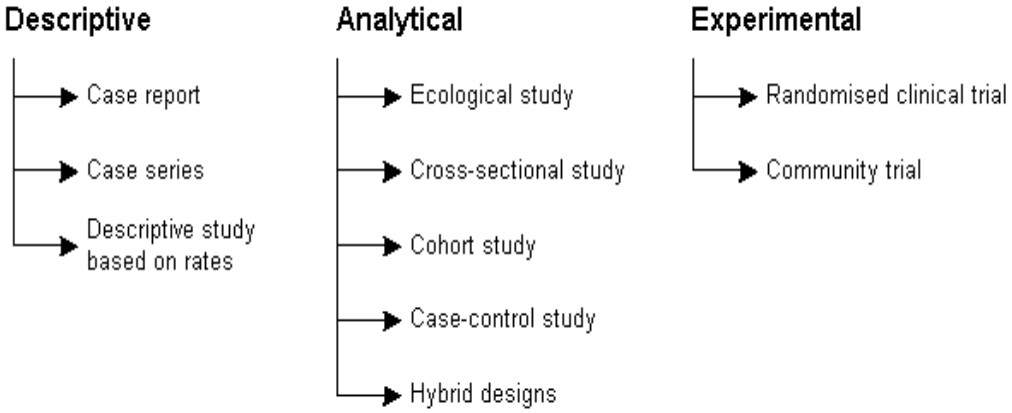
Study design

- A study generally begins with a research question. Once the research question has been specified the next step is to choose a study design. A study design is a plan for selecting study subjects and for obtaining data about them. There are three main study types:

(1) descriptive studies,

(2) analytical studies,

(3) experimental studies.



- Descriptive studies are those undertaken without a specific hypothesis. They are often the earliest studies done on a new disease in order to characterise it, quantify its frequency, and determine how it varies in relation to individual, place and time.
- Analytical studies are undertaken to identify and test hypotheses about the association between an exposure of interest and a particular outcome.
- Experimental studies are also designed to test hypotheses between specific exposures and outcomes — the major difference is that in experimental studies the investigator has direct control over the study conditions.

1- Descriptive studies

The hallmark of a descriptive study is that it is undertaken without a specific hypothesis

A - Case reports

- A case report describes some ‘newsworthy’ clinical occurrence, such as an unusual combination of clinical signs, experience with a novel treatment, or a sequence of events that may suggest previously unsuspected causal relationships. Case reports are generally reported as a clinical narrative

B - Cases series

- Whereas a case report shows that, something can happen once, a case series shows that it can happen repeatedly.
- A case series identifies common features among multiple cases and describes patterns of variability among them.

C - Descriptive studies based on rates

- Descriptive studies based on rates quantify the burden of disease on a population using incidence, prevalence, mortality or other measures of disease frequency.
- Most use data from existing sources (such as birth and death certificates, disease registries or surveillance systems).
- Descriptive studies can be a rich source of hypotheses that lead later to analytic studies.

2 - Analytical studies

- Analytical studies are undertaken to test a hypothesis. In epidemiology the hypothesis typically concerns whether a certain exposure causes a certain outcome — e.g. does cigarette smoking cause lung cancer?
- The term exposure is used to refer to any trait, behaviour, environmental factor or other characteristic as a possible cause of disease. Synonyms for exposure are: potential risk factor, putative cause, independent variable, and predictor.

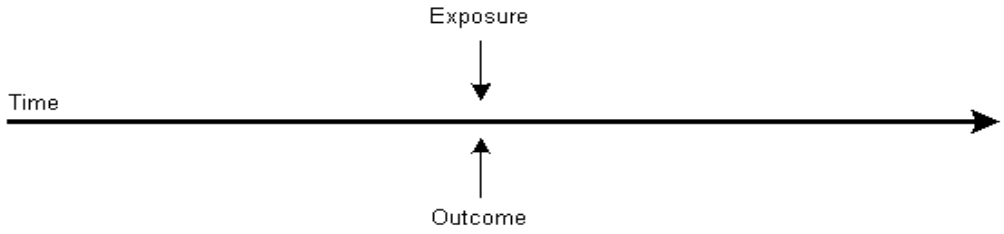
- The term outcome generally refers to the occurrence of disease. Synonyms for outcome are effect, end-point, and dependent variable.
- The hypothesis in an analytic study is whether an exposure actually causes an outcome
- (Not merely, whether the two are associated). Each of Hill's criteria for causation are usually required to be met to support a case for causality, but probably the most important is that exposure must precede the outcome in time.

