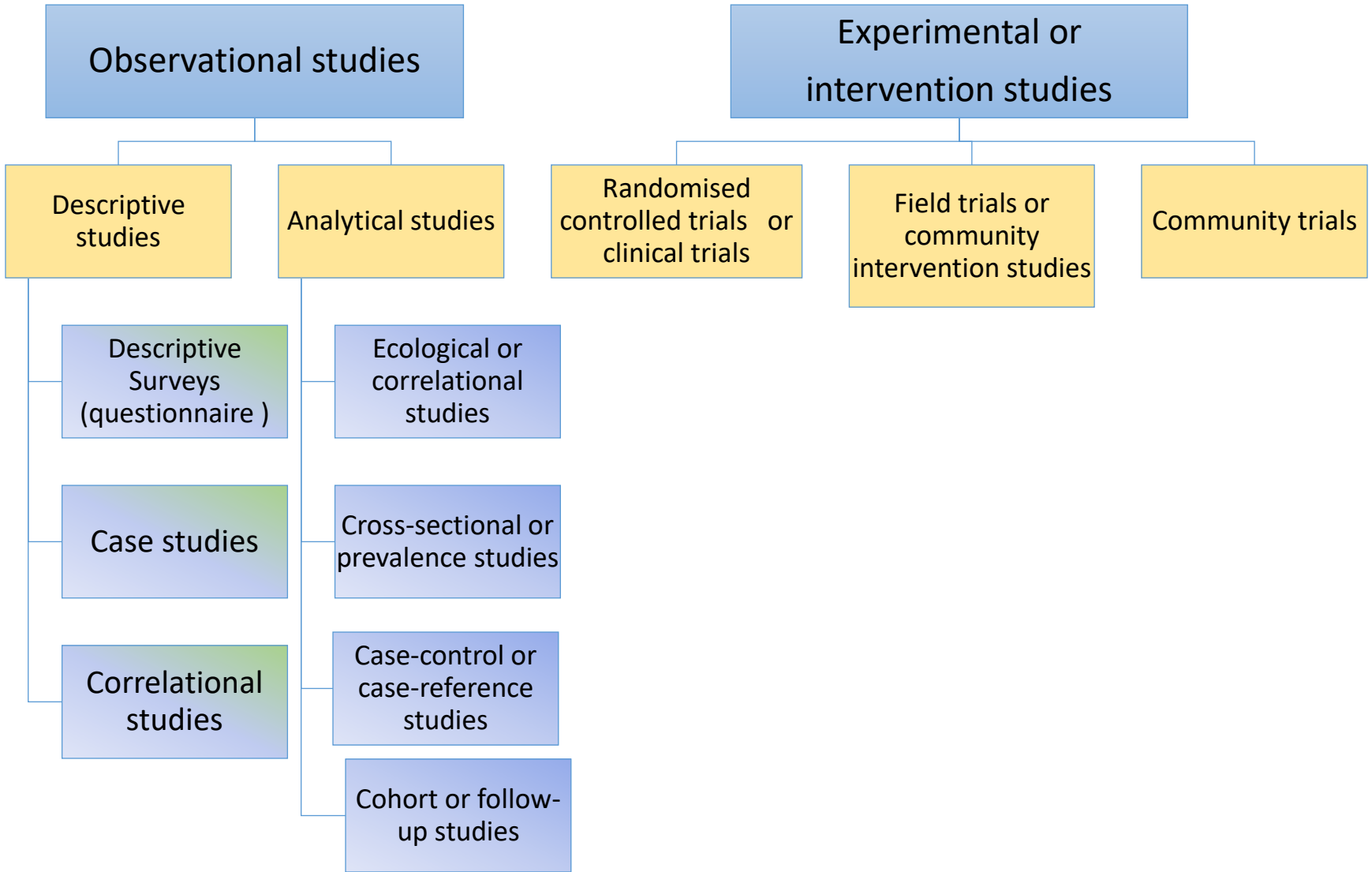
Overview of epidemiological studies

Albert Ndagijimana

Classification of Epidemiologic studies



Descriptive study

- Concerned with observing the distribution of disease or health related characteristics in human population
  - Eg. Surveys.
  - Defining population:denominator
  - Defining the disease:operational definition.
  - Describing disease-time,place and person

