Introduction to Study Designs

Objectives:

- Describe the common types of study designs .
- List the differences between qualitative and quantitative studies.
- Understand the process of selecting the suitable design
- Identify the most appropriate study design for the research proposal you are developing.

Team Members:

Njoud Alenezy - Doaa Abdulfattah – Abdulaziz Alangari – Ghaida Alsaeed

Team Leaders: Rawan Alwadee & Mohammed ALYousef

Revised By: Jumana Alghtani

Resources:

• 436 Lecture Slides + Notes

Important – Notes

436researchteam@gmail.com

Editing file

Feedback link

Definition

Strategy that you choose to integrate the different components of the study ,**ensuring you will effectively address the research problem**

Types

Qualitative:

- Text -based
- Used to formulate theory or hypotheses
- More in-depth information on a few cases.

Important:
If I don't have any previous hypothesis I will use qualitative.

Quantitative :

- **N**umber-based.
- Used to test pre-specified Hypotheses.
- Less in-depth but more breadth of information across a large number of cases .

Divided into:

- Experimental (Interventional)
- Observational (Non Interventional)

Important:
Measure or association between groups فاذا احتاج
Quantitative research.
Main advantage is the ability to manipulate or assign independent variables.(exposure variable).

Outcome (dependent variable)

A broad term for any defined disease, state of health, health-related event or death.

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Exposure

The exposure of interest may be associated with an increased, a decreased or no effect on the occurrence of disease or other specified health outcome .
The term **risk factor** is often used to describe an exposure variable.

What is a Study Design

The research design refers to the overall strategy that you choose to integrate the different components of the study in a coherent and logical way, thereby, ensuring you will effectively address the research problem; it constitutes the blueprint for the collection, measurement, and analysis of data.

Note that your research problem determines the type of design you should use, not the other way around!

Sometimes 2 groups conducting the same topic, but the research question and objective are different between those 2 groups, so the study design will be different!! That's way, selecting an appropriate study design depends on Research Question. So the research question determines which study design is suitable.

A study design is a specific plan or protocol for conducting the study, which allows the investigator to translate the conceptual hypothesis into an operational one.

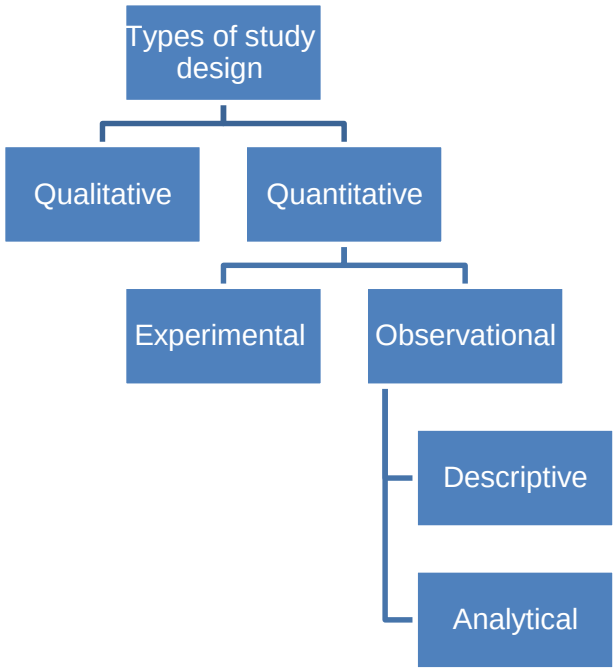
Selection of Study Design

- There is NO best type of a study design.
- Choosing the study design depends on:
  - Research question, objectives and goals
  - The knowledge already available about the problem
  - Available resources (*cost, time, expertise of the researcher)
  - research ethics and researcher beliefs and values
  - Time and Funds
  - Status of existent knowledge
  - Occurrence of disease
  - Duration of latent period
  - Nature and availability of information
  - Available resources
  - Researcher beliefs and values

* E.g. If I have limited cost I Can not conduct "randomized control trials"

