1. The Scientific Method

The distinctive characteristic of science is its methodology. Science is not just a body of knowledge, but knowledge assembled by the application of the scientific methodology. This methodology comprises a system of rules and procedures on which research is based. The basic requirement is competence in logical reasoning and analysis. The rules and procedures of the scientific method are constantly being updated as scientists look for new and better ways of making observations, inferences, generalizations and analysis. As new developments occur, and experience with using them is gained, they get incorporated into the system of rules that govern the scientific methodology.

The primary goal of scientific research is to describe and explain reality (see figure 1.1). Research begins with defining and describing what is already known about a subject. This requires reviewing the literature and synthesizing the information generated by various studies in the past. Arising from the review one or more research questions are developed by the investigator. Each question is then carefully thought over, further sharpened, and expressed as one or more hypotheses, which are well-grounded in theory. Development of a research project involves examining the initial question and distilling it to precise testable statements or hypotheses. In doing so a number of subsidiary questions arise. For example:

What kind of study design will best provide the answer?
What tools are to be developed for obtaining the data?
What kind of information needs to be generated?
How many subjects?
What statistics are to be employed?
Will the answers be useful?

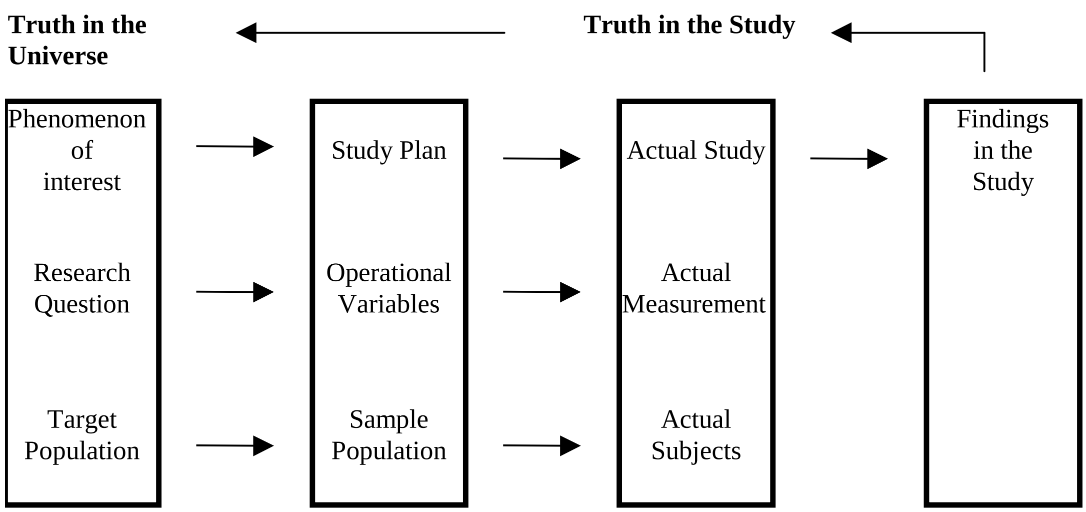

Figure 1.1: The goal of scientific research is to describe reality.

The process is circular, and as it carries on the study question gets more refined. The *potential value* of a study depends on the relevance of the research question that generates it. A researcher may use any one of several ways to answer the research question. The soundness of the methodology used determines the *ultimate worth* of the research. The key aspects of the methodology are study design; selection of subjects (sampling); definition of the study variables; data collection techniques; data analysis and interpretation of the results. At the end comes the final step of drawing inferences from the study, and how they feed back into the existing pool of knowledge.

In the application of the scientific method a great deal of clarity of thought and logical reasoning is called for. Clear definition of terms, classification, methods of drawing inferences, sampling, measurement and statistical calculation of results are the working tools of science. Rational criticism is at the heart of all scientific work.

The main elements of the scientific method are the following:

1).Hypotheses

A hypothesis is a statement that proposes a relationship between specific factors or variables. The factor concerned may be an attribute or characteristic of the person, place or time. For example, the personal attribute may be related to age, sex, race, income, social status, and so on. The factors related to place may be home, school, work place, rural or urban residence; those related to time can be time of the day, months, years, season etc.