Case study: it is an intensive investigation of a person, a family, a group, a social institution or an entire community in a natural setting

Correlational study: it is a descriptive research technique utilized to identify consistent relationship among variables

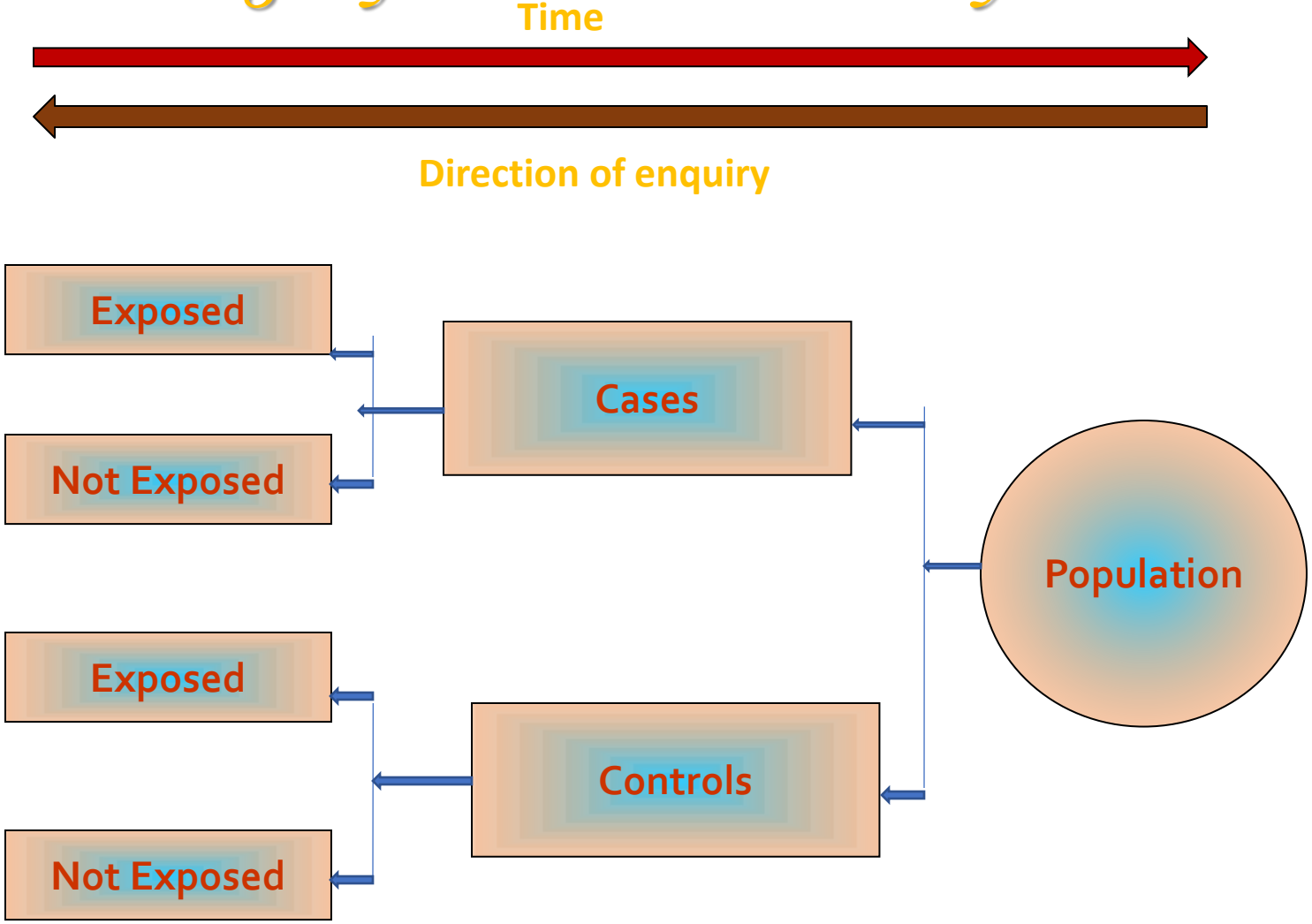
Analytical study

Second major type
Subject of interest –individual with in population
Object –not to formulate but test hypothesis

