

Column: Research Methods in Psychiatry

RESEARCH DESIGNS—AN OVERVIEW

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ABSTRACT

A research design is a systematic plan to study a scientific problem. The research problem determines the type of design. Research designs can be qualitative or quantitative; the latter can be experimental (interventional) and non-experimental (observational). Observational studies are further classified into descriptive (such as case reports, case series and cross-sectional studies) and analytical studies (like case-control and cohort studies). Experimental studies compare experimental groups exposed to different treatments or interventions. All these are briefly discussed along with systematic reviews, meta-analysis, qualitative research, basic sciences research, translational and implementation research.

Keywords: design, research, qualitative, quantitative, translational, implementation

A research design is a systematic plan to study a scientific problem. It is intended to provide an appropriate framework for a study. The choice of research design is very significant in the process of designing research since it determines how relevant information for a study can be obtained.¹ The research design refers to the overall strategy that is chosen to integrate the different components of a study in a coherent and logical manner to ensure that the research problem is addressed effectively. It constitutes the blueprint for the collection, measurement and analysis of data. The research problem determines the type of design and not the other way round. Research designs can be qualitative or quantitative. While qualitative research is primarily exploratory research, used to gain an

understanding of underlying reasons, opinions and motivations, quantitative research is used to quantify the problem by generating data that could be analysed statistically.

Quantitative Research Designs

In epidemiologic research, the basic quantitative design strategies can be broadly categorized into experimental (interventional) and non-experimental (observational) studies. Based on whether the studies focus on describing the distribution of disease or elucidating its determinants, the observational studies can be further classified as descriptive studies and analytical studies, respectively. See Table.1 for the classification of quantitative research designs.^{2,3}

Observational studies are those in which the

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Table 1. Classification of quantitative research designs^{2,3}

Research designs			
Non-experimental studies/ Observational	Descriptive studies	Individual-based	Case reports
			Case series
			Cross-sectional surveys
		Population-based	Ecological studies
	Analytical studies		Cross-sectional studies
			Case-control studies
		Cohort studies	
Experimental/ Interventional studies			Clinical trials
			Field trials
			Community intervention trials

the investigator is just observing the study variables, not intervening or acting upon study participants. The aim is to find the general characteristics of the distribution of the disease (the descriptive studies) or analyse the relationship between factors and outcomes (the analytical studies).

Descriptive studies are primarily useful for the development of hypotheses which can be tested later by the analytical studies. They can be population-based or individual-based. Population-based studies include ecological studies; while individual-based studies include case reports, case series and cross-sectional surveys.

Ecological studies are observational studies in which data is analyzed at the population level rather than individual level. Health outcomes studied are aggregates of individual health data like prevalence, incidence or rate of disease. The ecological risk or exposure data could be aggregate measures like the percentage of malnourished children, environmental measures like mean annual exposure to pesticides or global measures like population density.⁴

Case reports are the most basic individual-based, descriptive study design. A careful,

detailed report of the profile of a single patient is provided by one or more clinicians. This can also be expanded to a *case series* describing the characteristics of a number of patients with a given disease.

Cross-sectional surveys assess the exposure and outcome in the study participants at the same point in time. They provide information about the prevalence of outcomes or exposures, but it cannot be distinguished whether the exposure preceded the outcome or the outcome affected the exposure.²

Analytical studies involve an explicit comparison of exposure and disease status. There are two basic types of observational analytical designs—case-control studies and cohort studies. Either design can be used to test a hypothesis. The association of exposure of interest with the outcome is studied in both the designs. The choice of design is based on the characteristics of exposure and outcome, the current status of knowledge and the resources available like time and money.

Case-control studies: In this, a group of subjects with a disease and a control group, without the disease, are chosen, and the proportion of exposure of interest is compared between the two groups.

Cohort studies: In this, subjects are classified based on the presence or absence of exposure to a particular factor and followed up for a period of time to assess the incidence of the outcome of interest in either group.

Experimental studies are typical experiments on human subjects in which experimental groups are created that are exposed to different treatments or agents. The investigator assigns the exposure status of each participant. If each subject is assigned treatment using a random assignment mechanism like a coin toss, it is called randomization. This strategy, on average, controls for all the other, extraneous factors, that could affect the outcome. Experimental studies can be randomized or non-randomized (quasi-experimental). They can be clinical trials, field trials or community intervention trials. Health economic evaluation studies are generally piggybacked on experimental studies.

Clinical trials are conducted with patients as subjects. The goal is to evaluate a potential treatment or cure for a disease or to assess a medication to prevent the sequelae of the disease. In **field trials**, the subjects are not defined by the presence of disease or the need for clinical care. They are conducted on subjects “on the field,” without the disease, to evaluate whether an intervention (like vaccination) reduces the risk of developing a disease. In field trials, if treatment is assigned randomly to a group of participants, it is said to be a *cluster-randomized trial*. **Community intervention trials** are an extension of the field trial, in which intervention is assigned to the whole community as a unit (like water fluoridation).

Economic Evaluation

Health economic evaluation informs policymakers, payers and others on how to

make the efficient allocation of resources (which are obviously scarce) over competing health care interventions. These analyses answer the question of efficiency of allocation, i.e., the opportunity cost (health gains when a particular intervention is given up for the alternative intervention). Economic evaluation can be *partial* when it considers the cost of an illness or cost comparison of different interventions without considering their health effects; while *full* economic evaluation compares costs and effects of competing alternatives.⁵

Systematic reviews and meta-analyses are at the top of the pyramid in the hierarchy of evidence. Systematic reviews attempt to answer a specific research question by collecting and combining empirical evidence that meets pre-specified eligibility criteria. The focus is on selecting the right articles for the clinical question than the analysis per se. Meta-analyses are a subset of systematic reviews. It is a statistical procedure that integrates the results of several independent studies. It often results in valid conclusions about a question from multiple studies, the results of which may be conflicting. Usually, randomized controlled studies are included in the meta-analysis. But cohort and case-control studies could also be used.⁶

Qualitative Research

The goal of qualitative research is to develop concepts related to social phenomena in real settings through the meanings, experiences and views of all the participants. These methods do not provide quantified answers to research questions. Qualitative techniques include participant observation, in-depth interviews and focus group discussions. Qualitative work can be conducted

preliminary to quantitative research and also to supplement it as in ‘triangulation’. It is also used to identify the terms and concepts to develop questionnaires for quantitative research.⁷

Scale development and validation (including diagnostic test evaluation)

Scale development and validation involve qualitative research and descriptive epidemiologic methods. Still, the process is unique, and it has its own methodology.⁸ Diagnostic test evaluation has certain similarities to the process of development and validation of the scale.

Now, let us have a peek into some of the nascent and perennial research strategies which provide insights into disease processes and health care.

Basic Sciences Research includes a rigorous enquiry at the molecular level relative to the fundamental biology. (for example, how a virus is produced, how the virus invades the cell, how the cell responds etc.) It gives a foundation for disease diagnosis, treatment and prevention. Basic science research provides insights only into the biological processes as opposed to social, psychological, environmental and care delivery issues. They are usually done at the laboratory and not by clinicians.

In translational research, either basic science research is tapped to benefit patients in terms of new diagnostic tests or treatments¹⁰ or translation of results from clinical studies to everyday clinical practice.⁹

Implementation research attempts to study implementation strategies that support the health services, programmes and policies.

They aim to understand what, why and how interventions work in the “real world” settings and to test approaches to improve them.¹¹

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