The statement "Administration of penicillin cures pneumonia" is a hypothesis. In this example the hypothesis specifies the nature of the relationship between two or more sets of observations e.g. observations regarding administration of penicillin and observations regarding cure from pneumonia.

There are two basic types of hypotheses, null and alternative. The Null Hypothesis states that there is no difference between comparison groups. The Alternative Hypothesis, on the other hand, predicts the difference and also the nature of the difference.

An important feature of scientific hypotheses is that the terms used must be clear, observable and measurable.

Hypotheses are tentative answers to research problems. In addition to being clear and specific, hypotheses have to be value free and amenable to testing with available research methods. The hypothesis determines what factors (variables) are to be measured. One starts with defining the outcome and the variable which expresses it. Previous research, experience chance observation or intuition suggests to the investigator that a logical relationship exists. The next step is to define the factors that are thought to determine the outcome. By manipulating these factors the researcher observes the effect on the outcome. By usage the variable representing an outcome is also called the dependent variable. Those representing the factors leading to the outcome are called independent variables. In observational studies it is usually not possible to manipulate the independent variables. The researcher looks for existing differences in the intensity or strength of the independent variable. For example, in a study of smoking and heart disease the investigator looks for difference in outcome between non-smokers light smokers and heavy smokers.

It is usually the case that the concepts expressed by the hypotheses need to be translated into measurable terms by means of definitions. These are referred to as the operational variables. In the above example, light smoking may be defined as less than five cigarettes per day, and heavy smoking as more than five. To take another example, if one wishes to test the hypothesis that breastfed infants have fewer episodes of infection, breastfeeding may be defined as exclusive, partial or none; and infection may be defined as respiratory illness, diarrhoea and so on.

At the end of the study the conclusions arrived at after analysis of the data are first interpreted as they relate to the operational definitions used for the purposes of the study. They are then inferred to the concepts contained in the hypothesis, and further beyond in terms of the population from which the study sample was drawn.

In sampling and choosing operational definitions as well as measurements the investigator wishes to be practical while keeping as close to the research question as possible. There is always the risk that the study may produce conclusions, which may be correct for the operational definitions used in the study, but do not fully answer the research question. The strength of the study is determined by considering how far the conclusions of the study are likely to differ from the proper answer to the research question.

2). Sampling, observation, description and measurement

Sampling is considered in detail in chapter 3. For reasons of practicality including resource constraints research is normally conducted on a sample of the target population. How well the sample represents this target population will determine the accuracy with which the results of the study can be inferred to the target population.

Precise, unbiased recording of observations about persons, objects and events is the hallmark of the scientific method. In making observations the personal perceptions of the investigator are to be transformed into descriptive statements and measurements which can be understood and replicated by other investigators.

Some observations are made with instruments. They comprise quantitative data. Other observations are descriptive. They form qualitative data.

Even though instruments are important in all scientific inquiry the key elements are accuracy and replicability. Sampling, observation and measurement is the area where errors are likely to creep in and distort the study conclusions. Errors are of two types - random and systematic. A random error leads to a wrong conclusion either way by chance. An unknown source of variation can distort a sample or a measurement. Systematic error leads to distortion of findings in a particular direction. This is also referred to as bias. Awareness of the possibility of errors (chance or bias) in sampling and measurement is essential to avoid drawing wrong conclusions. For a variety of reasons the actual sample can end up different from the intended one, and so do measurements. Differences between the study plan and the actual study can distort the answer to the research question.

When observations are properly summarized and confirmed by others they form the factual basis of scientific knowledge.

3). Induction

Statements arising out of observations form the explanatory systems of science. For example, take the statement "Penicillin cures pneumonia". The observation was made in a small number of patients, but then generalized. This is the process of induction.

In the inductive process the researcher begins with meticulously conducted observations, and builds up ideas and testable hypotheses from them for further testing on the basis of more observation. A complementary approach is the deductive process, described fully below. Here the investigator starts with general ideas and theory, and develops testable hypotheses from them. The hypotheses are tested by gathering and analyzing the data.

