



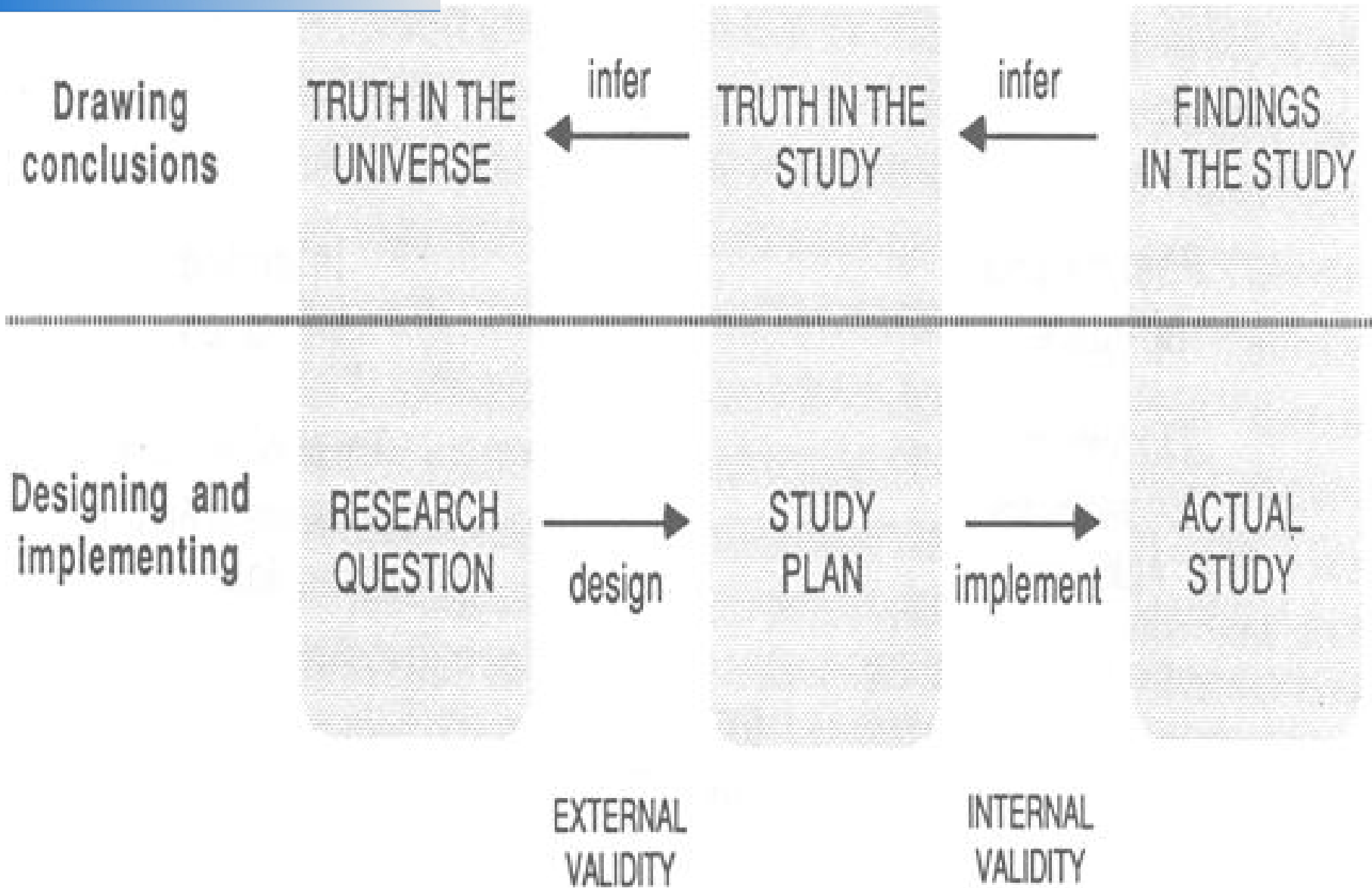
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