Structured Notes According to

PSM

Revision friendly **Fully Colored Book/Structured Notes**

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1. Phases of Clinical Trials — **Good to Know**

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Hills Criteria

1 DEFINITIONS, COMPONENTS AND TOOLS OF EPIDEMIOLOGY

Definition of Epidemiology

- Study of distribution and determinants of health – related states / events or disease in population groups and application of the study to control health problems

- Definition of epidemiology – Given by John M Last

Components Studied in Epidemiology

00:04:59

Disease Frequency	• Talks about the incidence (No. of new cases) and prevalence (No. of Existing cases) of a disease • Disease frequency is expressed in the form of 3 tools – Rate, Proportion and Ratio
Disease Distribution	• How disease is distributed according to time, place and person. ○ E.g. in the early stage of the incidence of COVID – 19 epidemiologists described it as pneumonia of unknown origin affecting during the winter months (Time) in Wuhan China (Place), in the male population (Person) working in bird markets in China. • Descriptive Epidemiology – Study of disease and its distribution according to time, place and person.
Disease Determinants	• Answer the 'why' and 'how' of the disease • Covered in Analytical epidemiology

Tools of Measurement in Epidemiology

00:10:14

Frequency of the cases is expressed in the form

- Rate = Numerator / Denominator × 1000 or 10,000 or 1,00,000
  - N is a part of D
- Proportion = Numerator / Denominator × 100
  - N is a part of D
- Ratio = Numerator / Denominator
  - N is not part of D

Rate

- It measures the occurrence of the event (disease or death) in a defined population in a defined time period.
- **Rate** = Numerator/Denominator × 1000 or 10,000 or 1,00,000

PYQ: FMGE 2020

Types of Rate

Crude rates	Specific rates	Standardized rates

• Unstandardized rates i.e. age and sex composition are not considered
  ○ Crude death rate (CDR) gives rates at which deaths are happening in a population.
  ○ Crude birth rate (CBR) gives rates at which births are happening in a population.
	• Age specific death rate
	• Cause specific death rate	

Proportion

- **Proportion** = Numerator/Denominator × 100
- For example,

PYQ: INICET 2021

$$Prevalence = \frac{Total\ no.of\ cases(old\ and\ new)}{Total\ population} \times 100$$

Ratio

- Ratio = $\frac{\text{Numerator}}{\text{Denominator}}$
  - N is Not part of D.

PYQ: NEET PG 2018

Example of ratio	• $Sex\ Ratio = \frac{No.of\ females}{No.of\ males} \times 1000$ • $Relative\ risk = \frac{Incidence\ of\ exposed}{Incidence\ of\ non\ exposed}$
Example of rate	• $Incidence\ rate = \frac{Total\ no.of\ new\ cases}{Total\ population\ at\ risk} \times 1000$
Example of proportion	$Case\ fatality\ rate\ (CFR) = \frac{Total\ no.\ of\ deaths\ due\ to\ disease}{Total\ cases\ of\ a\ disease} \times 100$

Incidence

00:23:12

PYQ: FMGE 2023

PYQ: AIIMS 2020

Definition	• No. of new cases of the disease or new spells or episodes of sickness occurring in a defined population during a specified time period. $Incidence\ rate = \frac{No.of\ new\ cases\ of\ a\ disease\ in\ a\ defined\ population\ during\ a\ specified\ time\ period}{Total\ population\ at\ risk} \times 1000$

High Yield Points	• Incidence measures the rate at which New cases occur. • Independent of the duration of the disease. • More important for a disease of acute onset • The primary level of prevention focuses on reducing the incidence of the disease • Cohort study calculates the incidence of a disease
MCQ	**Q.** Incidence of a disease in a population of 30,000 and 300 new cases is A. 0.1 per 1000 **B. 10 per 1000** C. 100 per 1000 D. 1 per 1000 **Explanation** Incidence = new cases/ total population at risk multiplied by 1000 = 300/ 30000 × 1000 = 10/ 1000 population
Special Incidence Rates	• Attack Rate used in an epidemic or outbreak of disease • Secondary attack Rate is used to measure the communicability or transmissibility of a disease.
Uses of the Incidence Rate	• Control of disease • Etiology, Pathogenesis and distribution of a disease. • Efficacy of preventive and therapeutic measures • Effectiveness of health services provided