In practice, one has an idea for a hypothesis and tests it against data in deductive fashion. If the hypothesis is refuted, one constructs a better theory in the light of the data obtained, and using induction constructs the improved theory. Hypotheses are not usually completely supported or refuted by the research data. Some aspects are supported, and others rejected. The investigator would commonly refine and modify the hypothesis, and again set out to test it.

4).Theories

Hypotheses get integrated into more general explanatory theories. Scientific theories are essentially explanations about natural phenomena. A theory brings together observations from many sources e.g. why antibiotics are effective against infectious diseases brings together evidence from microbiology, cell physiology and clinical medicine.

Scientific knowledge is thus built up by forming concepts to describe natural phenomena. These concepts then get interwoven into theoretical systems. An essential feature of scientific theories is correct use of *language and logic*. Formulation of concepts is necessary for effective communication, for classification or generalization, and serves to provide the building blocks for theories.

Scientific theories explain and specify causes of events, and provide a background for predicting. Some theories are in the form of models, which are mathematical or physical representations of how theories work.

Explanations of natural events or phenomena are of two types - deductive and probabilistic. A deductive explanation gives universal generalization and the conditions under which the generalization holds true. The Laws of Gravity is a good example of deductive explanation. But not all scientific explanations are of the deductive type. Some are of the probabilistic type by which we mean a high probability of an event occurring when certain conditions are present.

Over time evidence accumulates and challenges the dominant concepts, leading to the gradual realization of the inadequacy of the existing theory to explain events and phenomena. For example, the cause of peptic ulcer as being infection with *Helicobacter pylori;* or the role of breast milk beyond that of providing nutrition and immune protection to fine tuning of development in the infant. Pressure for change eventually occurs leading to what is often called a ‘paradigm shift’, and the new theory supplants the old one. The shift from old to new is not always painless.

5).Deduction.

A theory should lead to a set of statements or hypotheses. They are deduced logically from the theory or models which specify the causal relationship postulated by a theory.

Deductive and probabilistic explanations constitute one important component of scientific knowledge. Another component is the ability to predict. When knowledge is deficient prediction is either inexact or not possible. The basis of prediction in science is the logic that once it has been established that X causes Y, then if X is present a prediction can be made that Y will occur.

Combining explanations and predictions together the underlying logic of scientific knowledge can be set out as follows:

1). A statement 'E' sets out the specific phenomenon or event to be explained. For example, malnutrition commonly follows severe measles.

2). A set of statements "A^1.....to.... A^n" describe the relevant conditions that are causally related to the phenomenon described by 'E'. In our example of measles it may be stated that:

i). During severe measles, there is inflammation of the mucus membrane of the mouth making eating and swallowing painful.
ii). All severe illness is accompanied by anorexia.
iii). Because of cultural beliefs food may be withheld from children suffering from measles.

3). A set of generalizations "L^1....to....L^n" are set out which state that "Whenever events of the kind described by A^1...to...A^n take place , an event of the kind described by 'E' occurs".

In our measles and malnutrition example, we can say that in severe measles if any of the conditions described in 2). above is present malnutrition is very likely to occur.

6).Controlled observation.

Hypotheses have to be tested under controlled conditions. The aim of control is to remove the influence of other factors which affect the phenomenon. As we have seen in the testing of hypotheses concepts are first converted into measurable variables. (A variable may be defined as a characteristic that has 2 or more values). A distinction is made between independent, dependent and control variables. We have already explored the relationship between dependent and independent variables. An independent variable is a presumed cause of a dependent variable (e.g. smoking and coronary heart disease). Control variables serve the purpose of testing whether the observed relations between independent and dependent variables are true or spurious.

Establishing a relationship between two or more variables involves determining what values of one variable covary with values of other variables. Values of related variables can vary positively (as the value of one increases the values of related variables also increase), or negatively (as the value of one increases the values of related variables decrease), and the magnitude of the change.

7). Drawing inference

At the most basic level, the researcher is attempting to describe and explain reality by:

i). sampling a portion of it ii). making measurements on the portion sampled iii). analyzing the measurements iv). interpreting the results.

In step i). and ii). the researcher moves away from the larger reality firstly by studying only a sample of it, and secondly by studying only selected operationally defined characteristics (variables) of those sampled.

