10 Research In Family Practice

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The process of research starts with asking questions and ends with publishing results. Each step depends on the one before and should be influenced by anticipation of later stages of the process.

Steps in research

Thinking about research

- Asking questions
- Forming ideas
- Reading the literature
- Stating the hypothesis (or objectives)

Conducting research

- Designing the study
- Funding research
- Organizing the research work

Understanding the results

- Analyzing results
- Interpreting results

Advocating the work

- Writing about research
- Speaking about research

Step 1: Asking questions

This represents the initial step in the research process. Without a good research question, useful research will not develop. Simple questions are more easily answered than complex ones.

A good research question

- Is relevant
- Is interesting
- Is answerable

A bad research question is one wherein the solution is beyond the resources of the research worker.

Step 2: Forming ideas

Having found a question which seems interesting, important and solvable, it is time to think in general terms about the possible ways of answering it. There are three principles which should guide all research planning.

1. Take time
2. Aim for perfection
3. Think for yourself what you think the possible or probable answer to your question is.

Take time: If a good question has been asked, do not be in a hurry to answer it. Undue haste may lead to disappointment later. Major flaws may lead to collection of wrong information.

Aim for perfection: Nothing does a greater disappointment to the concept of research in general practice than poorly conceived and poorly carried out research. Aim to design a project that provides valid, even if relatively simple findings.

Think for yourself: Start the attempt to explain or solve your research problem by stating honestly to yourself what you think the possible or probable answers to your own question are.

- Try first to develop the idea to help answer your question from your own insights into the problem. It is from this position that you will be best able to

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benefit from advice you need to seek from other sources.

- It is very important to consult in the early stages of research interest, colleagues with experience in general practice research, who have a reputation for being critical and are known to be constructive as well. If you choose well, you are bound to gain from their experience.

Step 3: Reading literature

The third step of the process of research is reading literature. However, literature review should not be confined to any step of developing a research idea.

Literature review is in two phase - exploratory reading and comprehensive reading:

1. **Exploratory reading:** Cover the preliminary review essential for any research project. It should be a part of the early stages of developing a research idea and will usually precede or immediately follow preliminary discussions of the idea with any colleagues who have been approached for advice. Start simply and extend the scope of the review if early results are encouraging. The Journal of the Royal College of General Practitioner (JRCGP) is a good starting point for a search of general practice literature.

Start with the subject heading: Then identify possible headings for cross references or related references. Get photocopies of the important articles and of the references quoted. Other journals which should be referred are the Lancet, British Medical Journal, Update and Practitioner. Repeat the search of the indexes of these journals.

How to get a good up-to-date knowledge of field being explored for study

- Read a recent relevant research paper
- Look at its references
- Work backwards.

2. Comprehensive reading

After discussing the preliminary review obtained from the exploratory reading with a colleague and confirming that the developing research idea is worth expanding,further steps to be carried out are:

a. Following more widely the references already collected, with the review extending to other specialist journals and to journals published in other countries.
b. Making use of an indexing system, the best known being the Index Medicus.
c. Searching articles which may have been missed because of the use of inappropriate titles.
d. Soliciting the services of 'Reviewing Services', such as Medline to get a review of relevant literature.

Is important to remember that information obtained from general reading and specific searching should be retained in a usable manner (eg, photocopying).

Step 4: Stating the hypothesis (or objectives)

What is a hypothesis?

A hypothesis is defined as a provisional supposition which accounts for known facts and serves as a starting point for further investigation by which it may be proved or disproved. The statement of the hypothesis will make it easier to design a sound research project

which will help answer the research question. With a hypothesis stated, the subsequent research then centers round proving or disproving the proposition. Despite advocacy of the hypothesis as against the simpler statement of aims, relatively few published papers state a hypothesis.

Step 5: Designing the study
The protocol
The protocol, or the investigation plan, is a written statement of the particulars of the study. It serves the very useful role of communicating what the investigator intends to do and how it will be done. Later, in an abbreviated form, it becomes the methods section of the final report. In writing a protocol, the investigator should carefully examine the clarity and the precision of presentation. A good protocol progresses in a logical fashion. Re-writing of the document may be necessary before the final draft of the protocol is prepared.

