# Study design, Pilot study and Data Analysis

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## **Outlines:**

- 1- Study Designs.
- 2- Definition of research design.
- 3- Elements of research design.
- 4- Types/approaches of research design.
- 5- Research Validity & Reliability,
- 6- Definition of Pilot Study.
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#### Study Designs:

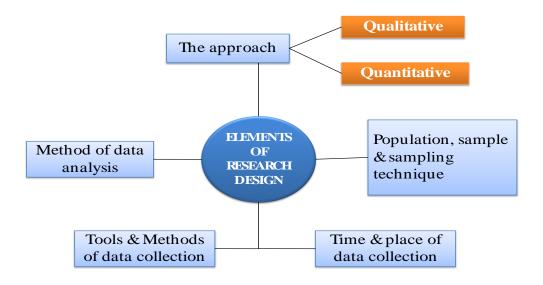
#### **Introduction:**

- ➤ A major issue in research is the preparation of the research design of the research project.
- > Study design is the procedure under which a study is carried out.
- The research designs form the decisions regarding what, where, when, how much and by what means a research study will be conducted.
- ➤ -Research approach & research design are two terms that are frequently used interchangeably; however research design is a broader plan to conduct a study, &
- > Research approach is an important element of the research design, which governs it.

## > Definition of research design:-

Research design can be defined as a blueprint to conduct a research study, which involves the description of research approach, study setting, sampling size, sampling technique, method of data collection & data analysis that all to answer a specific research questions or for testing research hypothesis.

#### **Elements of research design:**



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#### **Types/approaches of research design:**

Generally research designs are classified into two broad approaches; that are:-

- 1) Quantitative research design:-
  - Role of Quantitative Research:
  - 1-Quantify data and generalize results from sample to population.
  - 2-Facilitates examination of large number of representative cases.
  - 3-Structured approach to data collection.
  - 4-Enables extensive statistical analysis.

## **♣** Outcome of Quantitative Research:

- 1-Confirmation of hypotheses, theories, etc.
- 2-Recommend final course of action.

<b>Broad Categories</b>	Types of Research Design	Main Features
	1 T	Maniaulatian af
	1- True experimental	- Manipulation of
	design:	independent variable, in the
	- Post-test –only control	presence of control group,
	design.	randomization.
	- Pre-test-posttest control	
	group design.	
I- Experimental		
research design	2- Quasi-experimental desi	- Manipulation of
	- Non-randomized control gr	independent variable, but
	design.	absence of either
	- Time-series design.	randomization or control
		group.
	3- Pre-experimental	- Manipulation of
	design:	independent variables, but
	- One- group pretest- post-	limited control over
	test design.	extraneous variables,
		- no randomization & control
		group.
		- Accurate description of
	1- Descriptive design:	characteristics of individual,
II- Non-Experimental		situation, or group, & the
Research design :		frequency with which a
		certain phenomenon occurs
		in natural setting without
		imposing any control or
		manipulation.

	1- Descriptive design:	<b>Uni-variant descriptive:</b>
	A- Univariant descriptive	Studies:
	design:	-undertaken to describe the
	- to describe characteristics	frequency of occurrence of a
	certain groups.	phenomenon rather than to stu
		relationship.
	1- Descriptive design:	
	B- Exploratory	Exploratory:
	descriptive design:-	- Investigating the phenomeno
- Non-Experimental	to formulate the problem.	its related factors about which
Research design		very little is known.
	1- Descriptive design:	
	C- Comparative	<b>Comparative:</b>
	descriptive design:-	Comparing occurrences of a
	- to provide evidence of	phenomenon in two or more
	the relationships between	group.
	variables.	
		- Examining the relationship
	2. Correlational	between two or more
	design:	variables in a natural setting
		without manipulation or
		control (cause & effect
		relationship).
	2. Correlational	<b>Prospective:</b> Examining
	design:	relationship from cause to
	A- Prospective design.	effect.
	<b>B-</b> Retrospective design.	- Examines data being

	collected in the present.
	<b>Retrospective:</b> Examining
	relationship from effect to
	cause.
	- Examines data already
	collected in the past.
3- Developmental	Examining the phenomenon
Research Design:	in respect to the time.
A- Cross-sectional	A- Cross-sectional: -
design.	Examining the phenomenon
	only at one point in time.
B- Longitudinal design	<b>B- Longitudinal:</b> Examining
	the phenomenon at more
	than one point in time.
4. Epidemiological	The investigation of the
design:	distribution & causes of
-Case-control	disease in a population is
studies.	known as epidemiology.
	- Survey studies are
5. Survey research	investigation in which self-
design.	reported data are collected
	from sample with the
	purpose of describing
	population on some variables
	of interest.

#### 2) Qualitative research design:

#### ➤ Role of Qualitative Research:

- 1- Search of academic, trade and professional literature (both traditional & Internet).
- 2- Use of interviews, brain-storming & focus groups.
- 3- Use of existing questionnaires/ constructs.

#### > Outcome of Qualitative Research:

- 1- Improve conceptualization.
- 2- Clarify research design, including data collection approach.

#### **Study Designs:**

Cross-sectional studies are simple in design and are aimed at finding out the prevalence of a phenomenon, problem, attitude or issue by taking a snap-shot or cross-section of the population.

This obtains an overall picture as it stands at the time of the study.

- ➤ For example, a cross-sectional design would be used to assess demographic characteristics or community attitudes.
- These studies usually involve one contact with the study population and are relatively cheap to undertake.

#### **Cross-sectional design:**

✓ Takes a measure of a population at a certain point in time (e.g., a survey research).

