

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- beside 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

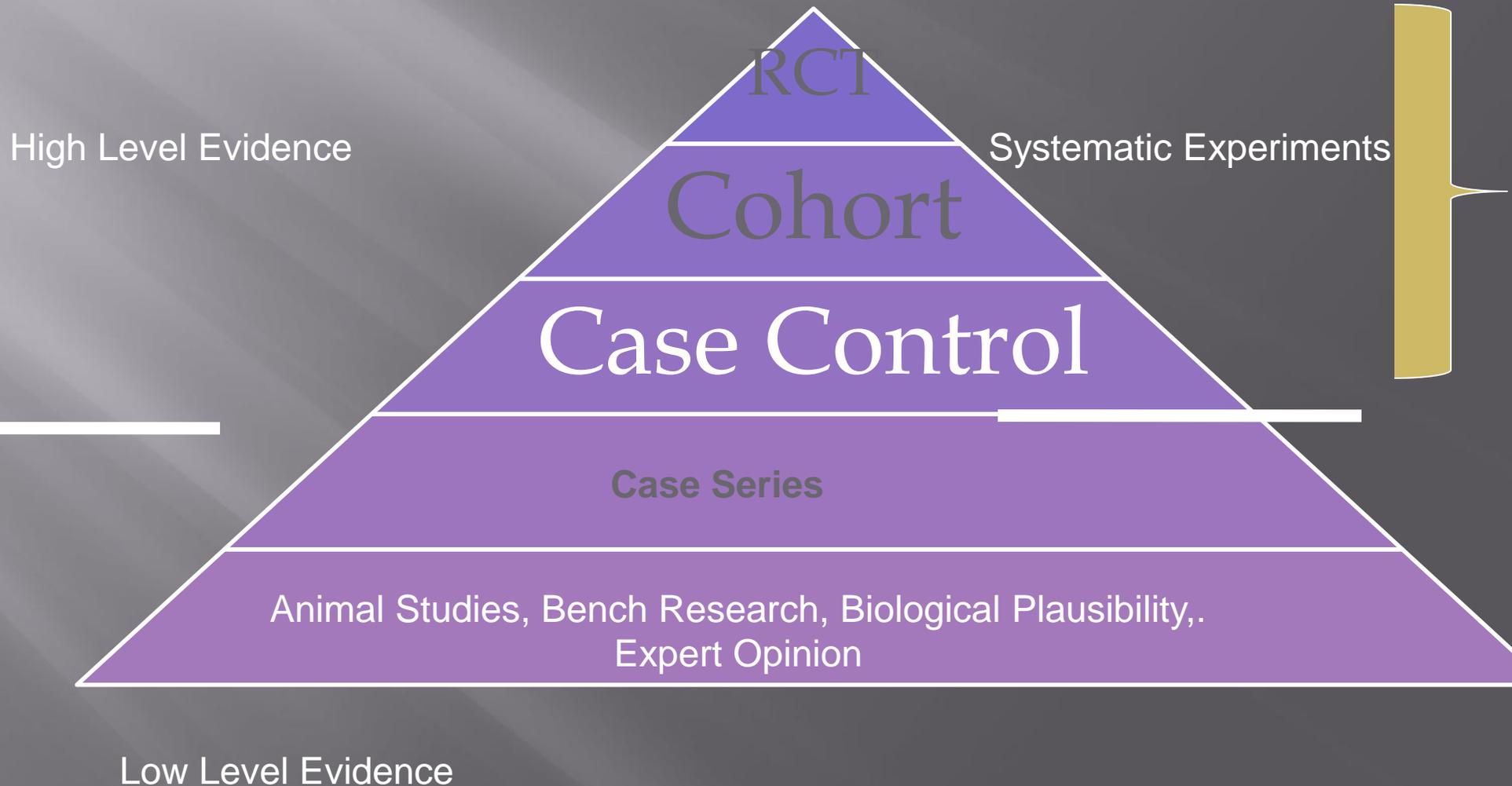
- Individual Analysis (Unit of Analysis: Individual)
- Ecological Studies (Unit of Analysis: Group)

- 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

- 
- Best
- Systematic review of RCTs
 - One good quality RCT
 - Observational studies
 - Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees
- Worst
- Someone once told me...

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