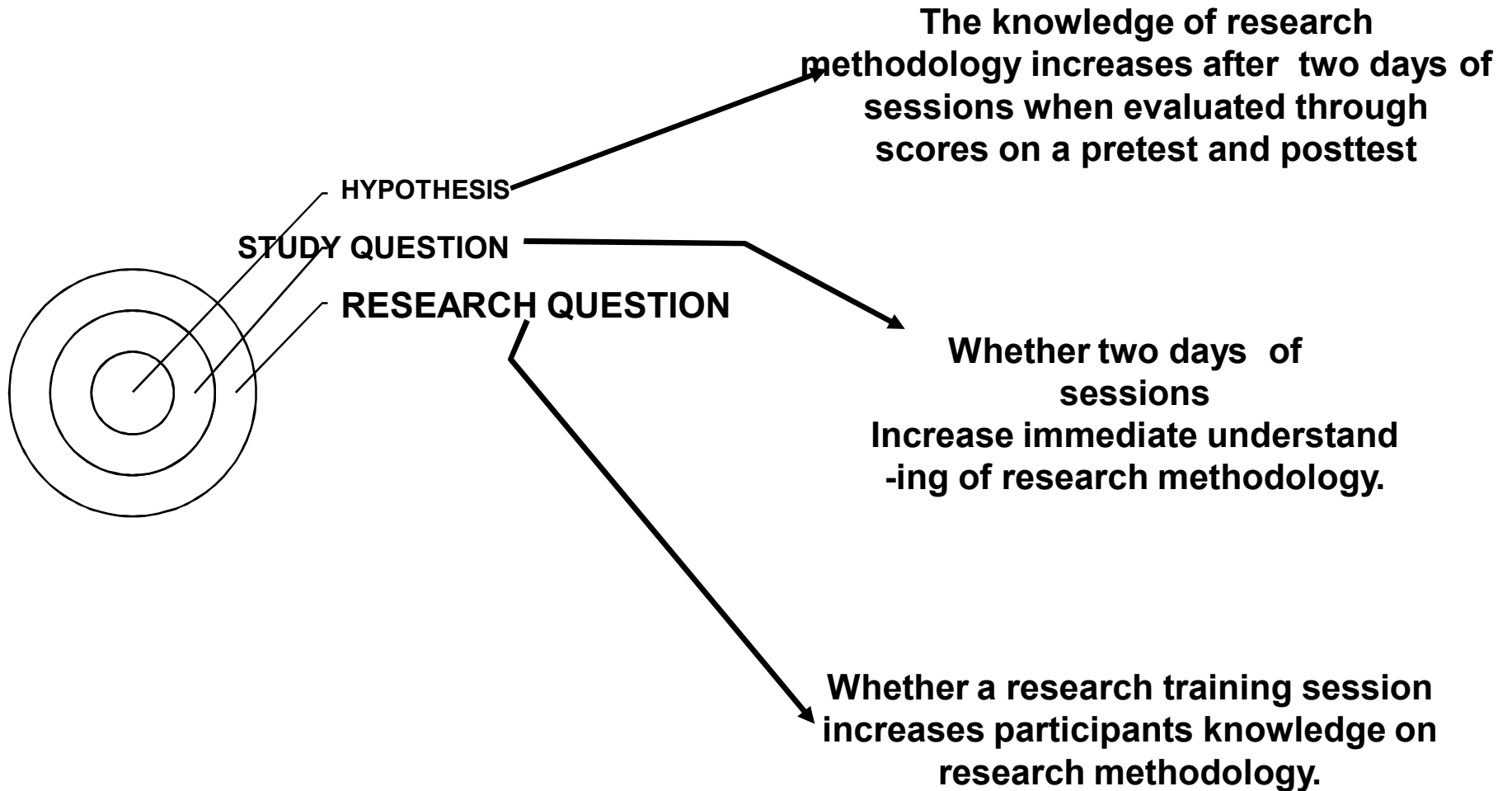
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Research Question, Hypothesis, Variables