Can determine:
1.Statistical association between disease and suspected factors
2.If exists--strength

Case control studies

Design of a case-control study



Defining the cases and controls:

- Case: you have to decide a case before the start of the study. The case has to fit in to two criteria.

1. Diagnostic criteria.

2. Eligibility criteria.
   only newly diagnosed cases within a specified period of time than old cases

Selection of cases

- The criteria for inclusion in the study must be clearly specified.
- Sources of cases:
  - Hospitals
  - General population

Controls

- they must be as similar to the cases as possible, except for the absence of the disease, which is under study.

- Selection of controls
  - Crucial step in case-control studies
  - Controls must be
    - Be similar to the cases except for the absence of the disease under study
    - Equal ratio
- Sources of controls
  - Hospitals:diff illness
  - Relatives
  - Neighborhood controls
  - General population

Matching

- Definition:

  the process by which we select controls in such a way that they are similar to cases with regard to certain pertinent selected variables, which are known to influence the outcome of disease and which, if not adequately matched for comparability, could distort or confound the results.

  Example: age.

- Confounding factor
  - One which is associated both with exposure and disease; and is distributed unequally in study and control groups
  - Although associated with 'exposure' under investigation, it itself is a risk factor for the disease

Measurement of exposure

- Exposure can be measured by
  - Interviews
  - Questionnaires
  - By studying past records
  - Examinations
- Bias/ systematic error should be avoided while measuring the exposure

Analysis

- Involves two steps

1. Exposure rates among cases and controls
2. Estimation of disease risk associated with exposure (odds ratio)

1. Exposure rates

A case control study of smoking and lung cancer

	cases	controls
Smokers	33 (a)	55 (b)
non Smokers	2 (c)	27 (d)
Total	35 (a+c)	82 (b+d)

Exposure rate among cases= (a/a+c)100 = (33/35) 100 = 94.2 %

Exposure rate among controls= (b/b+d)100 = (55/82) 100 = 67 %

2.Estimation of risk

Relative risk (RR) or Risk ratio

$$\text{Relative risk} = \frac{\text{Incidence among exposed}}{\text{Incidence among non exposed}} = a/(a+b) \,/\, c/(c+d)$$

	Cases	Controls
Smokers	33 (a)	55 (b)
Non smokers	2 (c)	27 (d)
Total	35 (a+c)	82 (b+d)

Odds ratio (cross product ratio)

- It is a key parameter in the analysis of case control studies
- A measure of the strength of the association between risk factor and outcome
- Derivation of odds ratio is based on 3 assumptions

    - Disease under investigation is a rare one
    - Cases are representative of those with disease
    - Controls are representative of those without disease

	cases	controls
smokers	33 (a)	55 (b)
Non smokers	2 (c)	27 (d)
total	35 (a+c)	82 (b+d)

Odds ratio = ad/bc = 33 X27/ 55X2 = 8.1

- Smokers have a risk of having lung cancer 8.1 times that of non smokers

- Bias in case control study

1. Bias due to confounding
2. Memory bias
3. Selection bias
4. Berksonians bias:different rates of admission to hosp for people with diff disease
5. Interviewer's bias

advantages of . . .

- Relatively easy to carry out
- Rapid and inexpensive (compared with cohort studies)
- Require comparatively few subjects
- suitable to investigate rare diseases or diseases about which little is known.
- No risk to subjects
- Allows the study of several different aetiological factors (e.g., smoking, physical activity and personality characteristics in myocardial infarction)
- No attrition problems, because case control studies do not require follow-up of individuals into the future
- Ethical problems minimal

Disadvantages of . . .