Prelavance

00:30:27

PYQ: FMGE 2019, 2020

PYQ: INICET 2021

Definition	• It is the total number of all individuals who suffer from a disease. $\frac{Total\ no.\ of\ cases\ in\ a\ community\ at\ a\ point\ of\ time}{Total\ population\ of\ the\ community\ at\ the\ same\ point} \times 100$ • Prevalence is actually a proportion
MCQ	**Q.** In a population of 5000, the number of new cases of TB is 500; old cases in the same population are 150. What is the prevalence of TB? A. 9% B. 12% **C. 13%** D. 18% **Explanation**: Prevalence = Total cases/ Total population x 100 = 500+150/ 5000× 100 = 650/5000 multiplied by 100 = 13%

Measurement of Prevalence	**Point prevalence** $\frac{\textit{Total number of diseased persons in a defined population at one point of time}}{\textit{Total number of population at the same point of time}} \times 100$ • E.g. On April 30th, 2022 community A has a population of 10000 • 1000 current cases of hypertension so prevalence is 1000/10000 × 100 = 10%
	Period prevalence $\frac{\textit{Number of persons with an episode of illness over a defined period of time}}{\textit{Number of persons in the population over the same period}} \times 100$ • **Period prevalence** = Number of existing cases/ total population • E.g. During a particular time period (Jan 1 - June 30th, 2022) ○ Include existing cases on Jan 1st and those newly diagnosed until June 30th.

Difference between the Incidence and Prevalence 00:36:48

Incidence	Prevalence
• Probability or chances of developing a disease	• Probability or chances of already having a disease
• Includes only new cases	• Includes both old and new cases
• Follow up is required of the individuals in a population to identify new cases	• No follow up required
• Independent of the duration of illness	• Depends on the duration of the disease (P= I x D)
• Suited measure when studying cause and effect	• Suited measure in estimating the burden of a disease or attribute
• Calculated from cohort study	• Calculated from cross-sectional study

Relationship between the Prevalence and Incidence

Prevalence (P) = Incidence (I) X Duration (D)

Examples

- Effect on incidence and prevalence
  - New preventive modality launched – Incidence decreased
  - New treatment modality launched – Incidence same
  - Improvement in treatment – Cures the person, duration decreased, prevalence decreased
  - If a new drug is effective in reducing deaths from the disease but not curing – duration increased prevalence increased
  - If a new drug is effective in curing a disease – duration decreased, prevalence decreased

Use of Prevalence :

1. Burden of a disease can be assessed.
2. Resources can be directed for management of a disease.
3. Control the disease.

MCQs

Q. Following is true about incidence and prevalence

A. Both are rates
B. Prevalence is a rate but Incidence is not
C. **Incidence is a rate but Prevalence is not**
D. Both are not rates

Explanation: Since the multiplier is 100 so prevalence is a proportion.

Q. If the prevalence is very low as compared to the incidence for a disease, it implies?

A. Disease is very fatal and/or easily curable
B. The disease is nonfatal
C. Calculation of prevalence and incidence is wrong
D. Nothing can be said as they are independent

Explanation

- $P = I \times D$
- Duration decreased thus prevalence decreased

Q. All the statements are true about the disease except?

A. Incidence is the probability that a healthy individual will develop the disease during the specified period of time
B. The incidence will decrease if the new drug is effective in reducing deaths from the disease
C. Incidence measures the absolute risk of developing disease
D. The incidence decreases if a particular prevention program is effective

Explanation

- If a new drug is effective in reducing deaths from the disease but not curing people who continue to suffer from disease and continue transmitting it, the incidence will remain the same and the prevalence will increase.
- If a new drug is effective in curing a disease both incidence and prevalence will decrease.