Health Research

- **Lab research:** develop procedures to prevent, control and treat mechanisms of health-related phenomena
- **Population-based (field) research:** study of distribution, determinants, control health-related phenomena in populations. Using suitable biostatistical techniques for generalization
- **Healthcare-facility (clinical) research:** application of epidemiological principles in research based in healthcare facilities, e.g. randomized clinical trials



Study Designs in Health Research

Important

Qualitative research General description	Quantitative research Measures of association or comparison
Qualitative research is especially effective in obtaining culturally specific information about the values, opinions, behaviors, and social contexts of particular populations.	Quantitative methods involve objective measurements and the statistical, mathematical, or numerical analysis of collected data.
Differences between quantitative and qualitative study designs:	
• Text-based • Methods of data collection include **focus groups, in-depth interviews, and reviews of documents** for types of themes • Used to formulate theory or hypotheses* • No statistical tests • More in-depth information on a few cases • Less generalizable غالباً السامبل سايز صغيرة	• Number-based • Methods of data collection include **questionnaires, structured interviews & observations, and reviews of records** for numeric information • Used to test pre-specified hypotheses • Statistical tests are used for analysis • Less in-depth but more breadth of information across a large number of cases • More generalizable غالبا السامبل سايز كبيرة
Methods: • Focus Groups • Interviews • Surveys • Self-reports • Observations • Document analysis • Sampling: Purposive	**Methods:** • Observational • Experimental • Mixed • Sampling: Random (simple, stratified, cluster, etc) or purposive
Quality Assurance: • Trustworthiness: Credibility, Confirming, Dependability, Transferability • Authenticity: Fairness, Ontological, Educative, Tactical, Catalytic	**Quality Assurance:** • Reliability: Internal and External • Validity: Construct, Content, Face

* To generate hypothesis because there is no previous studies.

Qualitative Designs

Qualitative Research Techniques:

- Participant observation (field notes)
- Interviews / Focus group discussions with key informants
- Video/Text and Image analysis (documents, media data)
- Surveys
- User testing

Involves Skills of:

- Observing
- Conversing
- Participating
- Interpreting

Rigor in Qualitative Research:

- Dependability
- Credibility
- Transferability
- Confirmability

Quantitative Designs

IMPORTANT NOTICE TO KNOW

Most health research involves the study of the relationship or the effect of one type of event or characteristic to another.

When we conduct a quantitative study in medical field, whether we look into the occurrence of disease, risk factors, prognosis, treatment, association, cause or effect; we have 2 factors we find a relation between them 1- the exposure 2- the outcome

Example\ Does alcohol intake increase the risk of lung cancer?

Alcohol (exposure) ⟶ lung cancer (outcome)

Exposure:

- The exposure of interest may be associated with an increased, a decreased or no effect on the occurrence of disease or other specified health outcome
- The term risk factor is often used to describe an exposure variable.

It can be:

- The **environment** (e.g. air pollution, indoor radon),
- **Lifestyle** (e.g., smoking habits, diet), or
- Inborn or **inherited** characteristics (e.g. blood group A, fair skin)

Outcomes:

- The outcome of a study is a broad term for any **defined disease, state of health, health-related event or death.**
- In some studies, there may be multiple outcomes.

Quantitative Designs	
Non-interventional (Observational)	**Interventional (Experimental)**
Investigators observe what happens, noting who is exposed on unexposed and who has or has not developed the outcome of interest. Just observe without any interfere	Investigators study the impact of some factors which they **can control** Interfering and manipulate the exposure

Observational studies do not involve any intervention or experiment.

❖ Observation Methods:

1- Selected Units: individuals, groups
2- Study Populations: cross-sectional, longitudinal

- ✓ Cross-sectional: where only **ONE** set of observations is collected for every unit in the study, at a certain point in time, disregarding the length of time of the study as a whole
- ✓ Snap shot of a population
- ✓ Longitudinal: where **TWO** or **MORE** sets of observations are collected for every unit in the study, i.e. follow-up is involved in order to allow monitoring of a certain population (cohort) over a specified period of time. Such populations are AT RISK (disease-free) at the start of the study.