- High chances for bias
- Validation of information obtained is difficult or sometimes impossible
- Selection of an appropriate control group may be difficult
- We cannot measure incidence, and can only estimate the odds ratio but not relative risk

- Not suited to the evaluation of therapy or prophylaxis of a disease
- Another major concern is the representativeness of cases and controls

Cohort studies

Usually undertaken to obtain additional evidence to refute or support the existence of an association

between suspected cause and disease

Other names

- Incidence study
- Forward looking study
- Longitudinal study
- Prospective study

Distinguishing Features of . . .

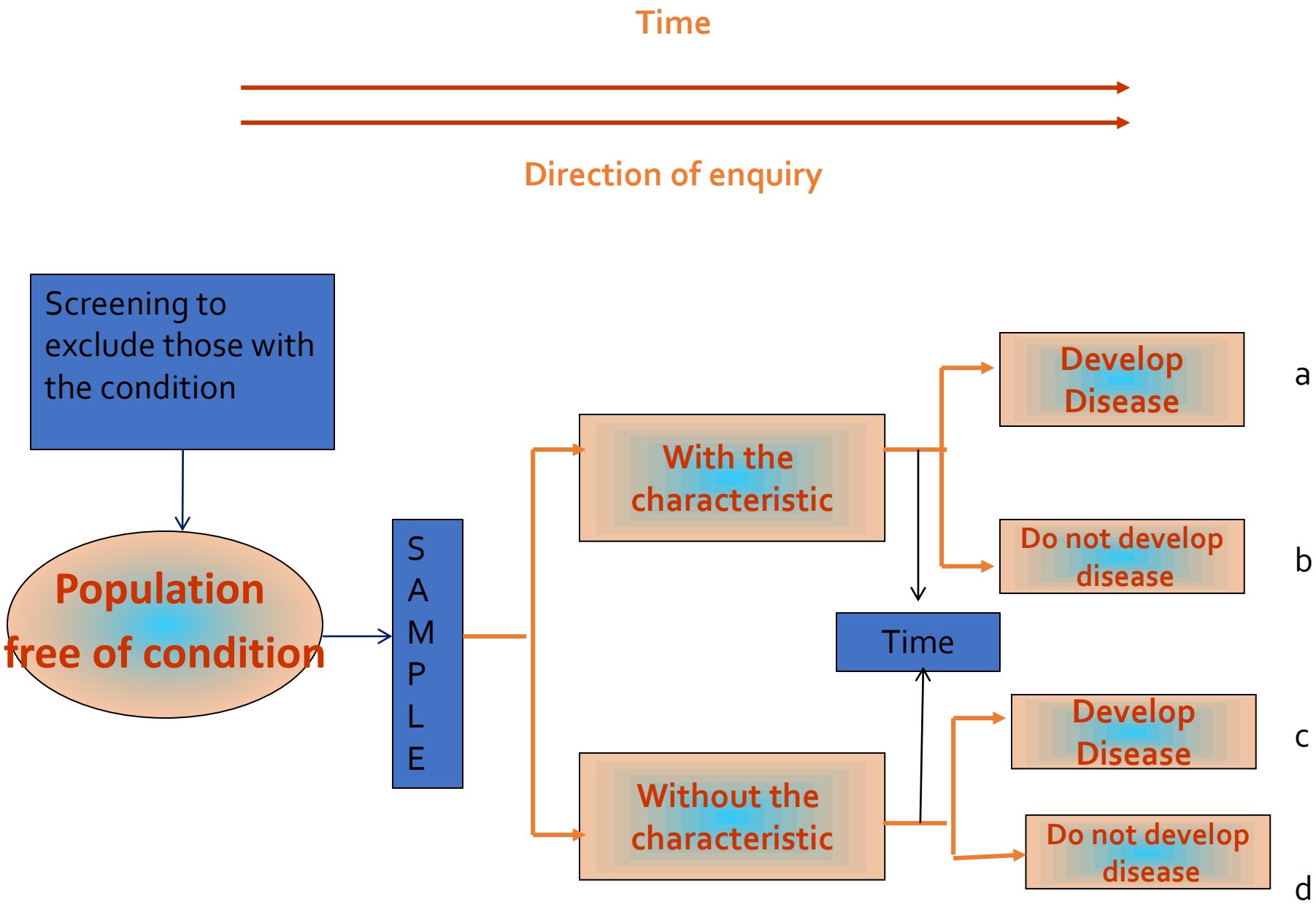
- Cohorts are identified prior to the appearance of the disease under investigation
- Study groups are observed over a period of time to determine the frequency of disease
- The study proceeds from cause to effect