Q. If a new effective treatment is initiated and other factors remain the same which of the following is most likely to happen

A. Incidence will not change
B. Prevalence will not change
C. Neither incidence or prevalence will change
D. Incidence and prevalence will change

Explanation:

- A new effective treatment is initiated and all other factors remain same, thus new cases will keep on occurring at the same rate therefore incidence will not change, however effective treatment will cure more cases so old cases will reduce therefore prevalence will reduce, however over long period of time incidence may also reduce if it is an infectious disease (as total case load in the community is decreasing).

Q. Improved prevention of acute, and nonfatal disease are likely to?

A. Decrease the prevalence of disease

B. Increase the prevalence of disease

C. Decrease the incidence of disease

D. Increase the incidence of disease

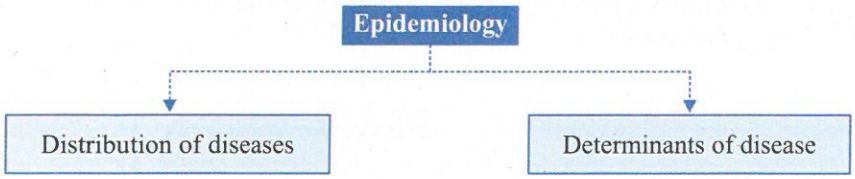
Explanation: As it is targeting the risk factor thus decreases the incidence of disease.

2 NEED, CLASSIFICATION, UNIT & APPROACH TO STUDY DESIGNS

Need of Study designs

00:01:20

- Epidemiology: Study of diseases.



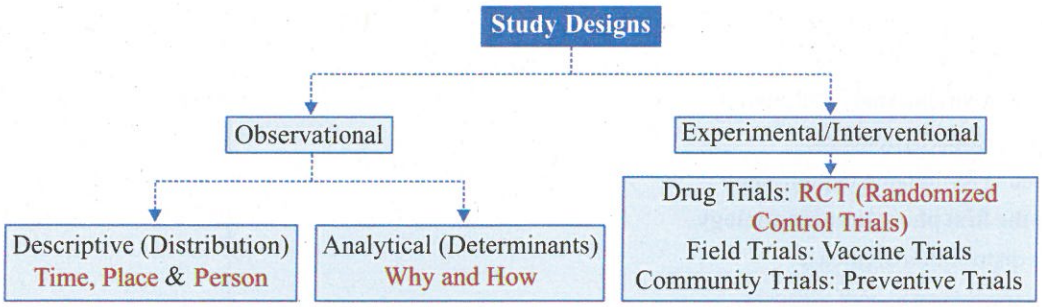
- Hypothesis: An assumption yet to be verified

The purpose of study designs

Formulate a Hypothesis	• A hypothesis is formulated when nothing is known about a new type of disease. • Done by Descriptive Epidemiology – Describing the disease in terms of Time, Place and Person when nothing is known. • For eg: In the case of COVID-19, in its initial stages, a hypothesis was formulated by terming it as a form of pneumonia.
Test a Hypothesis	• Answers the question: Why and How (a disease took place). • Deals with Analytical Epidemiology. • For eg: The people who suffered from COVID-19 were compared to people who did not suffer from COVID-19.
Confirm a Hypothesis	• The disease is confirmed by means of Experimental or Interventional Epidemiology. • For eg: After the confirmation of the COVID-19 virus, vaccines and drugs manufacturing took place.

Classification of Epidemiology Study Designs

00:07:38



Difference between Descriptive and Analytical Study

Descriptive Epidemiology	Analytical Epidemiology
• No Comparison Group	• A comparison group is always present
• **Examples:** Case Report & Case Series	• **Examples:** Case-Control study design, Cohort study design, Cross-Sectional study design, and Ecological study design.

