

Individual are selected from a parent population using defined inclusion criteria.

* DIRECT METHOD

Priori / Posteriori Sampling

→ Both requires same set of successive steps, but the order of some of these operation differs depending on the mode of selection.

1st step: for producing reference value

Collection of quantitative information about the source of biological variation for analyte studies

It may be
controllable variable non-controllable variable

can be controlled by standardization of procedure for preparation of reference individuals & specimen collection

controlled by relevant positioning criteria.

* PRIORI STRATEGY :-

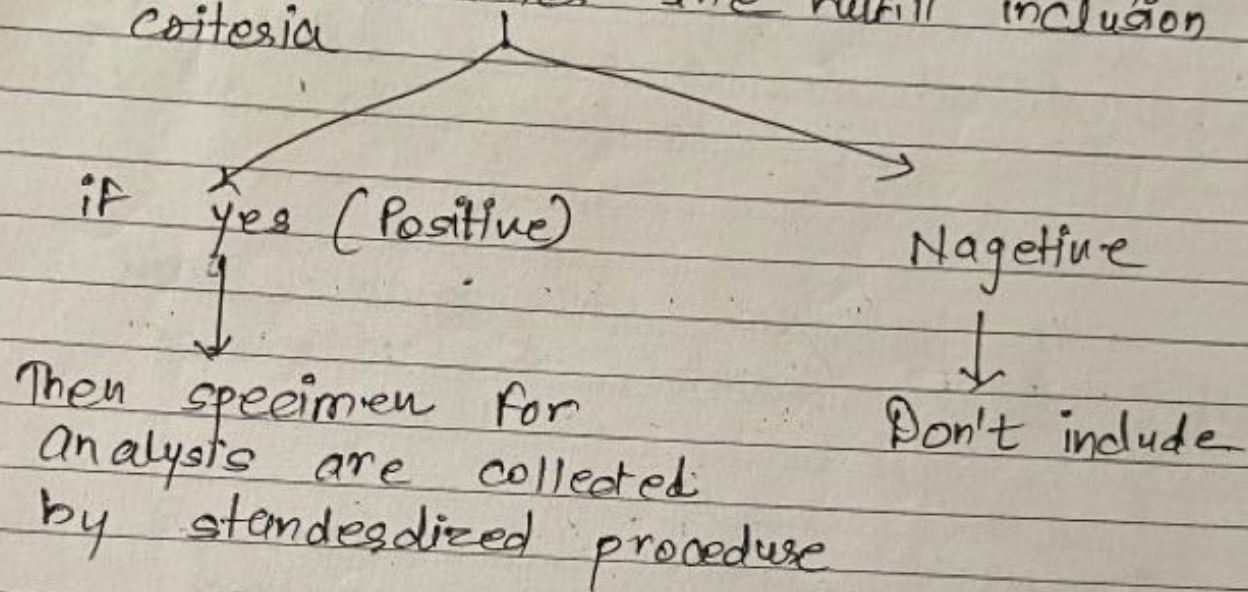
→ Best suited for smaller studies.

→ Direct method

→ Individual are selected for specimen collection & analysis if they fulfill defined inclusion criteria.

→ In this sampling

↓
Representative individual from parent population are interviewed & examined clinically & by selected laboratory method whether they fulfill inclusion criteria



* POSTERIORI METHOD :-

→ Best suited for large collection of data.

→ Direct Method.

→ Using an already existing database containing analysis result & information on a large number of individuals.

↓
Then values of individuals fulfilling defined inclusion criteria are selected.

→ Database should contain the following information as follows :-

① Sampling from the parent population.

- Date _____
Page _____
- ② Registration of demographic & clinical data on participating individuals
 - ③ Preparation for & execution of specimen collection
 - ④ handling & analysis of the specimens.

↓

If these above criteria fulfill ^{by} the value of individual

↓

Those values are selected after application of defined inclusion criteria

↓

By using this value - reference ~~values~~ should be defined, individuals can be selected

↓

In this study practical problem met when reference individuals are selected: the number of subjects fulfilling the inclusion criteria may be too small.

↓

Then problem has two solution

↓

The exclusion criteria may be relaxed

↓

he may define minimum set of exclusion criteria

↓

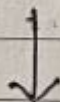
Another design of the sampling procedure could reduce the practical problem,

* INDIRECT METHOD:-

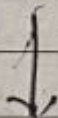
⇒ "Individuals are not considered, but certain statistical methods are applied to analytical values in a laboratory database to obtain estimates with specified characteristic"



method is based on the observation that most analysis result produced in the clinical laboratory seems to be "Normal" if its distribution is Gaussian.



The underlying assumption of indirect method is that the peak of Gaussian distribution is mainly composed of "Normal value".



So it is possible to estimate the normal interval if the distribution of normal values from this distribution is extracted.



But, it is ~~see~~ biased method.

It has two major disadvantages:-

→ If individuals are randomly selected from the entire population.



Then inclusion criteria are applied to sort out the subset of individuals fulfilling these criteria. * even

→ Usually this situation is less satisfactory

→ So In Random Sampling:-

" Process of selection giving each ^{item} (individual or test result) an equal chance of being chosen "

* Non Random Sampling:-

→ " Process of selection giving each item an unequal chance of being chosen "

→ Most commonly & practically used method.

* Examples of selection (exclusion) criteria:-

⇒ Risk factors :

- Obesity

- HT

⇒ Intake of pharmacologically active agents:-

- oral contraceptives

- Alcohol
- Tobacco

⇒ Specific physiologic stress state:-

- Pregnancy
- Stress
- Excessive exercise

* Examples of partitioning criteria:-

- Age
- Gender
- Genetic factors : Ethnic origin
ABO
HLA
genes.
- Physiologic factors : stages in menstrual cycle
stage in pregnancy
physical condition
- Other factors : Socioeconomic
Environmental
Chronobiological.

Date _____
Page _____

① depend on particular mathematical method used and its underlying assumption

② Result for each hospital depend on characteristics of hospital's patient group at that particular time



So, these results would vary not only across hospital at different time



but also for the same hospital at diff. times.

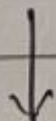
Destroy scientific basis of obtaining and comparing reference value.

* Random Sampling:

→ Ideally, the group of reference individuals should be a random sample of all individuals fulfilling the inclusion criteria defined in the parent population.

→ Random sampling is practically impossible.

→ Because it would imply the examination of application of inclusion criteria to the entire population.



Then Random selection of a subset of individual from among those accepted.