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Designing & Implementing a Research Project





The research question

- All studies should start with a *research question* that addresses what the investigator would like to know
- Goal is to find an important research question that can be developed into a feasible and valid study plan

Research Question



Study Design



Data Collection



Data Analysis



Interpretation

Sections of the study protocol

- **Research question**
- **Significance (background)**
- **Study design**
- **Study population and sampling**
- **Variables and measurements**
- **Statistical issues**
- **Ethical issues**
- **Quality control and data management**

Origins of a research question

- Mastering the literature
 - . Scholarship -- be a scholar and know the literature
 - . Get a mentor

- Be alert to new ideas and techniques
 - . Importance of teaching

- Be imaginative

Narrowing and Clarifying

- Narrowing, clarifying, and even redefining your questions is essential to the research process.
- Forming the right questions should be seen as an iterative process that is informed by reading and doing at all stages.

The research question

■ Format for descriptive study

What is the prevalence (or mean, median, etc.) of [outcome variable] in a population of [study population]?

■ Format for analytic study

Is [predictor variable] associated with [outcome variable] in a population of [study population]?

IRIVER characteristics

- Feasible
- Interesting to the investigator
- Novel
- Ethical
- Relevant

Characteristics criteria for feasibility

- Adequate number of subjects
- Adequate technical expertise
- Affordable in time and money
- Manageable in scope

Characteristics criteria for Interesting

- Should be of academic interest

Characteristics Criteria for

Novelty

- Confirms or refutes previous findings
- Extends previous findings
- Provides new findings

Characteristics criteria for Relevance

- To scientific knowledge
- To clinic, public health or health policy
- To future research directions

Problems and solutions: Research plan is not *FINER*

- Not feasible
 - . Too broad
 - . Not enough subjects available
 - . Methods beyond skill of investigator
 - . Too expensive

- Not interesting, novel or relevant

- Uncertain ethical suitability

Problems and solutions: Research plan is not feasible

- Too broad
 - . Smaller set of variables
 - . Narrow the question

- Not enough subjects available
 - . Expand inclusion criteria
 - . Modify exclusion criteria
 - . Add other sources of subjects
 - . Lengthen the time frame for entry into study
 - . Use strategies to decrease sample size

Problems and solutions: Research plan is not feasible

- **Methods beyond skill of investigator**
 - . Collaborate with colleagues who have skills
 - . Consult experts and review literature for alternative methods
 - . Learn the needed skills yourself

- **Too expensive**
 - . Consider less costly study design
 - Fewer subjects and measurements
 - Less extensive measurement
 - Fewer follow-up visits

Problems and solutions: Research plan is not *FINER*

- Not interesting, novel or relevant
 - . Consult with mentor
 - . Modify the research question

- Uncertain ethical suitability
 - . Consult with institutional review board (ethics committee)
 - . Modify the research question

Problems and solutions

- Study plan is vague
 - . Write the research plan at an early stage
 - . Get specific in the 1 to 2-page study plan
 - How the subjects will be sampled
 - How the variables will be measured

Primary and Secondary Questions

- More than one primary question has advantages and disadvantages
- A sensible strategy is to establish single primary research question around which build the study plan
- This can be supplemented with secondary questions

Five Important Terms

- Outcome variable
- Exposures
- Bias
- Confounder(s)
- Chance factor

Search Questions

Primary/ Secondary

- What is the prevalence of a condition or mean of a characteristics?
- Correlation/Agreement between parameters
- What are the diagnostic characteristics of a candidate test (quantitative/categorical) with reference to a %Gold Standard+?.
- What is incidence of an outcome?.
- What are the predictors of an outcome?
- What are the risk factors associated with an outcome?
- Evaluation of a candidate intervention against a comparative (standard/control) intervention?.

Hypothesis: Definition

**the word hypothesis is derived form the Greek words
“hypo” means under
“tithemi” means place**

Under known facts of the problem to explain relationship between these

- .. is a statement subject to verification**
- .. a guess but experienced guess based on some facts**
- .. is a hunch, assumption, suspicion, assertion or an idea about a phenomena, relationship, or situation, the reality of truth of which one do not know**

A researcher calls these assumptions, assertions, statements, or hunches and they become the basis of an inquiry.

In most cases, the hypothesis will be based upon either previous studies or the researcher’s own or someone else’s observations

Hypothesis is a conjectural statement of relationship between two or more variable

Definition

Hypothesis is proposition, condition or principle which is assumed, perhaps without belief, in order to draw its logical consequences and by this method to test its accord with facts which are known or may be determined (Webster's New International Dictionary of English).