In step iv). the researcher moves back to the larger world by making inferences from the sample-specific study to the operationally defined variables. From there to the concepts contained in the hypothesis, and further on to the larger population of interest.

There are four types of inferences.

Statistical inference. The sampling frame should include all individuals in the population being studied, and the study sample should be selected in such a way that each individual has the same probability of being included. In such a case it is legitimate to infer the study findings to the larger population. Just as the sampling method provides the legitimacy, sample size determines the certainty of the inference. All things being equal, as sample size increases so does the confidence in the accuracy of the inference drawn from the sample to the study population. It is necessary that sample size should be determined as part of the study design.

Causal inference. Observational studies are rather weak in providing evidence of causation, because in nature a number of additional influences are also operating at the same time. These cannot be controlled. In the example of the effects of smoking on heart disease, there are other factors like blood pressure, exercise, diet, and life style which also have an influence on eventual outcome. Experimental designs are stronger in providing evidence of causal relationship between two variables. This is so because the experimenter does not just observe, but actually intervenes by controlling the independent variable under study. Unfortunately studies concerning etiology and prognosis in humans do not allow experimental manipulation of risk factors in real life. Study design becomes the primary determinant of legitimacy in making causal inferences. Between the two broad categories of experimental and non-experimental designs there are many variations each with its own strength and weakness in terms of inferring causation.

Inference to concepts in the hypothesis. As we have seen concepts in the hypothesis have to be translated to operational definitions in order to determine what type of data are to be collected using what methods. In some cases translation from theoretical concepts to operational definitions is easy. In more abstract concepts proxy measures have to be used. In the example of breastfeeding and protection from infection clear definitions about diarrhoea and respiratory infection are needed. When the results are analyzed the inference from the operational definitions employed viz. diarrhoea and respiratory infection to the concept of "protection from infection" must be made.

Inference to other settings. The application of the findings to other populations, places and times away from the study situation is largely determined by how rigorously the study was carried out. With observational studies, the study sample is considered representative of the larger population if the sampling was random, and generalizability to that population is straightforward. But generalization to other places and times is not so simple. In experimental design generalizability is even more complex. As we have seen causal inference is strong because of control over the intervention, assignment of subjects and so on. But the controls that strengthen causal inference weaken inferences to other populations, places, and times. No study is totally free of errors, and the inferences which have been described are never perfectly valid. The goal is to come up with conclusions which can be usefully applied to the target population and to other settings. Errors can be minimized by careful attention to detail in the design, implementation and analysis stages of studies.

7). Validity

Validity is the extent to which research findings correctly reflect and explain reality. This is where the research actually began viz. to explain and describe reality. At the end of the research, do the findings correctly answer the research question? Research findings are often subject to controversy, partly because of the

controversial nature of all research that is relevant, and partly because of the role of inference in the scientific method. As we have seen the scientific method begins with the larger world of reality, moves to a circumscribed world of the study, and then back to the larger world. All the different types of inference discussed so far, including generalizability, involve estimating reality in the larger world from the conclusions of the study. Careful adherence to the scientific method increases the likelihood that such inferences are valid.

There are four aspects of validity corresponding to the four types of inferences.

Statistical validity relates to whether the conclusions arrived at are correct. Errors occur due to inadequate sample size and from incorrect use of statistical tests. One may conclude that there is no relationship between two variables whereas in fact there is one. Or the conclusion may be that there is a relationship whereas there is none. (This is referred to as Type I and Type II errors respectively, and the concept is further explained in Chapter 3).

Internal validity is shaky when the study design fails to control for factors that could enhance or mask the relationship between the variables under study. (This is referred to as Bias and Confounding).

Validity with regard to the concepts contained in the hypothesis. As already discussed the study deals with operationally defined variables rather than concepts contained in the hypothesis. The validity can be enhanced by using reliable definitions and measures.

External validity. This refers to the strength with which generalizations can be made of the study findings to other settings, populations, and times. External validity is strengthened by careful attention to sampling and study design. Generalizability can be possible only for a valid result. A result which is on shaky grounds with regard to the sample or the population from which the sample is drawn can never be valid for the larger population. The usefulness of research lies primarily in the generalisation of the findings rtather than in the information gained about the subjects in the study.

