

# RESEARCH DESIGN

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# What is research design ?

- ▣ Logic of the study
- ▣ What, How and Why of data collection
- ▣ The general strategy for gathering, analyzing and interpreting data

RESEARCH QUESTION – THE  
RESEARCH QUESTION SHOULD  
DETERMINE TO A LARGE  
EXTENT THE STUDY DESIGN

# Various classifications used

- ▣ Basic research
- ▣ Applied research
- ▣ Translational research ( T1– bench to bedside, T2– bedside to people in the community at large)

# BASIS OF CLASSIFICATION

- ▣ Retrospective
- ▣ Prospective
- ▣ Ambispective,
- ▣ Cross-sectional
  
- ▣ Observational ( non-experimental)
- ▣ Experimental (Non-Observational)
- ▣ Quasi- experimental (usually translational research)
  
- ▣ Descriptive (normative studies, developmental studies, qualitative)
- ▣ Analytical

# BASIS OF CLASSIFICATION

- Quantitative
- Qualitative
- Primary Research
- Secondary Research
- Observational
- Experimental
- Quasi experimental

# STUDY DESIGN OPTIONS

- ▣ Case Report
- ▣ Case Series
- ▣ Correlation Study
- ▣ Cross-Sectional Study
- ▣ Opinion / KAP Study (Health Social Sciences)
- ▣ Longitudinal Study
- ▣ Case-Control Study
- ▣ Cohort Study

# STUDY DESIGN OPTIONS

- ▣ Ecologic Study
- ▣ Research on Diagnostic Tests
- ▣ Economic Evaluation
- ▣ Program Evaluation
- ▣ Health System Research
- ▣ Experimental Study (Trials)
- ▣ Systematic Reviews (Meta-Analysis)
- ▣ Methodological Research

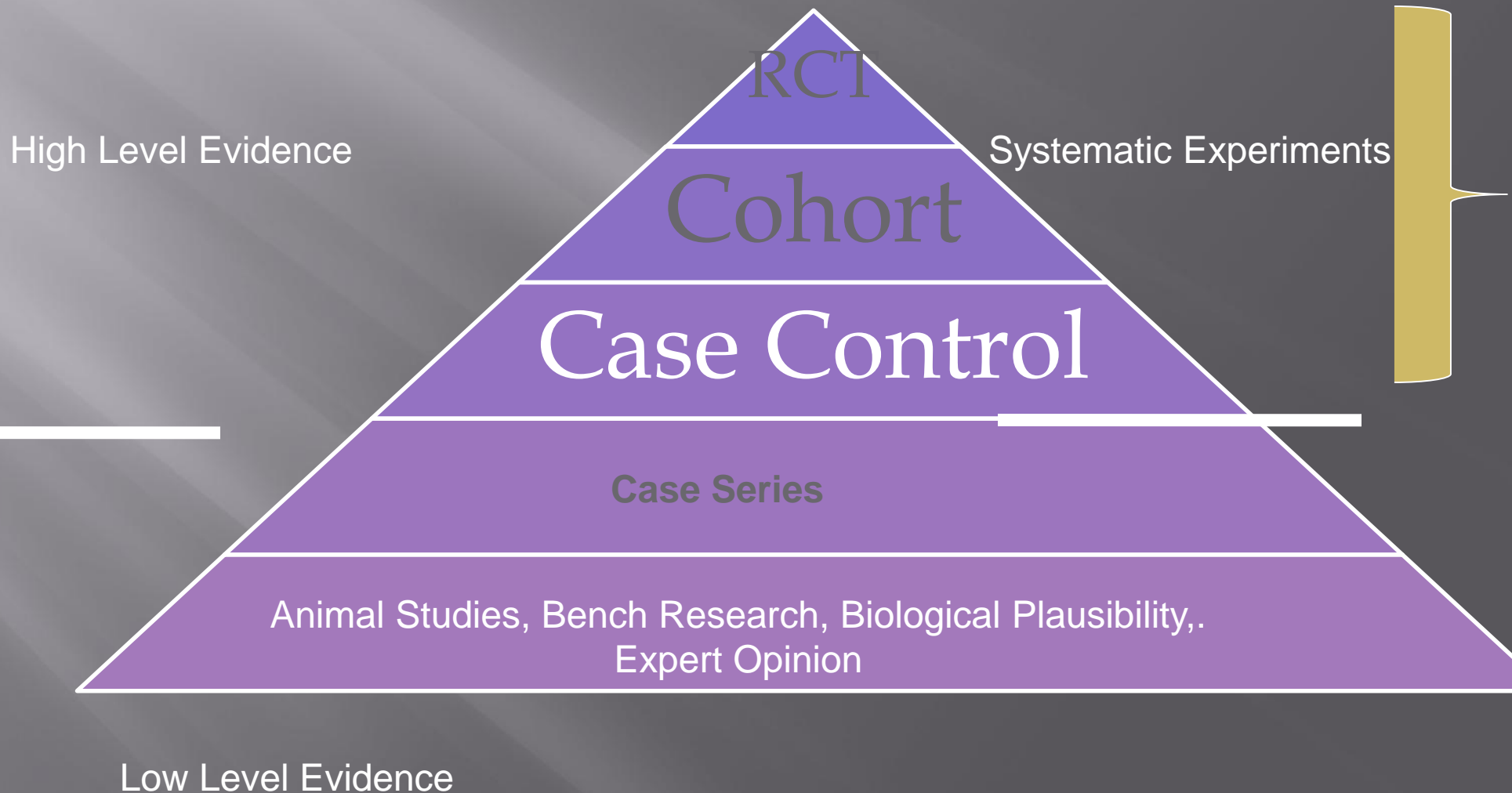
Each Design: Subtypes



# BASIS OF CLASSIFICATION

- Individual Analysis (Unit of Analysis: Individual)
- Ecological Studies (Unit of Analysis: Group)
- Exploratory
- Explanatory
- Hypothesis Generating
- Hypothesis Testing
- Qualitative
- quantitative

