Research Methodology

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research

Definition of a research:

- careful study and investigation for the purpose of discovering and explaining new knowledge.
- The strict definition of scientific research is: performing a methodical study in order to prove a hypothesis or answer a specific question.

Components of a research project

Pre- investigation Steps

1- IDENTIFY THE PROBLEM

The first step in research is to identify a problem area to work on. An alert researcher will find a large number of issues floating around. For selection, match the research area to:

(i) relevance and applicability for improving health in one way or the other,

(ii) interest and expertise of you and your collaborators, and

(iii) the feasibility of completing the work with available resources, time, subjects, tools, etc.

- These three aspects should considerably narrow down the problem area. If the situation permits, select a topic that is in debate or meets a current demand. It must be well-defined and focused.

2- COLLECT AND EVALUATE EXISTING INFORMATION

The next step is to collect as much information on the identified problem as possible and evaluate it critically. One major source is the literature. Secondary data might be available in various organizations that can enhance the focus of the problem.

3-FORMULATE RESEARCH OBJECTIVES AND HYPOTHESES :

- Critical evaluation of the literature and other data on the problem will greatly assist in focusing thoughts regarding what exactly to investigate. Translate these to the research objectives.
- The objectives must match with the perceived utility of the results.

  For example, for interventions, the objectives could be to find efficacy, effectiveness, affordability, efficiency, safety, acceptability, etc.
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- Clearly identify the specific aspect to concentrate on and formulate the research objectives accordingly. They should be amenable to evaluation, and should be realistic: clearly phrased and stated in logical sequence. The objectives should be consistent with meaningful decisions taken in actual practice.

3- IDENTIFY THE STUDY SUBJECTS:

The definition of the subject of study and the target population should be clearly spelt out.

EX. Iodine deficiency can be diagnosed either on the basis of the palpable or visible goiter, or now on the basis of urine iodine concentration <100 g/l. Borderline hypertension may be defined to start from 135/85 mmHg or from 140/90 mmHg.

Choose a definition that is consistent with the objectives and justify it.

- Besides **inclusion criteria**, the **exclusion criteria** should also be clearly stated so that the cases are not excluded mid-way through the study. For this, anticipate the type of cases that can become ineligible later on after inclusion. If there are two or more groups, define them.

4-THINK OF A DESIGN:

Now, think of a strategy to get valid and reliable answer to the questions, or to get a solution of the problem.

The strategy would be in terms of collection of data in a manner that inspires confidence. this means:

- sample design for survey;
- prospective, retrospective or cross-sectional strategy for observational study;
- deciding on the specifics of intervention if any;
- determining the variables on which the data would be collected: the variables that are valid to provide the correct answer;

- the strategy to handle any ethical problem that might arise during the course of that investigation;
- the number of cases or subjects that should be included in this kind of investigation;
- the method of selection of the subjects of the study;
- the method of randomization, blinding, matching, etc., and
- the method of statistical analysis of data.

Most medical professionals do need expert advice from a biostatistician to develop an appropriate design. If needed, catch him at early phase of planning and seek his collaboration for all phases of the study.

5-WRITE THE PROTOCOL

- All the hard work put into the preceding steps culminates into the draft of a research protocol.
- It incorporates all the information regarding the plan of research in a concise manner.
- ***Developing a protocol is just about the most important step in conducting a research.***
- Protocol contains much more information. For example, it states the work plan and identifies the resources required for the project, including the time-line. The latter comprises the time point when each step is to be initiated and how much time this will take to complete. Work on two or more steps of research can go together, and this time-line will indicate this overlap also.

6-DEVELOP THE TOOLS:

Tools for medical research are of two types.

- First is the recording questionnaire, schedule, or Performa that is uniformly followed throughout the investigation.
- Second are the measurement and investigation tools such as those to be done in a laboratory. For some this may require procuring kits with the help of external facilities. For a large-scale investigation, instruction manual may be needed.
- The staff may have to be trained in interview, examination, or laboratory methods so that valid and uniform data are generated.

INVESTIGATION STEPS:

- Note that pre-investigation steps are complex, and their major component is the thought process.
- After these steps comes the actual investigation. This also requires some preliminary steps before actually embarking upon the real study.

PRETEST AND DO PILOT STUDY:

- No matter how thoughtful you have been in developing the tools of the investigation, there is always a need to pretest them for their performance in actual conditions on the same kind of subjects as the main study.
- Experience suggests that almost invariably some deficiency is detected, and the tools or their implementation are found to require some modification.

- Similarly, a pilot study, which is a small forerunner of the actual investigation, also provides useful inputs regarding changes required in the measurements to be taken, in the interview or examination method, in the laboratory investigations, etc.

COLLECT THE DATA:

- The objective of this step is collection of the relevant data. Data are obtained by inspecting the records, by conducting interview or physical examination or laboratory investigations, or by a combination of these data-eliciting methods.
- Continuous effort is maintained to ensure that the data remain of good quality—that is they are correctly obtained for each subject and honestly recorded. The methods earlier decided should be strictly followed. The data forms should be legibly filled, and they should be fully completed.

HANDLE THE NONRESPONSE AND ETHICAL ISSUES

- In a science such as medicine, it is difficult to complete the investigation in all the planned subjects. Some subjects will invariably drop out during the course of the investigation. Anticipate such non-response and keep it at the minimal level to avoid bias in the results. Make all efforts to extract at least the basic information that can help in adjusting for any bias.

- Then there are ethical issues that need to be constantly monitored, particularly if the research involves an intervention such as a therapeutic maneuvre. Even when informed consent is taken, medical ethics requires that the intervention and data generation or collection should not subjugate the interest of the patient.

SCRUTINIZE THE DATA تدقيق

Despite all the care exercised at the time of taking history of patients, at the time of physical examination, and at the time of laboratory investigation, errors do occur. Most of these can be detected by scrutinizing the data for internal consistency and external validity.

A woman of age 20 years can not possibly have six children. Such errors look odd but they are practical occurrences particularly in a large-scale research. Some times called data cleaning, this step of scrutiny is considered essential for quality research.

POSTINVESTIGATION STEPS:

- After the data are collected, which should be adequate in terms of quality and quantity, they need to be exploited to their full potential to draw conclusions. This requires the following steps:

ANALYSE THE DATA

- Analysis of data is an umbrella term that incorporates a large number of mini-steps. First is preparing a master chart by tabulating the data in a manner that all the information on one subject constitutes one record. In an Excel format, this really means that there is only one row of data for each person. Also each field (column in Excel) must contain only one piece of information. The next step is grinding the data through the process of statistical analysis.

INTERPRET THE RESULTS

- Whereas statistical analysis is mostly computer-based, interpretation of the results requires critical thinking. A series of steps can be suggested.
- (i) Examine the results in the context of the questions that prompted the research.
- (ii) Verify that various results are consistent with one-another and a proper explanation is available for the inconsistent ones.
- (iii) Check that all the potential biases have been either ruled out by design, or the results are properly adjusted for the biases.

- (iv) Confirm that a convincing biological explanation is available.
- (v) Ensure that the final conclusions are indeed a further development and not repeat of previous knowledge.
- In short, not only that you should be convinced about the correctness of the conclusions but also there should be enough reasons to convince others. Results should not be speculative, instead should be based on evidence as revealed by the data and other facts. If the results are too good to believe, reexamine them.

WRITE THE REPORT

- Report is a generic term that includes a thesis, a dissertation, an article, a paper, and a project report. It should contain all the details in a concise manner.