3- Data collection timing: prospectively, retrospectively, combination
4- Data collection types: primary, secondary

- ✓ **Primary**: where the investigator is the first to collect the data. Sources include: medical examinations, interviews, observations, etc. Merits: less measurement error, suits objectives of the study better. Disadvantage: costly, feasibility to be assessed.
- ✓ **Secondary**: where the data is collected by OTHERS, for other purposes that those of the current study. Sources include: individual records (medical / employment); group records (census data, vital statistics done by MOH)

Observational Designs: classification

- ✓ **Exploratory**: used when the state of knowledge about the phenomenon is poor: small scale; of limited duration.
- ✓ **Descriptive:** used to formulate a certain hypothesis: small / large scale.

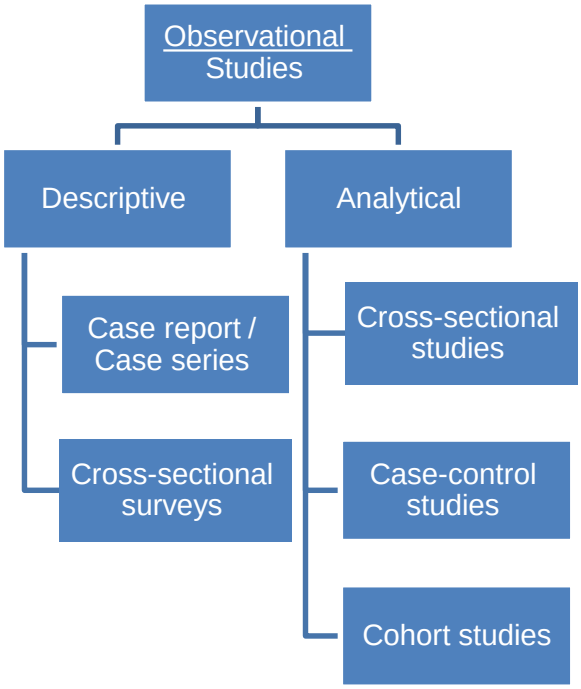
Examples: case- studies / series; cross-sectional studies

- ✓ **Analytical:** used to test hypotheses: small / large scale.

Examples: case-control, cross-sectional, cohort.

Analytical Observational Studies	Descriptive Observational Studies
➢ Proceed with a "preformed hypothesis" ➢ Used to **test** hypothesis about exposure-outcome relationships ➢ Measure the **association** between exposure and outcome ➢ Include **a comparison group** ➢ Answer questions related **to why and how.**	➢ **Describes occurrence of disease** (or of its determinants) within a population. ➢ Characterize disease occurrence by time, place and person. **Person**: characteristics (age, sex, occupation) of the individuals affected by the outcome. **Place**: geography (residence, work, hospital) of the affected individuals. **Time**: when events (diagnosis, reporting; testing) occurred. ➢ Attempt to answer questions 'Who', 'Where', 'What' and 'When'? ➢ Generate testable hypothesis as to the cause of disease, that can be tested in "analytical" studies

What is the different between generating hypothesis here in descriptive observational study and generating hypothesis in qualitative study?
Generating hypothesis in descriptive observational is numerical as it a quantitative study while in qualitative there is no numbers



Quantitative Designs

❖ Experimental:

- Studies that entail manipulation of the study factor (exposure) and randomization of subjects to treatment (exposure) groups
- Used mainly in the area of clinical and field trials for testing new drug or intervention programs.
- Not suitable for every research question : Feasibility & Ethical issues.

Advantages of Experimental Designs Important

1. The ability to manipulate or assign independent variables.
2. The ability to randomize subjects to experimental or control group.
3. The ability to control for confounding and eliminate sources of bias.
4. The ability to ensure temporality Mean: make sure the Exposure happens before the outcome.

