prevent serious or irreversible harm
- Incompetence in which someone is unable to give permission (or to refuse permission) for testing or treatment
- Waiver- Patient comes up personally and says that he does not want to know about the procedure and asks the doctor to do what is best.
- Therapeutic privilege- If we tell something to the patient, he may commit suicide, so rather not tell him about it.
- Note: Patient cannot demand unnecessary treatment from the physician and the doctor cannot carry on with the same treatment if it has failed already.

Consent for Minors

Overview

- The general rule is that minors are not capable of giving consent for medical treatment.
- As a result, the consent of a minor for medical treatment is ineffective, and the physician must secure the consent of the minor's parent or other person standing in loco parentis prior to treating the minor.

Minor

- A minor is generally any person < 18 years old.

Emancipated minors

1. When a minor is validly married;
2. When an individual reaches the age of 18 years;
3. During the period when the minor is on active duty with the armed forces
4. Self-supporting
5. Has children

Parental consent is not required for the following cases

6. Emergency situation
7. Prescribing oral contraceptives
8. Treating STDs
9. Medical care in pregnancy
10. Drug addiction

Decision-making capacity

Decision capacity

- The ability of health care subjects to make their own health care decisions.
- You must not assume that because a patient lacks capacity to make a decision on a particular occasion,
- Capacity is to use that information in making the decision – a person should be able to weigh up the pros and cons of making the decision. Communicate their decision – if a person cannot communicate their decision – for example, if they are in a coma – the Act specifies that they should be treated as if they lack capacity.

How to asses capacity?

- Understand the information relevant to the decision;
- Retain that information;
- Use or weigh up that information as part of the process of making the decision;
- Communicate their decision by talking, using sign language or other means of communication.

Components of decision-making capacity

- Decision is consistent with patient's values and Goals
- Patient is Informed (knows and understands)
- Patient Expresses a choice
- Decision is not a result of altered Mental status (eg, delirium, psychosis, intoxication), Mood disorder
- Decision remains Stable over time
- Patient is ≥ 18 years of Age or otherwise legally emancipated

Confidentiality

- Confidentiality is the right of an individual to have personal, identifiable medical information kept private.
- Such information should be available only to the physician of record and other health care and insurance personnel as necessary

Exceptions to patient confidentiality

- If there is a serious risk to the patient or another person
- Potential physical harm to others is serious and imminent
- Likelihood of harm to self is great
- No alternative means exist to warn or to protect those at risk
- Physicians can take steps to prevent harm
- Although physicians must always maintain confidentiality about their patients. Psychologists can (or must) break confidentiality, and take other appropriate actions, as warranted, if:

1. You are a danger to yourself and threaten to harm yourself (e.g., suicidal).
2. You threaten to harm another specific person (e.g., assault, kill).
3. Children/ elderly abuse
4. Epileptic patients and other impaired automobile drivers.
5. Reportable diseases HIV, Syphilis, Chlamydia, (Anthrax, small box), Hepatitis A, B, C, Rabes, lymes and tularemia
6. Preventable diseases Measles, mumps, rubella, varicella

Healthcare

Standard insurance

- The insurance company helps patient pay for health care in exchange for a periodic payment by patient (premium) and patient shares in payment by means of Deductible, Copayment and Blue Cross Blue Shield

HMO health maintenance organization

- Limited insurance provider that provide medical care for fixed annual fee
- is a prepaid group practice that either hires physicians or contracts with physicians to provide services.
- Physicians are paid for the number of patients they are responsible for, not for how much they do for each patient
- Physicians make money when patients stay well and do not need to use services.
- HMOs often require members to select a primary care physician (PCP), a doctor who has a direct access to medical services. PCPs are usually internists, pediatricians, family doctors, geriatricians, general practitioners (GPs)

PPO Preferred provider organization

- Network of providers supply discounted treatment for plan members
- Its most common type of health plan
- The network includes physicians, hospitals with negotiated discounts
- PPO network of physicians no referral needed

Government methods of payments for services

Medicare

- Program pays health care costs for the elderly (age >65), disabled, and dependents of disabled.