#### **Cross-sectional design characteristics:**

- 1-Descriptive.
- 2-Are easy, fast, and inexpensive.
- 3-Can determine prevalence of disease.
- 4-Can look at associations between variables.
- 5-Cannot determine cause and effect.

#### Pre-test/post-test:

- ➤ Studies measure the change in a situation, phenomenon, problem or attitude. Such studies are often used to measure the efficacy of a program.
- ➤ These studies can be seen as a variation of the cross-sectional design as they involve two sets of cross-sectional data collection on the same population to determine if a change has occurred.
- ➤ **Retrospective studies:** investigate a phenomenon or issue that has occurred in the past.
- ➤ Such studies most often involve secondary data collection, based upon data available from previous studies or databases.
- ➤ For example, a retrospective study would be needed to examine the relationship between levels of unemployment and street crime in city over the past 100 years.
- **❖ Prospective studies**: seek to estimate the likelihood of an event or problem in the future.
- these studies attempt to predict what the outcome of an event is to be.
- ➤ General science experiments are often classified as prospective studies because the experimenter must wait until the experiment runs its course in order to examine the effects.
- ➤ Randomized controlled trials are always prospective studies and often involve following a "cohort" of individuals to determine the relationship between various variables.

#### ➤ Longitudinal studies:

- > Follow study subjects over a long period of time with repeated data collection throughout.
- Some longitudinal studies last several months, while others can last decades.
- ➤ Most are observational studies that seek to identify a correlation among various factors.

➤ Thus, longitudinal studies do not manipulate variables and are not often able to detect causal relationships.

#### > Study Validity:

- The degree to which a measurement or study reaches a correct conclusion.

#### > Types of Validity:

- **1-Internal**: Do the results of an investigation accurately reflect the true situation of the study participants?
- **2-External** (i.e., generalizability): Are the results of a study applicable to other populations?
- ➤ **Research Validity(Precision):** Are you measuring what you say you are measuring?
- ➤ **Research Reliability:** Does the measure give the same result each time it measures the same thing?
- **-Reliability (consistency):** describes the extent to which a measuring technique consistently provides the same results if the measurement is repeated.

#### **Definition of Pilot Study:**

- ❖ A pilot study can be defined as a 'small study to test research protocols, data collection instruments, sample recruitment strategies, and other research techniques in preparation for a larger study.
- ❖ A pilot study is one of the important stages in a research project and is conducted to identify potential problem areas and deficiencies in the research instruments and protocol prior to implementation during the full study.
- ❖ It can also help members of the research team become familiar with the procedures in the protocol, and can help them decide between two competing study methods, such as using interviews rather than a self-administered questionnaire.
- ➤ Pilot studies represent a fundamental phase of the research process.

#### > The importance of a pilot study:

- 1-To determine the feasibility of the study protocol and identify weaknesses in a study.
- 2-To test whether the study instrument(s), is asking the intended questions, whether the format is comprehensible and whether the selected validated tool is appropriate for the target population.
- 3- To test the appropriateness of data collection using the selected interview technique (face-to-face or telephone) or self-completed questionnaire.
- 4- To test the data collection process the time taken to complete questionnaire, and the subjects' willingness to participate in the study.
  - 5- To test data entry, coding of the items, and appropriateness of statistical tests.
- 6-To obtain preliminary data for the primary outcome measure, in order to calculate a required sample size (especially in randomized control trials).
  - ❖ Pilot studies may be used to gain experience, develop the researcher and to understand the related possible risks and study costs.
- ❖ Pilot studies help researchers decide if they should pursue larger-scale studies and if so, areas for development to ensure a feasible full-scale study.

## How to interpret a pilot study:

- Sample size may vary in pilot studies (different articles present different sample size calculations) but the pilot study population, from which the sample is formed, must be the same as the main study.
- the participants in the pilot study should not be entered into the full-scale study. This is because participants may change their later behaviour if they had previously been involved in the research.

## **♥** Why Include a Pilot study?

- Pilot Studies should be routinely incorporated into research designs because they:
- 1- Help define the research question.
- 2-Test the proposed study design and process. This could alert the researcher to issues which may negatively affect your project.
- 3-Educate researcher on different techniques related to the study.
- 4-Test the safety of the medical treatment in preclinical trials on a small number of participants.
- 5-This is an essential step in clinical trials.
- 6-Determine the feasibility of the study, so don't waste resources and time.
- 7-Provide preliminary data that can use to improve the chances for funding and convince stakeholders.

#### **Data analysis:**

- is the process of bringing order, structure and meaning to the mass of collected data.
- ✓ It is a messy, ambiguous, time-consuming, creative, and fascinating process. It does not proceed in a linear fashion; it is not neat. Qualitative data analysis is a search for general statements about relationships among categories of data."

#### ✓ Data Analysis:

#### ✓ WHY DO WE ANALYZE DATA:

- ✓ The purpose of analyzing data is to obtain usable and useful information.
- ✓ The analysis, irrespective of whether the data is qualitative or quantitative, may:
- ✓ Describe and summarize the data.
- ✓ •Identify relationships between variables.
- ✓ •Compare variables.
- ✓ •Identify the difference between variables.
- ✓ •Forecast outcomes.

## **Six Steps in Qualitative Data Analysis:**

- 1. Give codes from the notes.
- 2. Note personal reflections in the margin.
- 3. Sort and sift the notes to identify similar and different relationships between patterns.
- 4. Identify these patterns, similarities and differences.
- 5. Elaborate a small set of generalizations that cover the consistencies.
- 6. Examine those generalizations and form grounded theory.

#### **Dissemination of Research:**

- Communicate your findings.
- Conference presentations.
- Posters.
- Practice guidelines.
- Publish! Publish! Publish!