Classification of Research Study Designs:

<table>
<tr><td colspan="2">I. Non-interventional (observational) studies</td><td colspan="3"></td></tr>
<tr><td colspan="2">▪ Exploratory</td><td colspan="3">Qualitative</td></tr>
<tr><td>▪ Ecological (correlational)</td><td>population as study unit</td><td rowspan="5">Descriptive Studies</td><td rowspan="6">Epidemiological study designs (Quantitative)</td></tr>
<tr><td>▪ Case reports
▪ Case series
▪ Cross-sectional surveys</td><td rowspan="4">individual as study unit</td></tr>
<tr><td>▪ Cross-sectional comparative study
▪ Case control
▪ Cohort</td></tr>
<tr><td colspan="2">II. Interventional studies</td><td rowspan="3">Analytical Studies</td></tr>
<tr><td colspan="2">▪ Experimental studies (Randomized)</td></tr>
<tr><td colspan="2">▪ Quasi-experimental studies (Not Randomized)</td></tr>
</table>

Quantitative Designs: More details in each type of study

Male slides

Ecological studies

- E.g. hardness of water, are correlated with health data collected on individuals say CHD rates.
- Conceptually, the ecological component is an issue of data analysis; not study design.
  - What is missing: relationship between exposure and outcome at the individual level (incomplete design)
  - Could be hypothesis generating analyses/design

Example of ecological fallacy:

INCOME - related to - CHD

- Within the cities studied, coronary heart disease is higher in the richer cities than in the poorer ones.
- We might predict from such a finding that being rich increases your risk of heart disease.
- In the industrialized world the opposite is the case, within cities such as London, Washington and Stockholm, poor people have higher CHD rates than rich ones.

- The ecological fallacy is usually interpreted as a major weakness of ecological analyses.
- Ecological analyses, however, informs us about forces which act on whole populations.

Female slides

Ecological Studies

- An Observational study in which at least one variable, either an exposure or the outcome, is measured at the group (not individual) level.
- The occurrence of disease is compared between groups that have different levels of an exposure.
- Easy to do, difficult to interpret.

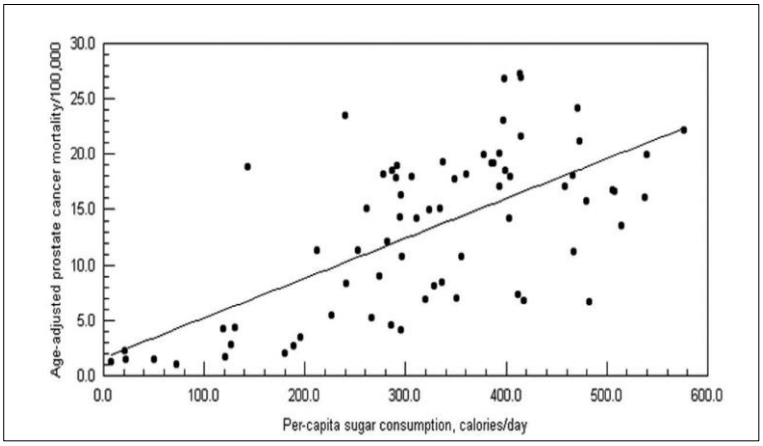
Examples

✓ The association between sunlight exposure at specific geographic location and development of skin cancer.

Disadvantage :

The association between variables at grouy level might not represent the association at the individual level.

The different between ecological study and other observational study is that, in ecological we are dealing with population level not individual level.



Administrative data: group data at country level, not individual based

Male slides

Case-series:

1. **Clinical case-series:** usually a coherent and consecutive set of cases of a disease (or similar problem) which derive from either the practice of one or more health care professionals or a defined health care setting, e.g. a hospital or family practice.