All these aspects of validity are important, because generalizability of results to other settings and populations is possible is possible only when validity is established (see figure.1.2).

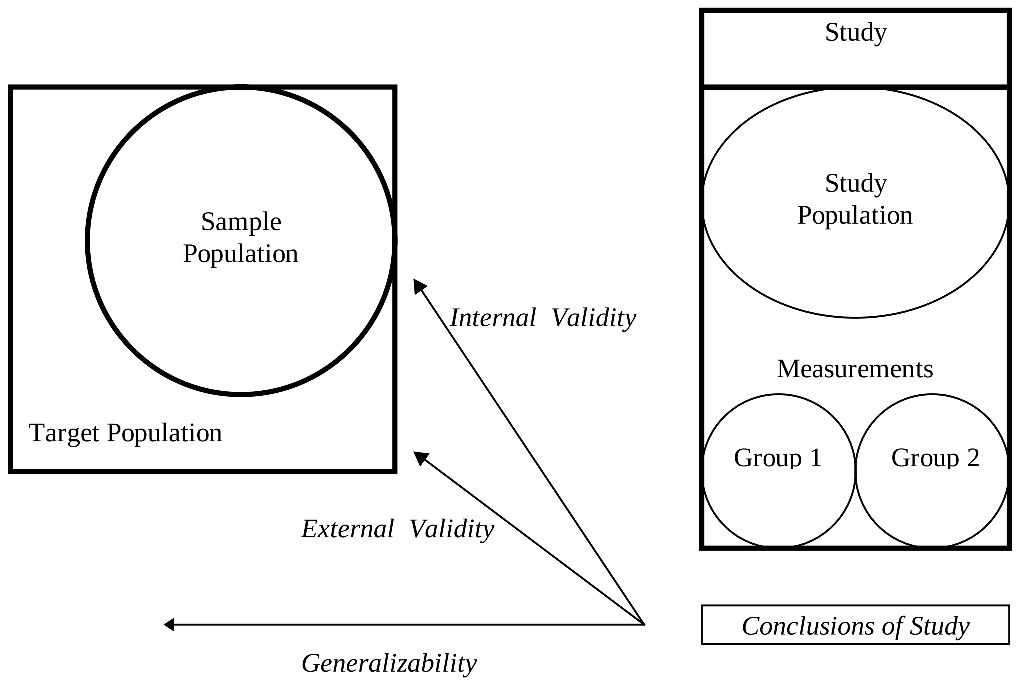

Figure 1.2: Internal and External Validity.

8).Verification / falsification.

After the data has been collected the investigator decides whether the findings are consistent with the hypotheses or not. Scientific theories are not absolute truths. They are the provisional explanations of available evidence. Scientific progress is often a matter of eliminating falsehood so as to be able to predict events with greater accuracy. The current scientific method consists of a system of rules and processes on which research is based, following the principle of hypothetico-deductive method. The result and outcome of the research is then subjected to verification / falsification. If the hypothesis can be falsified, the investigator would develop another one. If not, other tests are used in further attempts at falsification. The aim is to distill out the truth.

Out of scientific observations hypotheses develop, which in turn go on to provide the framework of scientific theories. Scientific theories are put to test by means of observations and hypotheses, and so the cycle continues.

Appendix 1.1.

Factors to consider in designing a study.

The Research process goes through the following stages

Research Question

What question will the study address?
What phenomenon is the subject of the study?

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Background to the research

Why is the question important?

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Design of the study

How will the study be carried out?

↓

Subjects

Who are the subjects? (sampling)
How will they be selected? (inclusion and exclusion criteria)

↓

Variables

What measurements are to be made? (descriptive, predictive and outcome variables)

↓

Quality Control

How would the accuracy of the information be checked?

↓

Statistical Issues

How large is the study? (sample size)
What analyses would be done?

↓

Appendix 1.1 (cont'd)

Writing the Study Protocol

An expanded version of the above. It is the main document to be used for planning and guidance during the various phases of the study.

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Operations manual

Specific procedural criteria and instructions, questionnaires and similar other matters so that all those involved in the research would follow a standardised uniform approach.