A – Ecological studies

- In an ecological study, the unit of analysis is a group of individuals (such as counties, states, cities, or census tracts) and summary measures of exposure and summary measures of outcome are compared.
- A key feature of ecological studies is that inference can only be made at the group level, not at the individual level.
- Ecological studies are relatively quick and inexpensive to perform and can provide clues to possible associations between exposures and outcomes of interest

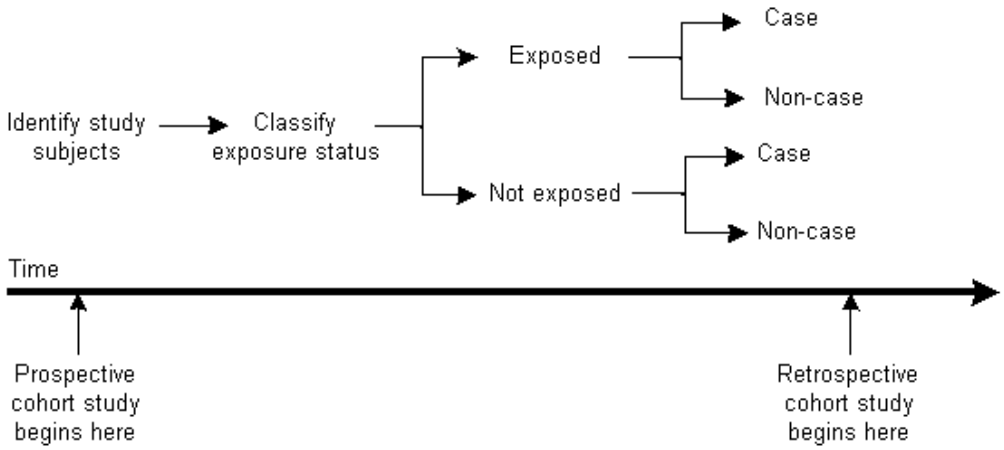
B - Cross-sectional studies

- In a cross-sectional study a random sample of individuals from a population is taken at a point in time. Individuals included in the sample are examined for the presence of disease and their status with regard to the presence or absence of specified risk factors.
- Cross sectional studies commonly involve surveys to collect data. Surveys range from simple one-page questionnaires addressing a single variable, to highly complex, multiple page designs.
- There is a whole sub-field of epidemiology associated with design, implementation and analysis of questionnaires and surveys.
- Advantages: Cross-sectional studies are relatively quick to conduct and their cost is moderate, compared with other study designs.
- Disadvantages: Cross-sectional studies cannot provide information on the incidence of disease in a population — only an estimate of prevalence. Difficult to investigate cause and effect relationships.



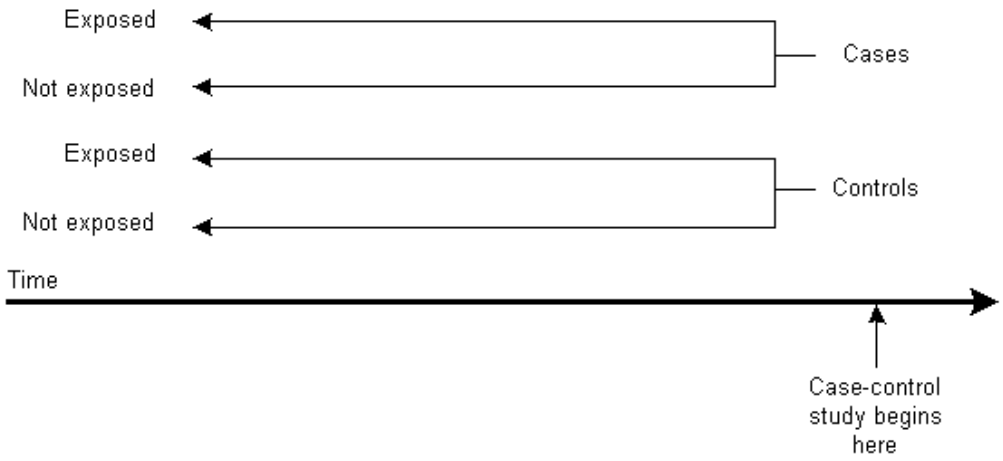
B – Cohort study:

- A cohort study involves comparing disease incidence over time between groups (cohorts) that are found to differ on their exposure to a factor of interest. Cohort studies can be distinguished as either prospective or retrospective
- A prospective cohort study begins with the selection of two groups of non-diseased animals, one exposed to a factor postulated to cause a disease and the other unexposed. The groups are followed over time and their change in disease status is recorded during the study period.
- A retrospective cohort study starts when all of the disease cases have been identified. The history of each study participant is carefully evaluated for evidence of exposure to the agent under investigation.
- Advantages: Because subjects are monitored over time for disease occurrence, cohort studies provide estimates of the absolute incidence of disease in exposed and non-exposed individuals. By design, exposure status is recorded before disease has been identified. In most cases, this provides unambiguous information about whether exposure preceded disease. Cohort studies are well-suited for studying rare exposures. This is because the relative number of exposed and non-exposed persons in the study need not necessarily reflect true exposure prevalence in the population at large.
- Disadvantages: Prospective cohort studies require a long follow-up period. In the case of rare diseases large groups are necessary. Losses to follow-up can become an important problem. Often quite expensive to run.



C – Case – control study:

- A case-control study involves comparing the frequency of past exposure between cases who develop the disease (or other outcome of interest) and controls chosen to reflect the frequency of exposure in the underlying population at risk. Figure 13 shows a diagram of the case-control design
- Advantages: Case-control studies are an efficient method for studying rare diseases. Because subjects have experienced the outcome of interest at the start of the study, case-control studies are quick to run and are considerably cheaper than other study types.
- Disadvantages: Case-control studies cannot provide information on the disease incidence in a population. The study is reliant on the quality of past records or recollection of study participants. It can also be very difficult to ensure an unbiased selection of the control group and, as a result, the representativeness of the sample selection process is difficult to guarantee.


Exposed
Not exposed
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Exposed
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Case-control study begins here