A tentative statement about something, the validity of which is usually unknown

Hypothesis is proposition that is stated is a testable form and that predicts a particular relationship between two or more variable. In other words, if we think that a relationship exists, we first state it is hypothesis and then test hypothesis in the field



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Definition

A hypothesis is written in such a way that it can be proven or disproven by valid and reliable data . in order to obtain these data that we perform our study)

A hypothesis may be defined as a tentative theory or supposition set up and adopted provisionally as a basis of explaining certain facts or relationships and as a guide in the further investigation of other facts or relationships

Characteristics

Hypotheses has the following characteristics:

- a tentative proposition
- unknown validity
- specifies relation between two or more variables

Functions

Bringing clarity to the research problem

Serves the following functions

- ✓ provides a study with focus
- ✓ signifies what specific aspects of a research problem is to investigate
- ✓ what data to be collected and what not to be collected
- ✓ enhancement of objectivity of the study
- ✓ formulate the theory
- ✓ enable to conclude with what is true or what is false



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Characteristics

Simple, specific, and contextually clear

Capable of verification

Related to the existing body of knowledge

Operationalisable

Typologies

Three types

- ✓ working hypothesis
- ✓ Null hypothesis
- ✓ Alternate hypothesis

Example

- ❑ Working hypothesis: Population influences the number of bank branches in a town
- ❑ Null hypothesis (H_0): Population do not have any influence on the number of bank branches in a town.
- ❑ Alternate hypothesis (H_1): Population has significant effect on the number of bank branches in a town. A researcher formulates this hypothesis only after rejecting the null hypothesis.

Typologies

Null hypothesis

A null hypothesis is formulated against the working hypothesis; opposes the statement of the working hypothesis

....it is contrary to the positive statement made in the working hypothesis; formulated to disprove the contrary of a working hypothesis

When a researcher rejects a null hypothesis, he/she actually proves a working hypothesis

In statistics, to mean a null hypothesis usually H_0 is used.

For example,

H_0 : There is no association between smoking and HTN

Typologies

Alternate hypothesis

An alternate hypothesis is formulated when a researcher totally rejects null hypothesis

He/she develops such a hypothesis with adequate reasons

The notion used to mean alternate hypothesis is $H_1 \rightarrow Q > O$

i.e., Q is greater than O

Variables

- Definition: Variables are properties or characteristics of people or things that vary in quality or magnitude from person to person or object to object (Miller & Nicholson, 1976)
 - . Demographic characteristics
 - . Anthropometric Characteristics
 - . Nutritional variables
 - . Clinical Variables
 - . Behavioral variables
 - . Abstract variables
 - . Construct variables; etc.,

- in order to be a variable, ***a variable must vary*** (e.g., not be a constant), that is, it must take on different values, levels, intensities, or states

exists because in health sciences things vary.

- Variables can be classified differently according to their utility and the vision of the scientific discipline.
- In medical research, an understanding of variables is important from both epidemiological (relational) and biostatistical perspectives.
- In epidemiology, variables are considered in terms of description or presentation, and relationships.
- From analysis perspective, allocation of specific variables into the specific classes is relative. It depends upon the level of knowledge, study questions and methodology.

Outcome Variable

- Outcome; Dependent; Effect, Response
- In which investigator is actually interested

■ <u>Study</u>	<u>Exposure</u>	<u>Outcome</u>
1	SMK	HTN
2.	HTN	CVD
3.	CVD	Death

Exposure Variables

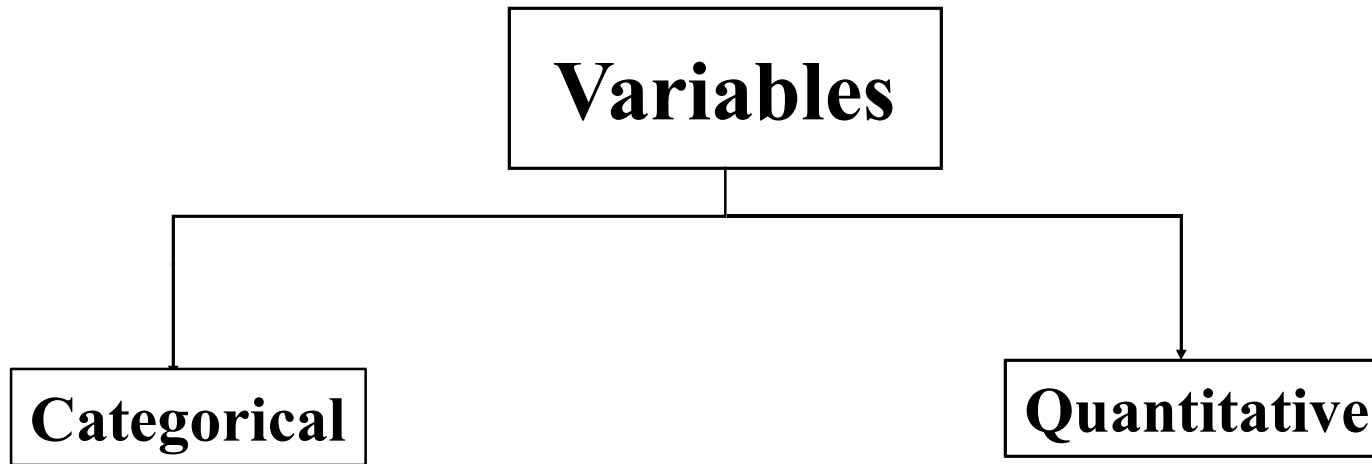
- Exposure; independent, covariate, factor
- Variable that is *manipulated* either by the researcher or by nature or circumstance
- These variables are also called %stimulus+%input+ or %predictor+variables
- analogous to the %cause+ in a cause-effect relationship