- Cohort is defined as a group of people who share a common characteristic or experience within a defined time period
- Eg, birth cohort,age cohorts, occupational cohorts, exposure to a drug cohorts, marriage cohort etc.
- The comparison group may be…
  - the general population from which the cohort is drawn

Indications for . . .

- When there is a good evidence of an association between exposure and disease
- When the exposure is rare but the incidence of disease is high among exposed
- When the attrition can be minimised
- When ample funds are available

Design of a cohort study



Considerations for selecting cohorts

- Cohorts must be free from the disease under study
- both the groups should be equally susceptible to disease under study
- Both the groups should be comparable in respect of all possible variables, except the assumed risk factors
- Diagnostic and eligibility criteria of the disease must be defined beforehand.
- Inclusion and exclusion criteria should be clearly stated before the commencement

Steps in . . .

- Selection of study subjects
- Obtaining data on exposure
- Selection of comparison groups
- Follow up
- Analysis

Selection of study subjects

- Cohorts can be selected from
  - General population
  - Special groups
    - Select groups (eg. Doctors, lawyers, teachers, etc.)
    - Exposure groups

Obtaining data on exposure

- Information can be obtained from
  - Cohorts
  - Review of records
  - Medical examination or special tests
  - Environmental surveys
- Information about exposure should facilitate classification of cohort members
  - According to whether or not they were exposed
  - According to the degree of exposure

Selection of comparison groups

- Internal comparisons: no outside comparision group is required
- External comparisons: when degree of exposure is not available,ext cohort .eg:smokers and non smokers,radiologists and opthamologists.
- Comparison with general population:mortality experience of exposure group is compared with mortality experience of general populationin same geographic area

Follow up

- Periodic medical examination of each member
- Reviewing physician and hospital records
- Routine surveillence of morbidity and mortality records
- Mailed questionnaires, telephone interviews, periodic home visits

Analysis

- Data is analysed in terms of

  i. Incidence rates of outcome among exposed and non-exposed

  ii. Estimation of risk

    - Relative risk
    - Attributable risk

Incidence rates

- Incidence can be measured directly
- Incidence rate among smokers = 70/7000 = 10 per thousand
- Incidence rate among non-smokers= 3/3000 = 1 per 1000

  P < 0.001

Cigarette smoking	Lung cancer	No lung cancer	Total
Yes	70 a	6930 b	7000 a+b
No	3 c	2997 d	3000 c+d

Relative risk

- Relative risk : The ratio of incidence among exposed and incidence among non-exposed
- Also called 'risk ratio'
- RR= $\frac{\text{Incidence among exposed}}{\text{Incidence among non-exposed}}$

10/1 = 10

- RR is the direct measure of strength of association between suspected cause and effect

Cigarette smoking	Lung cancer	No lung cancer	Total
Yes	70 a	6930 b	7000 a+b
No	3 c	2997 d	3000 c+d

RR-i= no assossiation

RR > 1= positive assossiation

Attributable risk

- The difference in incidence rates between exposed and non-exposed groups
- Also called risk difference
- $\frac{\text{Incident rate among exposed} - \text{incidence rate among non-exposed}}{\text{Incident rate among exposed}} \times 100$ of lung cancer was due to their smoking

(10-1/10) X 100 = 90%

- It indicates to what extent disease can be attributed to the exposure
- Suggests the amount of disease that might be eliminated if the factor could be controlled