- A case-series is, effectively, a register of cases.
- Analyze cases together to learn about the disease.
- Clinical case-series are of value in epidemiology for:
  - ✓ Studying symptoms and signs
  - ✓ Creating case definitions
  - ✓ Clinical education, audit and research

2. Population-based Case-series:

- When a clinical case-series is complete for a defined geographical area for which the population is known, it is, effectively, a population based case-series consisting of a population register of cases.
- Epidemiologically the most important case-series are registers of serious diseases or deaths (usually NCDs), and of health service utilization, e.g. hospital admissions.
- Usually compiled for administrative and legal reasons.
- Full epidemiological use of case-series data needs information on the population to permit calculation of rates
- Key to understanding the distribution of disease in populations and to the study of variations over time, between places and by population characteristics.
- Case-series can provide the key to sound case control and cohort studies and trials.
- Design of a case-series is conceptually simple.
- Defines a disease or health problem to be studied and sets up a system for capturing data on the health status and related factors in consecutive cases.

Case-series, Requirements for interpretation:

To make sense of case-series data the key requirements are:

- The diagnosis (case definition) or, for mortality, the cause of death
- The date when the disease or death occurred (time)
- The place where the person lived, worked etc (place)
- The characteristics of the person (person)
- The opportunity to collect additional data from medical records (possibly by electronic data linkage) or the person directly
- The size and characteristics of the population at risk

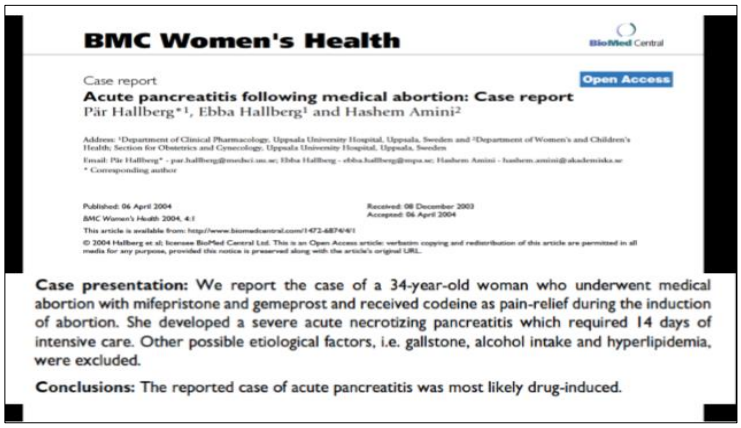
Strengths:

- Population case-series permit two arguably unique forms of epidemiological analysis and insight.
- Paint a truly national and even international population perspective on disease.
- The disease patterns can be related to aspects of society or the environment that affect the population but have no sensible measure at the individual level.

Case Report (Case Study):

Female slides

- Careful and detailed report of the profile of a SINGLE patient by one or more clinicians
- Condition is unusual medical occurrences
- Can generate hypothesis, provide clues in identification of a new disease or adverse effects of exposures (E.g. It was a single case report that formulated the hypothesis of oral contraceptive use increases venous thromboembolism).
- It is made using; simple history, physical examination and Lab./ radiological tests



BMC Women's Health

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Case report

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Acute pancreatitis following medical abortion: Case report

Pär Hallberg*[1], Ebba Hallberg[1] and Hashem Amini[2]

Address: [1]Department of Clinical Pharmacology, Uppsala University Hospital, Uppsala, Sweden and [2]Department of Women's and Children's Health, Section for Obstetrics and Gynecology, Uppsala University Hospital, Uppsala, Sweden

Email: Pär Hallberg* - par.hallberg@medsci.uu.se; Ebba Hallberg - ebba.hallberg@mpa.se; Hashem Amini - hashem.amini@akademiska.se