nal studies: Not assigned

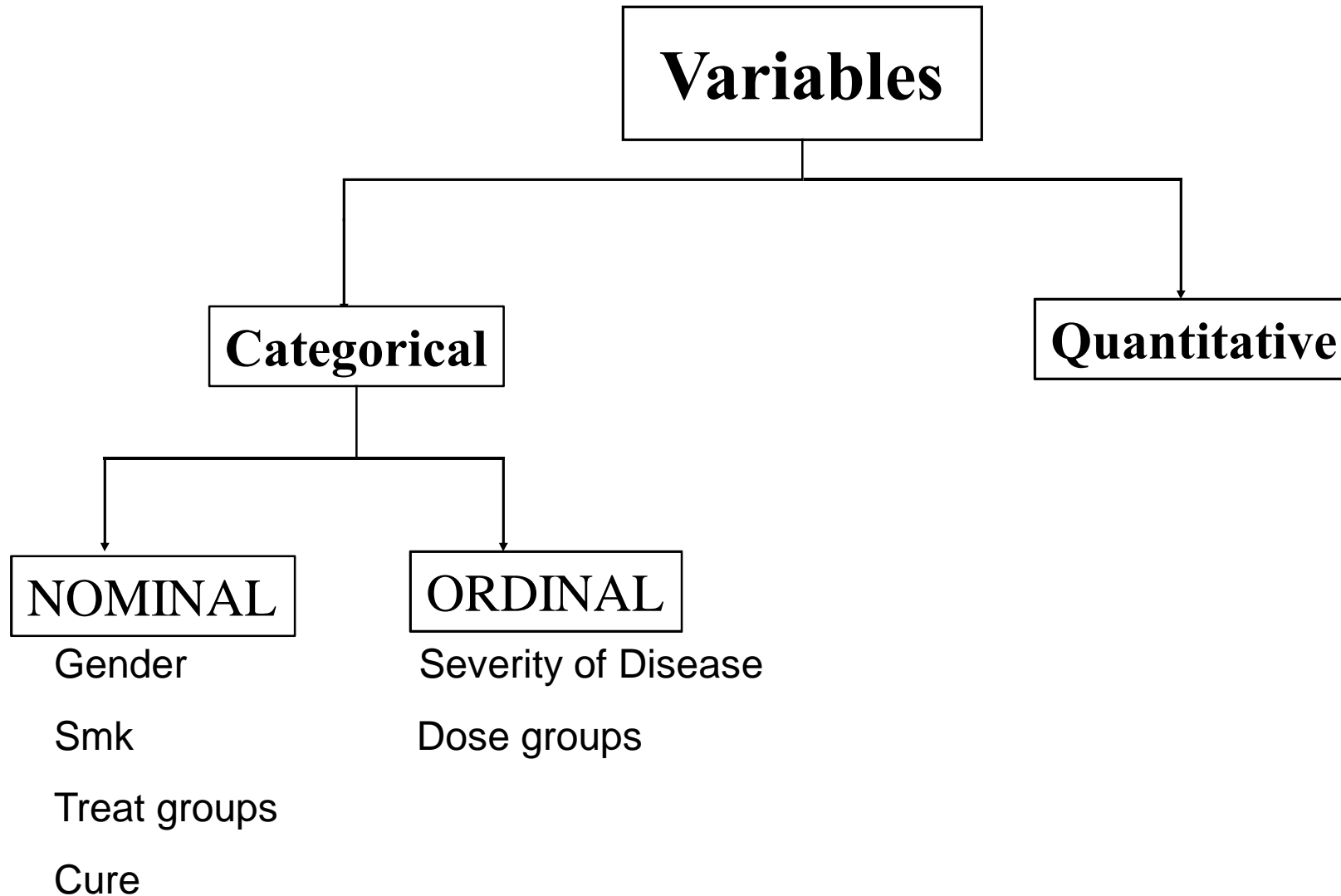
Modifiable/Non-Modifiable

- Intervention studies : Assigned by the Investigator
- Any factor which has potential to influence the outcome would be an