Difference between Case Report and Case Series

Case Report	Case Series
• Case report pertains to a single individual.	• A Case Series is an aggregation or a collection of case reports.
• It is an individual case with a finding.	• It is an aggregation/collection of case reports that have similar findings.

Important Information

- Formulation of hypothesis: Descriptive epidemiology
- Testing of hypothesis: Analytical epidemiology
- Confirming of hypothesis: Experimental epidemiology

Q. Interventional Study is used for:

A. Hypothesis formation
B. Hypothesis testing
C. Hypothesis confirmation
D. Hypothesis manipulation

Q. Case series is a type of:

A. Descriptive study
B. Observational study
C. Analytical study
D. Interventional study

Q. Ecological study is a type of:

A. Descriptive study
B. Observational study
C. Analytical study
D. Interventional study

Q. The difference between Descriptive and Analytical studies.

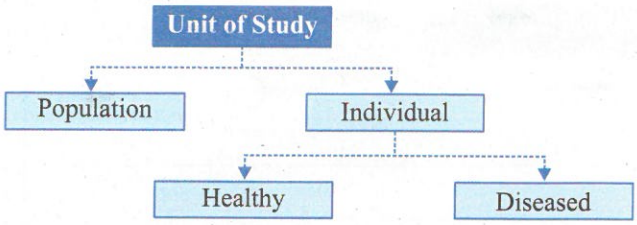
A. Descriptive studies are used to test hypothesis.
B. Analytical studies are used to formulate a hypothesis.
C. Descriptive studies are the first phase in epidemiology.
D. Analytic studies observe distribution of disease.
E. Descriptive studies answer why and how of a disease.

Important Information

Correlational	Ecological Study
Prevalence	Cross Sectional Study
Case Reference	Case Control Study
Incidence/follow up	Cohort Study

Unit of Study

00:24:14



Important Information

- All study designs have individuals as the unit of study except ecological study (unit of population: population)
- All study designs (case control/cohort/cross-sectional): Have individual as unit of study.
- Unit of study in RCT: Diseased individuals.