* Corresponding author

Published: 06 April 2004

BMC Women's Health 2004, 4:1

Received: 08 December 2003

Accepted: 06 April 2004

This article is available from: http://www.biomedcentral.com/1472-6874/4/1

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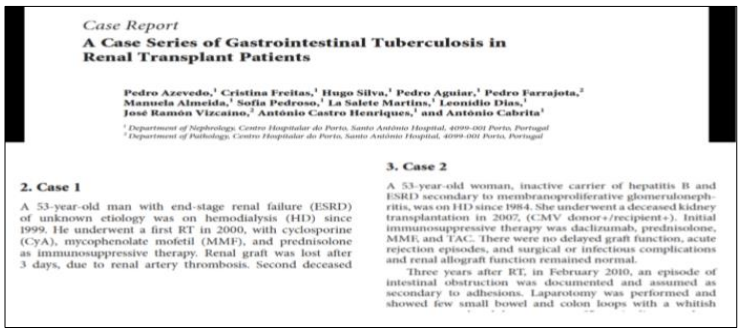
Case presentation: We report the case of a 34-year-old woman who underwent medical abortion with mifepristone and gemeprost and received codeine as pain-relief during the induction of abortion. She developed a severe acute necrotizing pancreatitis which required 14 days of intensive care. Other possible etiological factors, i.e. gallstone, alcohol intake and hyperlipidemia, were excluded.

Conclusions: The reported case of acute pancreatitis was most likely drug-induced.

Case Series Studies :

Female slides

- Description of clinical/epidemiologic characteristics of a number of patients (usually 5 -12) with a given disease having similar diagnosis
- Collection of individual case reports occurring within a fairly short period of time
- Used as an early means to identify the beginning or presence of an epidemic, generate hypothesis and gives information about natural history of disease



Case Report

A Case Series of Gastrointestinal Tuberculosis in Renal Transplant Patients

Pedro Azevedo,[1] Cristina Freitas,[1] Hugo Silva,[1] Pedro Aguiar,[1] Pedro Farrajota,[2] Manuela Almeida,[1] Sofia Pedroso,[1] La Salete Martins,[1] Leonídio Dias,[1] José Ramón Vizcaíno,[1] António Castro Henriques,[1] and António Cabrita[1]

[1] Department of Nephrology, Centro Hospitalar do Porto, Santo António Hospital, 4099-001 Porto, Portugal

[2] Department of Pathology, Centro Hospitalar do Porto, Santo António Hospital, 4099-001 Porto, Portugal

2. Case 1

A 53-year-old man with end-stage renal failure (ESRD) of unknown etiology was on hemodialysis (HD) since 1999. He underwent a first RT in 2000, with cyclosporine (CyA), mycophenolate mofetil (MMF), and prednisolone as immunosuppressive therapy. Renal graft was lost after 3 days, due to renal artery thrombosis. Second deceased

3. Case 2

A 53-year-old woman, inactive carrier of hepatitis B and ESRD secondary to membranoproliferative glomerulonephritis, was on HD since 1984. She underwent a deceased kidney transplantation in 2007, (CMV donor+/recipient+). Initial immunosuppresive therapy was daclizumab, prednisolone, MMF, and TAC. There were no delayed graft function, acute rejection episodes, and surgical or infectious complications and renal allograft function remained normal.

Three years after RT, in February 2010, an episode of intestinal obstruction was documented and assumed as secondary to adhesions. Laparotomy was performed and showed few small bowel and colon loops with a whitish

Uses of Case Report and Case Series Studies :

Female slides

- Identifying the potential health problem (e.g. acute outbreak)
- Can be valuable early evidence for associations between exposures and diseases which can be studied in more detail
- Recognition of new diseases
- Constructing the natural history of a disease
- Stimulate research interest in an area

The Main aim of case reports and case series is: generating hypothesis and be aware of health condition or what is going on.

Limitations:

- Limited amount of information > we can't generalized the finding
- No appropriate comparison group > we can't test any hypothesis or causality
- Based on the experience of one person so Can't be used to test for presence of a valid statistical association
- Little evidence of causality

Male slides

Cross-Sectional Studies: (Community health studies, surveys)