# The Evidence Pyramid



# HIERARCHY OF STUDY DESIGNS

- Isolated Case Reports
- Case Series
- Cross-Sectional Study
- Longitudinal Study
- Case-Control Study
- Cohort Study
- Non-Randomized Trials
- Randomized Controlled Clinical Trial
- Meta-Analysis

# Hierarchy of evidence for assessing effectiveness



# Levels of Evidence

## Low Level Evidence

- Animal Studies
- Case Studies
- Case Series
- Biological Plausibility

## High Level Evidence

- Intervention Studies
- Cohort Studies
- Case Control Studies

# Low Level Evidence

- ▣ Called Low evidence not because they are methodologically unsound.
- ▣ Most commonly leaps of faith are required to assume that knowledge on biological mechanisms, or results obtained from animal or bench experiments translate into clinical decisions that lead to a tangible patient benefit.

# Key Achievements from Low Evidence Research

- ▣ Discovery of DNA structure
- ▣ Discovery of antibiotics
- ▣ Synthesis of insulin
- ▣ Discovery of handwashing

# Case Reports

- ▣ Detailed presentation of a single case.
- ▣ Useful tool by which unusual disease or unusual presentation of a disease are brought to attention.



# Case Series

- ▣ Case series comprise a description of a group of individuals with a particular disease.
- ▣ Common way of describing the clinical picture in an uncommon presentation of an illness.
- ▣ Example – Case Series with historical controls led to the identification of bisphosphonates as a cause for osteonecrosis of the jaw.

# Continuum of research

Descriptive

Exploratory

experimental

RCT/ true experiment



Cohort studies  
Case control studies

Developmental research  
Normative research  
Qualitative research

Case studies

# Study Design VS Methods

- ▣ “Qualitative research” is used in practice in two different ways
- ▣ To describe the orientation and the design of the study (qualitative methodology)
- ▣ To describe the data collection methods used (qualitative methods)

## Qualitative methods

## Quantitative methods

When the subject matter is unfamiliar.

When the subject matter is clearly defined and familiar.

For exploratory research, when relevant concepts and variables are unknown or their definitions are unclear.

When measurement problems are minor and have been resolved.

For explanatory depth: when one wants to relate particular aspects of behaviour to the wider context.

When this setting is already sufficiently understood, and depth and the details of the data are known and only “how many?” needs to be known.

## Qualitative methods

## Quantitative methods

When **meaning** rather than frequencies are sought.

When detailed numerical description for a representative sample is required.

When **flexibility of approach** is needed to allow for discovery of the unexpected, and an in-depth investigation of particular topics.

When **repeatability of measurement** is important.

For studying selected issues, cases or events **in depth** and detail.

When **generalizability of results and comparison across populations** is required.

RESEARCH QUESTION  
SHOULD DETERMINE TO A  
LARGE EXTENT THE STUDY  
DESIGN

# Choosing the best design for each research question

**It is time to stop squabbling over the “best” methods**

Focusing on methods rather than questions has largely been arguing about the wrong things.

- The question being asked (usually) determines the appropriate research strategy, not tradition.
- Each method should flourish, because each has features that overcome the others limitations.

Level of existing evidence

- **Which way of answering the question provides us with the most valid, useful answer**

*(Sackett DL, Wennberg JE. BMJ. 199 7;3315:1636)*

# Dictionary definition of “cohort”

## Concept

A group of individuals that are all **similar**  
**in some trait and move forward**  
**together as a unit**



# Epidemiology definition of “cohort”

**Cohort:** A group of individuals that share a common characteristic

- **Birth cohort** : all individuals in a certain geographic area born in the same period (usually a year)
- **Inception cohort**: all individuals assembled at a given point based on some factor, e.g. where they live or work
- **Exposure cohort**: individuals assembled as a group based on some common exposure
  - e.g. radiation exposure during desert testing
  - e.g. asbestos exposure in the shipyard

## Types of cohort studies

- Single group (inception cohort)
- Multiple groups (Double or Comparison cohort)
  - From the same inception cohort (internal controls)
  - Assembled separately (external controls)
- n Prospective
- n Retrospective
- n Ambispective
  - Both prospective and retrospective components

A COHORT IS A GROUP OF PEOPLE WHO  
SHARE A COMMON CHARACTERISTIC OR  
EXPERIENCE WITHIN A DEFINED PERIOD

## Observational cohort study

In the 1920's lung cancer rates were rising in many countries. At that time this was popularly attributed to factors like air pollution, damp climate, exhaust from motorized vehicles and carcinogens from the tar used to make roads.



# Biases in study designs

- ▣ **recall bias** is likely to occur in cross-sectional or case-control studies where subjects are asked to recall exposure to risk