Q. The analytical study where the population is the unit of study is:

A. Cross-sectional
B. Ecological
C. Case-control
D. Cohort

Q. The best study of first choice for assessment of Unknown or New Disease with no etiological hypothesis

A. Cohort study
B. Case-control
C. Cross-sectional
D. Descriptive Epidemiology

Summary of Types of Epidemiological Studies

00:27:35

Observational Studies

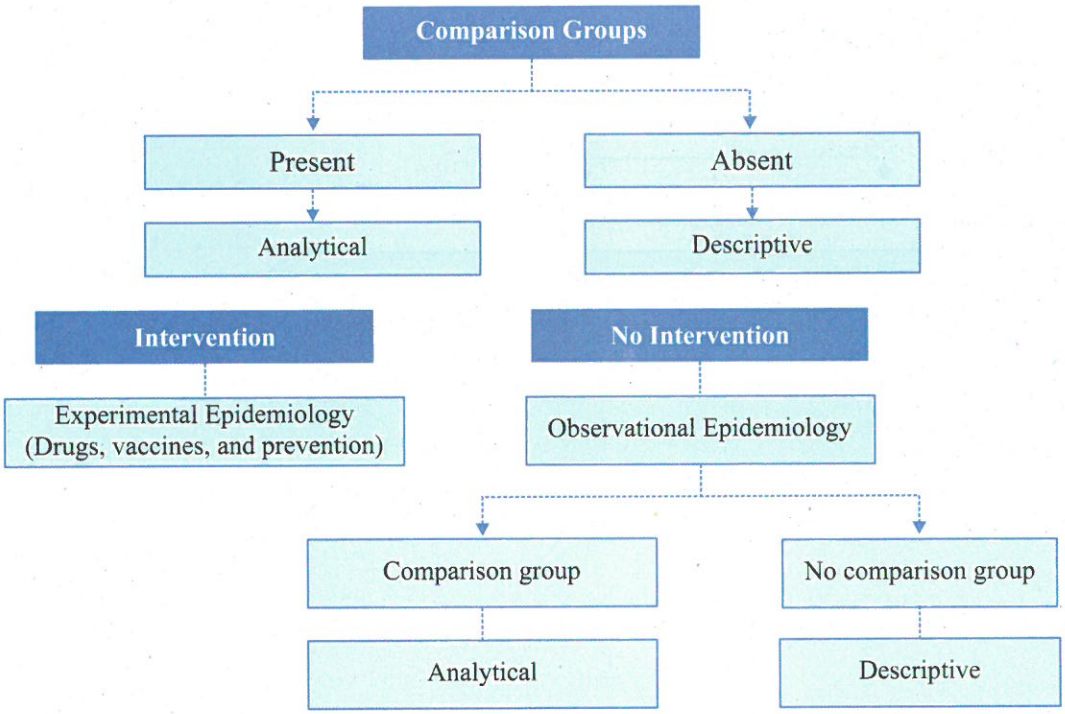
Types of studies	Alternative name	Unit of study
Descriptive studies Analytical studies	Case report, Case series	Individuals
Ecological	Correlation	Populations
Cross-sectional	Prevalence	Individuals
Cohort	Follow-up	Individuals

Experimental Studies

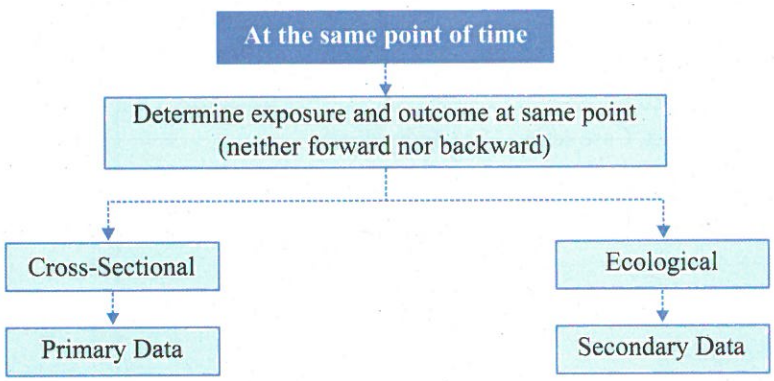
Types of studies	Alternative name	Unit of Study
Randomized Control Trials	• Clinical Trials	• Patients/Diseased Individuals
Field Trials (Vaccine Trials)	–	• Healthy People
Community Trials	• Community Studies	• Communities

Basic Approach to Identify Study Designs

00:29:21



- In case of Analytical Epidemiology, keep the following point in mind.
  - Start of the Study
  - Comparison: Exposed vs Non- Exposed (Cohort) or Diseased vs Non-diseased (Case-Control).
  - The direction of Arrow:
    - → Forward → Cohort
    - → Backwards → Case Control



Q. A total of 5000 patients of glaucoma are identified and surveyed by patient interviews regarding family history of glaucoma. Such a study design is called?