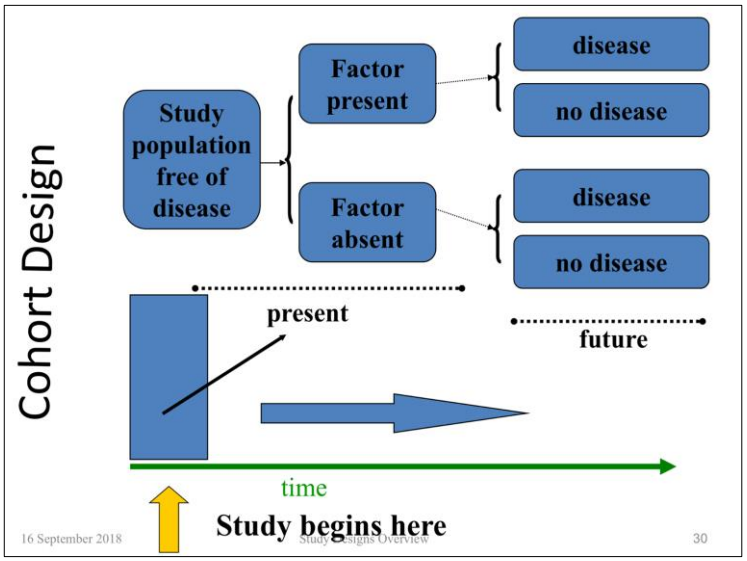
- **Characteristics**: detects point prevalence; relatively common conditions; allows for stratification; different from surveillance / registers
- **Merits**: feasible; quick; economic; allows study of several diseases/exposures; useful for estimation of the population burden, health planning and priority setting of health problems
- **Limitations**: temporal ambiguity (cannot determine whether the exposure preceded outcome); possible measurement error; not suitable for rare conditions; liable to survivor bias
- **Effect measure**: Odds Ratio + CI

Case-Control Studies:

- **Characteristics**: two source populations; assumption that non-cases are representative of the source population of cases.
- **Merits**: least expensive; least time-consuming; suitable for study of rare diseases (especially NCDs)
- **Limitations**: not suitable for rare exposures; liable to selection bias and recall bias; not suitable for calculation of frequency measures.
- **Effect measure**: Odds Ratio + CI

Cohort Studies:

- **Characteristics**: follow-up period (prospective; retrospective)
- **Merits**: no temporal ambiguity; several outcomes could be studied at the same time; suitable for incidence estimation
- **Limitations** (of prospective type): expensive; time-consuming; inefficient for rare diseases; may not be feasible
- **Effect measure**: Risk Ratio (Relative Risk) + CI



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Experimental Study Design:

A study in which a population is selected for a planned trial of a regimen, whose effects are measured by comparing the outcome of the regimen in the experimental group versus the outcome of another regimen in the control group. Such designs are differentiated from observational designs by the fact that there is manipulation of the study factor (exposure), and randomization (random allocation) of subjects to treatment (exposure) groups.

Why Performed?

1. Provide stronger **evidence** of the effect (outcome) compared to observational designs, with maximum confidence and assurance
2. Yield more **valid results**, as variation is minimized and bias controlled
3. Determine whether experimental treatments are safe and effective under "**controlled environments**" (as opposed to "natural settings" in observational designs), especially when the margin of expected benefit is doubtful/narrow (10 - 30%)

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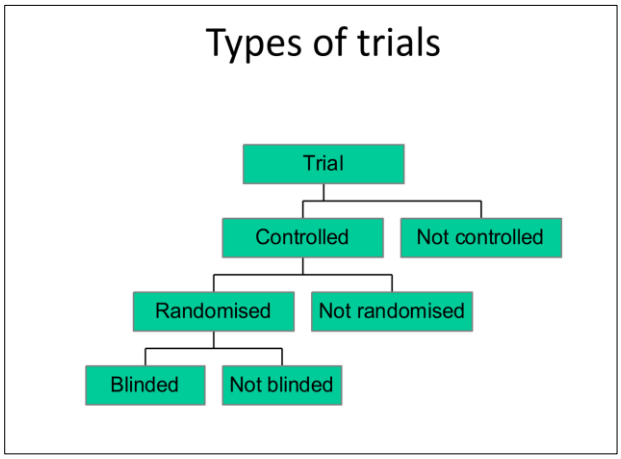
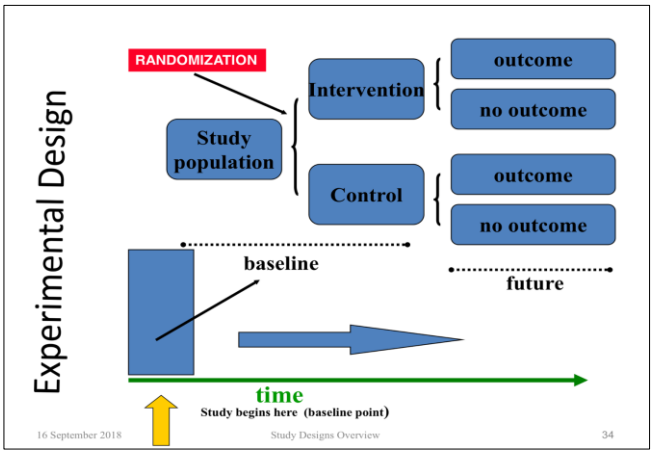