Types of Medicare

- Part A: pays for hospital care
- Part B: pays for physician services and basic medical bills (doctor´s fees, diagnostic testing)
- Part C: (parts A + B = Combo) delivered by approved private companies
- Part D: Prescription Drugs
- Everybody gets (A)but you have to opt for the others

Medicaid

- Medicaid payments to providers are generally far below standard fees (poor and immigrants)
- A joint state/federal program that covers all care, including hospital stays, physician services, medication, and nursing homes
- If poor and over age 65, Medicare is first used, then Medicaid

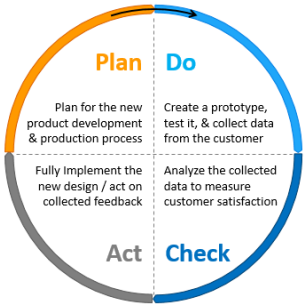
Compensation

- Fee for service
- Overtreat is pitfall
- Capitation fixed amount of money per patient Regardless test, time, healthy patient
- Capitation is a payment arrangement for health care service providers.
- It pays a set amount for each enrolled person assigned to them, per period of time, whether or not that person seeks care.

The role of human factor in health care

- Applying human factors to healthcare reduces medical errors and allows clinicians to deliver better care to their patients and that helps in:
- Improve patient safety and satisfaction
- Standardization improves process reliability (eg, clinical pathways, guidelines, checklists).
- Reduce clinician burnout
- Simplification reduces wasteful activities (eg, consolidating electronic medical records).
- Boost process efficiency
- Mitigate the risk of error

PDSA cycle



- Is shorthand for testing a change by developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act).

Quality measurements in health care

Outcome measures

- Measure impact on the patient such as mortality rates, readmissions rates, Average HbA1c of patients with diabetes and surgical site infection rates

Balancing measures

- These are the metrics a health system must track to ensure an improvement in one area isn't negatively impacting another area (impact on other systems and outcomes)
- Example: Incidence of hypoglycemia among patients who tried an intervention to lower HbA1c
- Financing
- Patient satisfaction

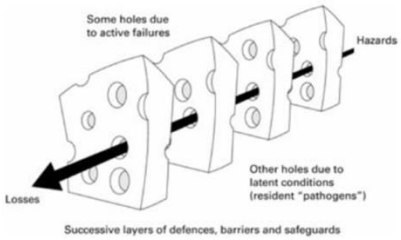
Processing measures

- Performance of system as planned
- Example:
- Reducing time in registration or rooming the patient
- Percentage of diabetic patients whose HbA1c was measured in the past 6 months

Structural measures

- Used to assess infrastructure of capacity, systems, and processes (Physical equipment, resources, facilities).

Swiss cheese model



- The swiss cheese accident causation model is a theoretical model used in risk analysis, risk management, and risk prevention.
- To explain the complex and layered health care system and how each healthcare workers could potentially prevent (and cause) medication errors
- According to this model, a series of barriers are in place to prevent hazards from causing harm to humans. However, each barrier, such as system alarms, administrative controls, surgeons, nurses, etc, has its unintended and random weaknesses, or holes, just like Swiss cheese.
- The presence of holes in one of the slices does not normally lead to a bad outcome; but when by chance all holes are aligned, the hazard reaches the patient and causes harm.

Types of medical errors

- The patient should be informed about any medical error might happen independent of immediate outcome (harmful or not).

- There are many ways that medical care can go wrong. Errors can be related to the administration of medications, adverse drug reactions, laboratory testing, surgery, and improper use or failure of medical devices

Active error

- Usually are human errors and involve individuals who are doing a task such as using the wrong IV pump dose programmed and the effect felt almost immediately

Latent error

- Occurs in processes indirect from operator but impacts patient care (eg, different types of IV pumps used within same hospital).