Relative risk X Attributable risk

Relative risk

- Etiological enquiries
- Larger the RR, stronger the association between risk factor and outcome
- Does not reflect the potential public health importance

Attributable risk

- Gives a better idea of the impact of a successful intervention might have in reducing the problem

Advantages of cohort studies

- Allow the possibility of measuring directly the relative risk of developing the condition for those who have the characteristic, compared to those who do not
- Allows for a conclusion of cause-effect relationship

- Because the presence or absence of the risk factor is recorded before the disease occurs, there is no chance of bias

- Cohort studies are capable of identifying other diseases that may be related to the same risk factor.
- Unlike case-control studies, cohort studies provide the possibility of estimating attributable risks, thus indicating the absolute magnitude of disease attributable to the risk factor.

Disadvantages of cohort studies

- Not always feasible.
- Relatively inefficient for studying rare conditions.
- They are very costly in time, personnel, space and patient follow-up.
- Sample sizes required for cohort studies are extremely large, especially for infrequent conditions; it is usually difficult to find and manage samples of this size.
- The most serious problem is that of attrition, which can affect the validity of the conclusion, if it renders the samples less representative, or if the people who become unavailable are different from those actually followed up. The higher the proportion lost (say beyond 10-15%) the more serious the potential bias.

- There may also be attrition among investigators who may lose interest, leave for another job, or become involved in another project.

- Over a long period, many changes may occur in the environment, among individuals or in the type of intervention, and these may confuse the issue of association and attributable risk.

Case control study

- Proceeds from effect to cause
- Starts with the disease
- Tests whether the suspected exposure occurs more frequently in those with the disease than among those without the disease.
- Involves fewer number of subjects
- Yields relatively quick results
- Suitable for the study of rare diseases
- Generally yields only estimate of RR (odds ratio)
- Cannot yield information about diseases other than that selected for study
- Relatively inexpensive

cohort study

- Proceeds from "cause to effect".
- Starts with people exposed to risk factor or suspected cause.
- Tests whether disease occurs more frequently in those exposed, than in those not similarly exposed.
- Involves larger number of subjects
- Long follow-up period often needed, involving delayed results.
- Inappropriate when the disease or exposure under investigation is rare.
- Yields incidence rates, RR as well as AR.
- Can yield information about more than one disease outcome.
- Expensive.

Experimental studies

- Study of epidemics among colonies of experimental animals such as rats and mice .
- AIMS
  - To provide scientific proofs of etiological factors
  - To provide a method of measuring the effectiveness and efficiency of health services
- has all adv and disadv of cohort study and also ethics,cost and feasibility
- Animal studies: important application

Advantages

1. Bred in lab,and can manipulated easily
2. They multiply rapidly

Disadvantages:

1. Not all human diseases can be reproduced
2. All conclusions – not applicable

- Human studies:

To investigate disease etiology and to evaluate the preventive ,therapeutic measures

1747-john lind-scurvy

1796-Edward Jennar-cowpox

1. Ethical and logistic considerations,benefits weighed againsts the risks involved
2. Volunteers –made fully aware of the experiment
3. WHO (1980)-strict code of practice