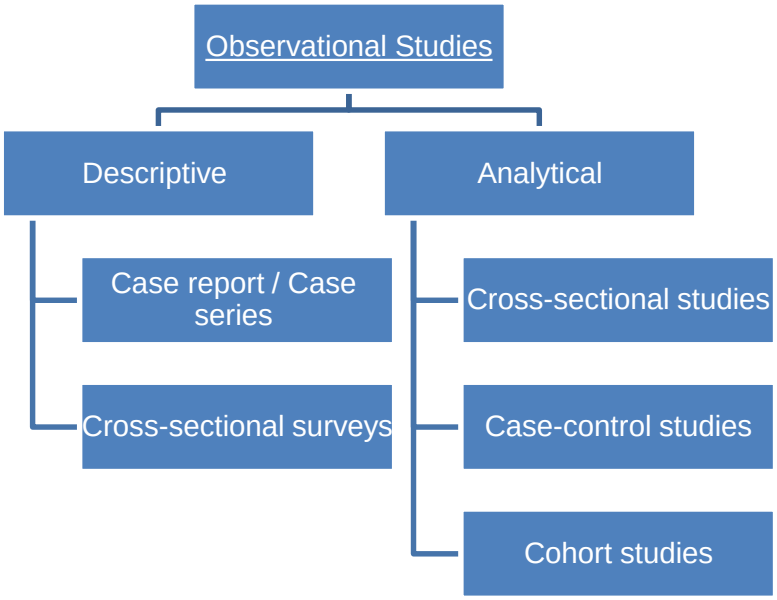
Conclusion:

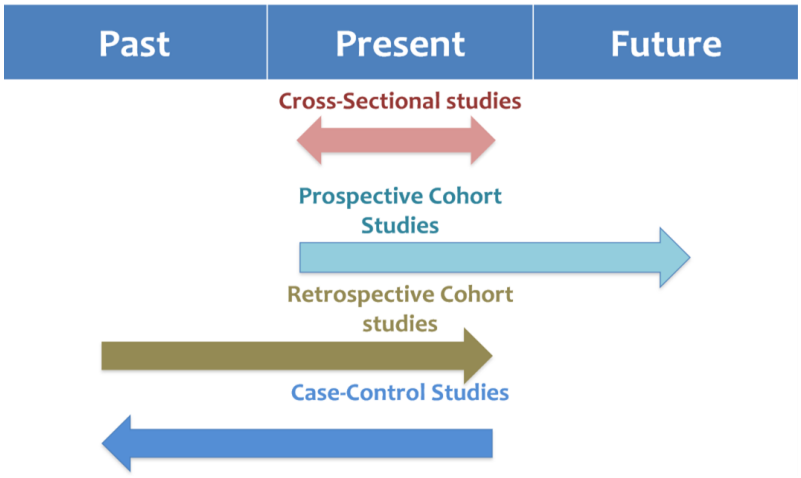
- Qualitative designs are complementary to quantitative designs, are important in study of social determinants of health problems
- Quantitative designs have a common goal to understand the frequency and causes of health related phenomena
- Seeking causes starts by describing associations between exposures (causes) and outcomes

Summary

Study designs broadly can be classified as:

1. Interventional (Experimental(
2. non-interventional (Observational)





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