exposure; however, interested in one exposure at a time, other factors would be termed as other factors (Confounders; Effect modifier; intervening)

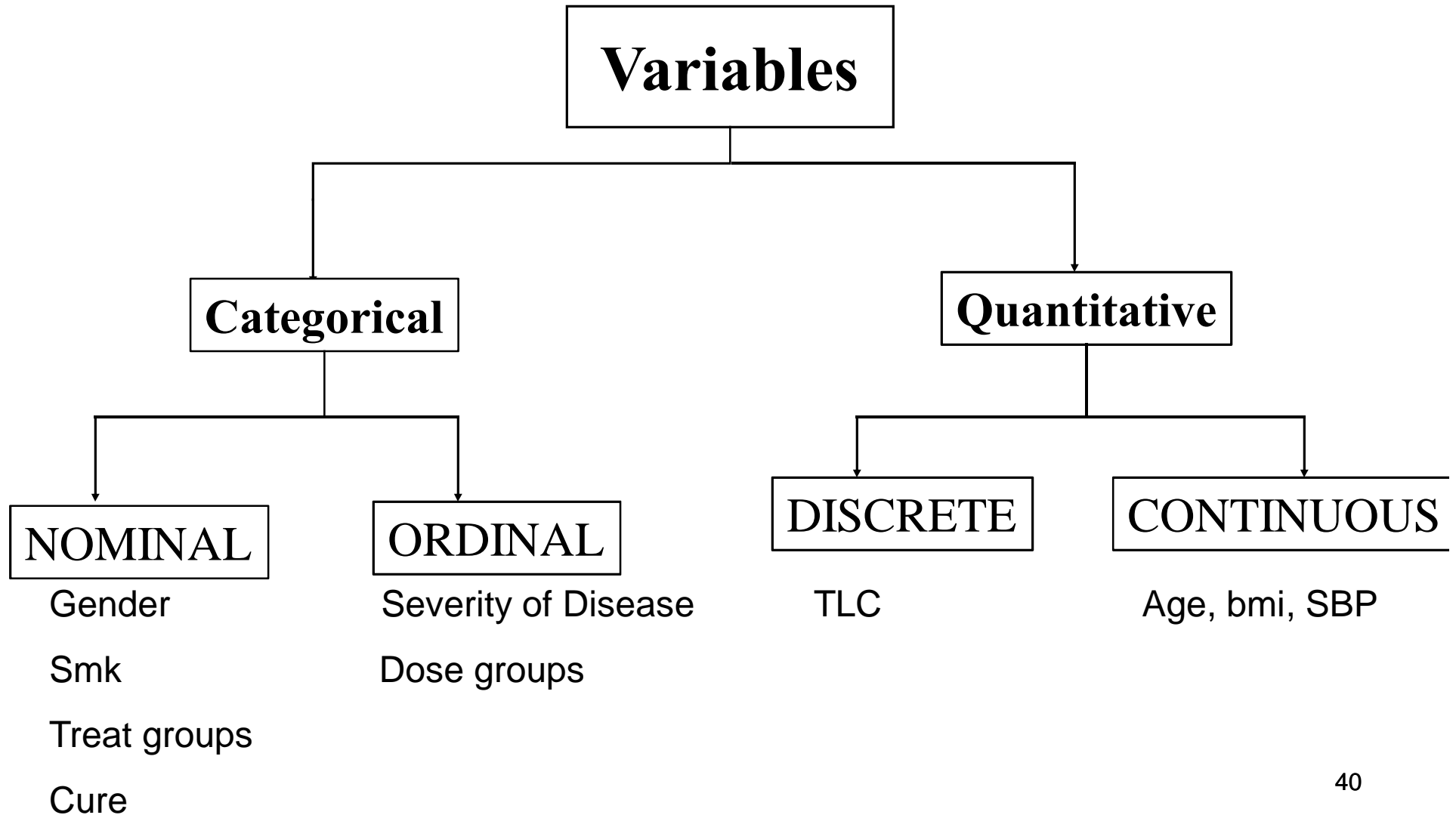
Types of Variables: Level of Measurement