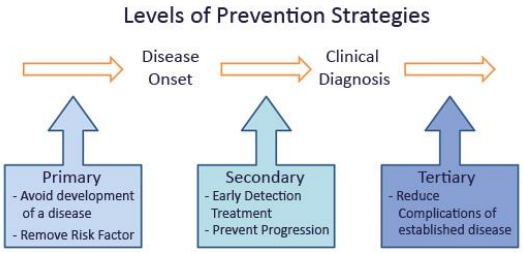
Medical error analysis

Retrospective approach: Applied after failure event to prevent recurrence.
Forward looking approach: Applied before process implementation to prevent failure occurrence.

Public health

Disease prevention strategies

Primary prevention:



- Primary prevention seeks to prevent the onset of specific diseases via risk reduction by enhancing resistance to the effects of exposure to a disease agent. HPV vaccination

Secondary prevention:

- Secondary prevention includes procedures that detect and treat preclinical pathological changes and thereby control disease progression. Screening procedures are often the first step to manage existing but asymptomatic disease (eg, Pap smear for cervical cancer)

Tertiary prevention:

- Tertiary prevention seeks to soften the impact caused by the disease on the patient's function, longevity, and quality-of-life. Chemotherapy

Quaternary prevention:

- Action taken to identify patient at risk of over-medicalization, to protect him from new medical invasion, and to suggest him interventions ethically acceptable. electronic sharing of patient records to avoid duplicating recent imaging studies

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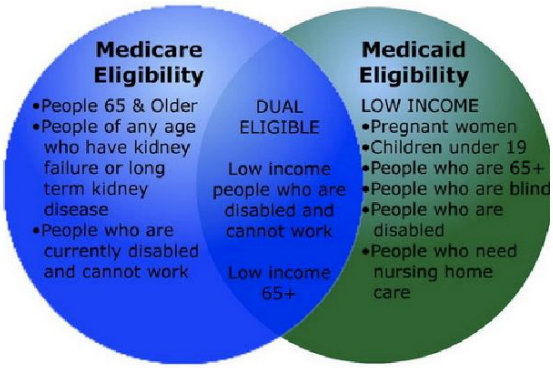
Medicaid and Medicare

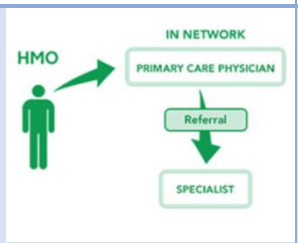
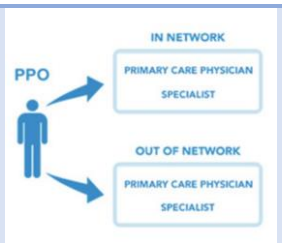
Medicaid	Medicare
Federally funded program	Federally funded program
Mainly benefits people who are > 65 years or < 63 but with disability, end stage renal failure	Poor or low income



Preventive medicine and Healthcare

Outline:

- HMO is a health insurance plan with a very low and affordable premiums and copayments
- Policyholders are obligated to select their health care professionals from a list of approved health care providers called PCP

HMO	PPO
	
1. Requires a primary care provider (PCP) 2. Needs referrer from PLP he could see a specialist 3. Less expensive 4. Smaller network 5. Must use network 6. Network is local	1. There is flexibility in selecting physicians 2. No need a referrer to see specialist between the managed network 3. More expensive 4. Larger network 5. Can go off network 6. Can move around

Disease prevention strategies

Primary prevention:

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Medical Malpractice

Definition

- Medical malpractice occurs when a physician fails to act as a reasonable physician would have acted under the circumstances
- The negligence might be the result of errors in diagnosis, treatment, aftercare or health management.
- For medical malpractice to be established, the patient must be able to prove the presence of the four Ds, which include negligence or deviation from the standard of care during medical practice by a physician.
- The four Ds of medical malpractice are:
- Duty to patient
- Derelict in Patient care negligence
- Direct cause
- Damages to patient