A. Case Series Report

B. Case-Control Study

C. Clinical Trial

D. Cohort Study

3 DESCRIPTIVE STUDY DISEASE DISTRIBUTION

Descriptive Epidemiology: Definition & concept

- Epidemiology: Study of distribution & determinants

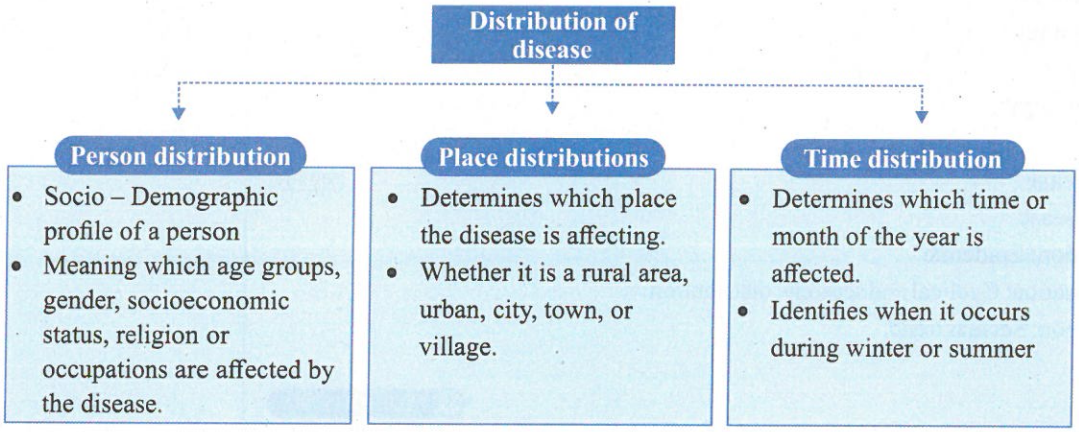
Definition of Descriptive Epidemiology

- Study of distribution of disease/health-related events & identification of characteristics associated with the disease.

Salient Features

00:04:00

- 1st phase of epidemiological investigation
- Helps in formulation of hypothesis: when the disease is new, or nothing is known about it.
- Helps in study distribution of disease: in terms of time (when), place (where), and person (whom).



Steps in Descriptive Study Design

00:08:32

Defining the population to be studied	• Sociodemographic profile of the population is defined.
	  ○ Age, gender, socioeconomic status etc.,
	• Certain essentialities that we demand in population
	  ○ Should be stable
	  ○ No migration
	  ○ Includes community participation - people of the community should come forward.
	  → Consider the entire population of the area or can take a sample of the population.
	  → In the second case, the sample should be representative of the population.

Defining the disease under study	• Clinical definition may not be specific; it can vary. • Epidemiologists should have clear-cut definitions, which should not change throughout the study. ○ All the eligibility criteria or Diagnostic criteria need to be specified.
Describing disease by	• Time - when • Place – where • Person - whom

Measurement of disease	• Mortality statistics • Morbidity statistics • Disability statistics
Comparing with known indices	• Compare what was the situation before and what is the situation now.
Formulation of an etiological hypothesis.	• Where the disease is happening in terms of time, place & person.

Q. Which study design helps us to formulate a hypothesis?
Ans. Descriptive Study Design

Q. Studying the distribution of disease or health-related characteristics in the human population and identifying characteristics with which disease seems to be associated is

A. Descriptive Epidemiology
B. Experimental epidemiology
C. Analytical epidemiology
D. Interventional epidemiology

Time Distribution of Disease

00:15:16

- In the occurrence of disease
  - Short-term fluctuation: Epidemic
  - Periodic term fluctuation: Cyclical and seasonal distribution
  - Long-term fluctuation: Secular trend.

Short-term fluctuation

PYQ: AIIMS 2018

PYQ: FMGE 2020

- Best example: Occurence of an epidemic.

Epidemic	• Occurrence of disease clearly in excess of normal expectancy.
	  ○ E.g. think about any disease 'X.' What is the normal expectancy of disease 'X"?
	  ○ Take an average or mean of the number of cases occurring in the previous or last 3-5 years.
	  ○ Mean = sum of all observations/ total no of observation.
	  ○ Can be said as: diseases occurs in frequency >2 S.D + mean or >80% of expected frequency.
	• Occurence of even a single case of previously eliminated disease: Epidemic.
	• Occurrence of a single case of an exotic disease. E.g., Yellow fever in India.

Endemic	• Constant presence of disease in a population. E.g., malaria, TB, etc. • Epidemiologically link cases in terms of time, place, or person.
Endemic vs Epidemic