Types of Variables: Level of Measurement

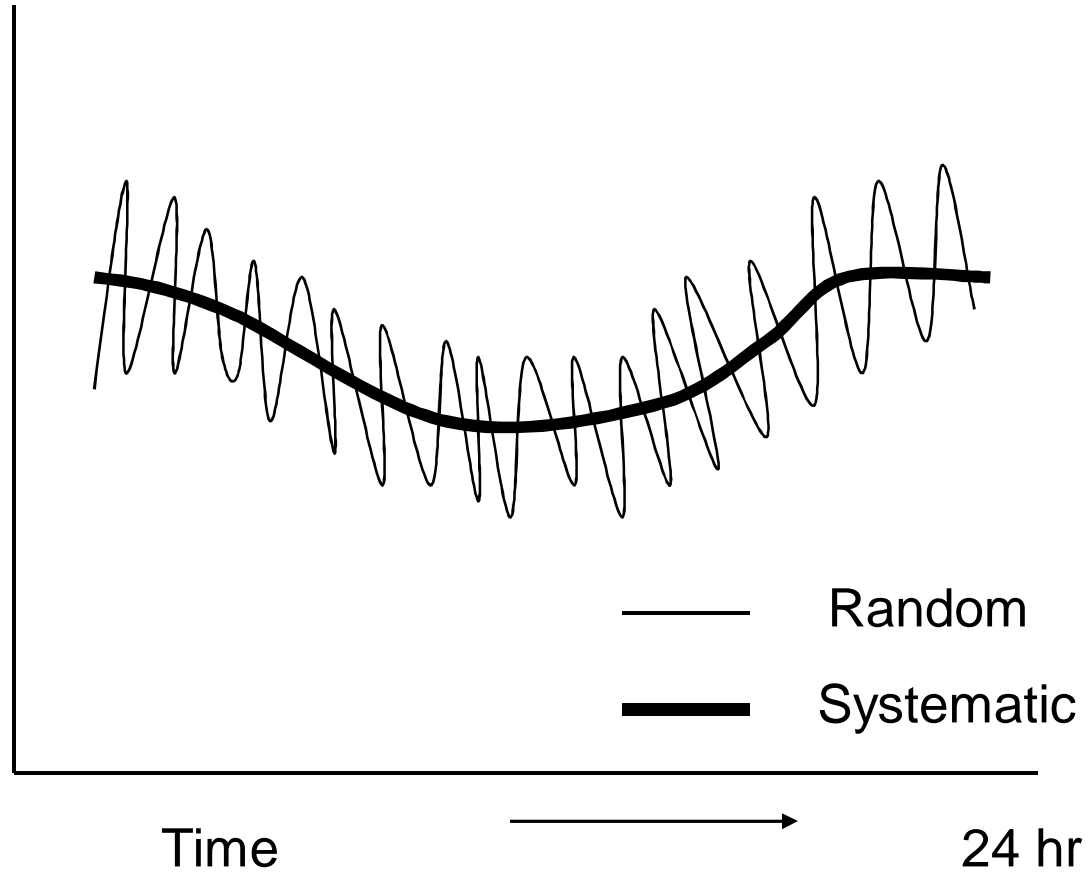


Types of Variables: Level of Measurement



Types of variability

Systolic
Blood
Pressure



Exposure-Outcome Association : Possibilities

- The observed statistical association between a certain outcome and the hypothesized exposure could be the result of systematic errors in collection of data (sampling, disease and exposure ascertainment) or its interpretation
 - role of bias

- Or it could be due to the effect of additional variables that might be responsible for the observed association
 - role of confounding