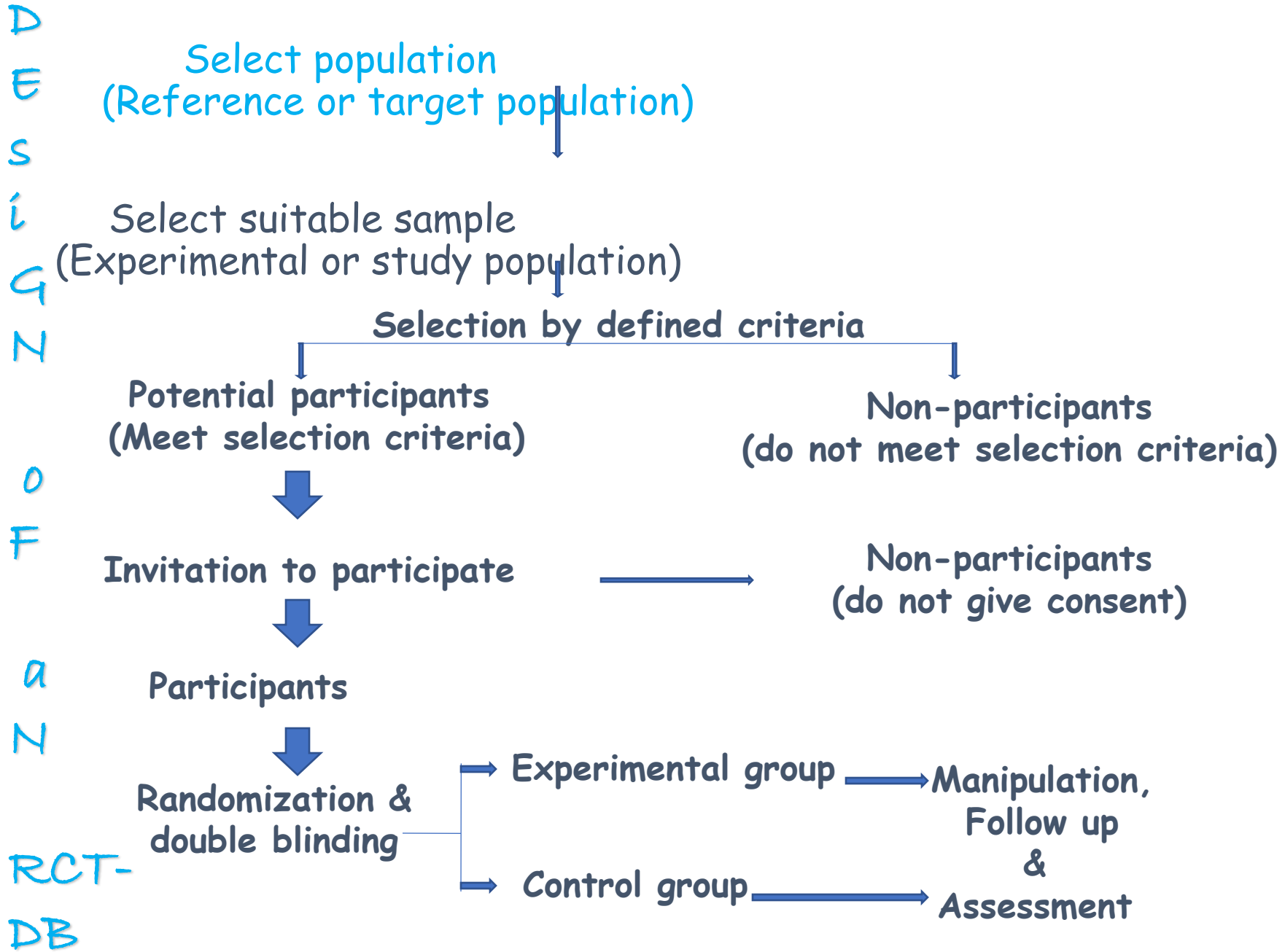
Experimental studies → Randomised controlled trials
Experimental studies → Non-randomized trials

- ## Randomised controlled trials:

Involves some action,intervention or manipulation such as deliberate application or withdrawl of suspected cause.

1. Drawing up a protocal
2. Selecting reference and experimental population
3. Randomization
4. Blinding
5. Manipulation or intervention
6. Follow- up
7. Assessment of outcome

DESIGN OF AN RCT-DB



- Positive results: benefit of exp measure----reduced incidence or severity of disease or other appropriate outcomes of study.

- Negative results: severity and frequency of side effects and complications ,if any death

Blinding:

- Randomization cannot guard against these sorts of bias nor the size of the sample.the technique known as blinding is adopted which can be done in

Single blind trial:

- here the participant is not aware whether he belongs to study group or control group.

Double blind trial;

- Here neither the doctor nor the participant is aware of the group allocation and the treatment received.

Triple blind trial:

- Here the participant,the investigator and the analyzer are all "blind".

THANK YOU