- Or it could be just a matter of chance

- Or it could be a real association

es of Variables: From Analysis Point of View

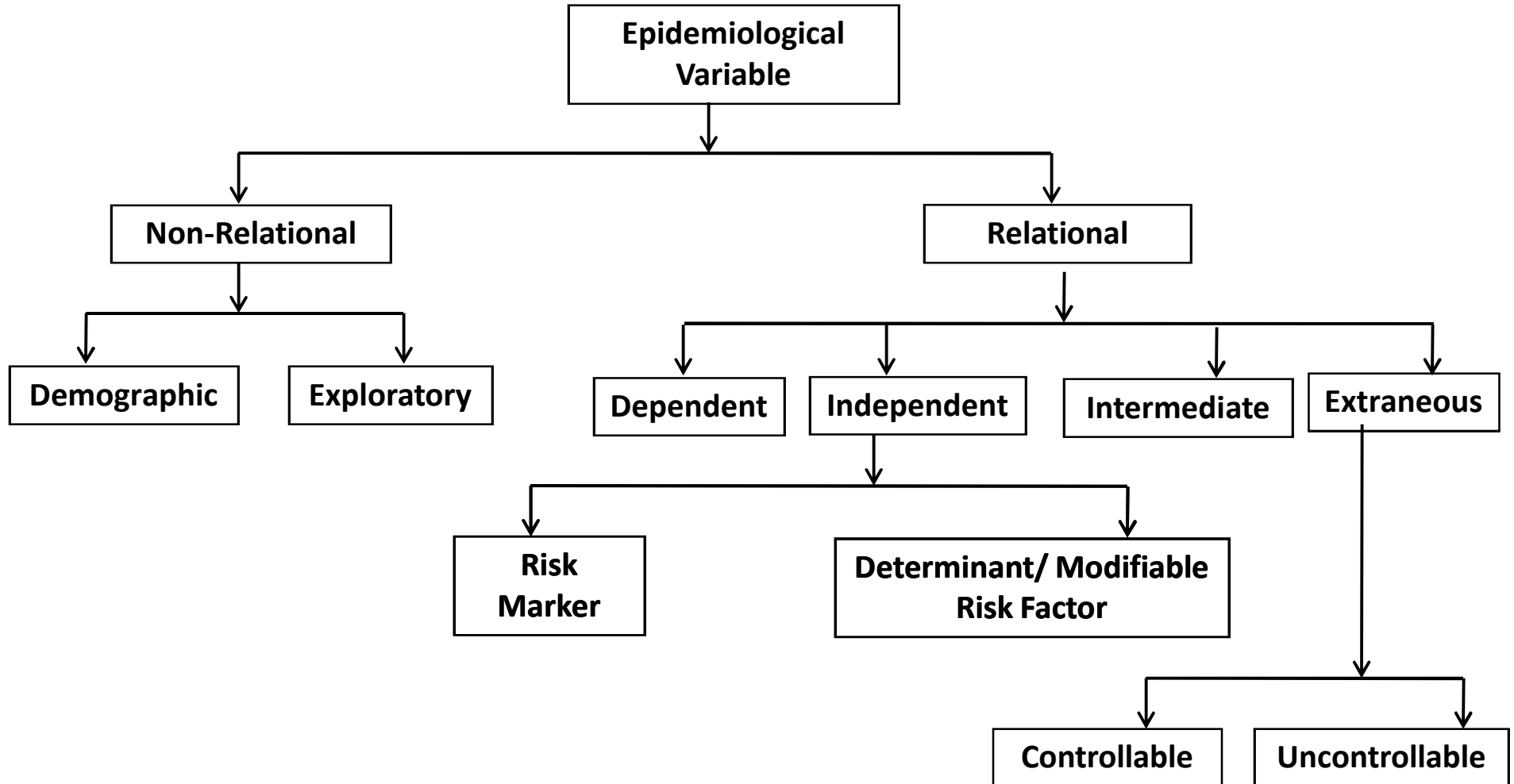
- Outcome

- Exposure

- Other factors
 - . Confounder
 - . Effect Modification
 - . Intermediate

From analysis perspective, allocation of specific variables into the specific classes is relative. It depends upon the level of knowledge, study questions and methodology.

Classification of Variables in Epidemiology





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QUESTIONS??