Key points for preparing a protocol
1. What is the purpose of the study?
2. What is already known about the problem?
3. Is the proposal a pilot or main study?
4. What design will be used in the project?
5. How are the subjects of the study to be chosen?
6. What data are to be collected, and why?
7. What are the treatment schedules or other activities forming the intervention in the study, and how are the variables to be defined and measured?
8. How are the data to be collected and the measurements to be made?
9. How will the data be processed and analyzed?
10. What problems of ethics and etiquette does the project raise?
11. What arrangements are to be made for treating or referring patients for whom new needs come to light as a result of the project?
12. What is the expected timetable for the study?
13. What will the project cost?

The contents of a research protocol include:
1. Title of the project
2. Review of relevant literature
3. Objectives of the study
4. Hypothesis (wherever necessary)
5. Methodology
6. Plan of implementation
7. Budget (with justification)
8. Limitations of the study
9. Sources of funds (if any).

Data collection
Almost any research involves the collection of information for numerical analysis, normally in some form of rate, for example, consultations per hour, night calls per day. The figure on the top line is the numerator and refers to the event or phenomenon being studied. The lower figure is the denominator and refers to the population (or sample of the population) in which the event (or phenomenon) was studied.

An ideal event
- Is easily defined
- Is easily recognized when present
- Is not identified when not present
- Occurs commonly enough.

A whole population or sample of a population
A population implies a complete group of people, patient, consultations or whatever is being surveyed. A sample is a part of a complete population. A properly drawn sample should reflect the attributes of the original population both in nature and in proportion.

Consistency in data collection
One of the best ways of assuring consistency in data collection is restricting the number of observers.

Types of research
a. Retrospective research
b. Prospective research
c. Clinical trials
   Double-blind/single-blind studies
   Cross-over studies
   Controlled studies

Method of collecting information
a. **An ideal method** of collecting research information is one, which is valid and reliable. A valid method is one which measures what it sets out to measure; a reliable method is one which produces repeatable results.
b. Records used
1. Routine records

2. Structured records (questionnaires)

The size of a study
Deciding how large a study should be, how long it should last and how many doctors should be asked to help are important and often difficult decisions.

Statistical advice
A statistician will advise on many different aspects of the design and analysis of a research project.

Ethics in research
Approval of a research committee should be obtained.

Step 6: Funding research
Part of planning a research project involves working out likely costs and thinking about how these are to be met. Many good research projects do not cost much and can be funded by the researcher. However, there are projects, which require the employment of full-time staff and support of expensive data processing resources.

Funding research can be considered under three heads:
- Costing the project
- Sources of research money
- Applying for money.

Step 7: Organizing the research work
Organization of research can be considered under the headings 'before fieldwork' and 'during fieldwork'.

Before fieldwork
a. Timing
b. Recruiting and explanation
c. Production of material
d. Specialist support
e. Pilot studies.

During fieldwork
a. Checking progress
b. Personnel management.

Step 8: Analyzing results
The primary methods of analysis should be chosen at the outset, not after all the data is collected. The investigator should program the study so that the requirements of the

chosen analytic methods are met.

When the study is concluded, the data should be examined for possible bias in the study population. When the study is a comparison, such a bias might include an abnormal distribution in age, gender, disease states, or other initial enrollment conditions.

Ratios or percentages will usually reveal whether the group of patient studied was comparable to other groups in similar studies. If the groups are found to be dissimilar, one should not attempt to compare them.

Conclusions should be based only on results obtained from definable groups of patients.

If population bias is not found, homogenicity among the patients studied can be safely assumed. Next, provided enough subjects were studied, they can be divided into subgroups based on their responses or other characteristics and provided the subgroups retain a close similarity to the study group as a whole.

Sub-grouping is designed to determine whether a particular characteristic (eg, gender, age, method of treatment, response to treatment) influences the outcome. The subgroups need not be of equal size; nevertheless there should be at least 5 patients in each; otherwise it might not be representative of a general population with similar characteristics.

The next step is to analyze the primary data by calculating such statistical values as Mean, Range, Standard deviation, and Confidence limit for each patient group or subgroup.

Analysis of primary data is most reliable when a precisely measured numerical value was given for the observation. It is less reliable when a scale or nominal value is assigned such as + to ++++.

Problems in analysis arise when different observers obtain different values for what is essentially identical information or when an observer cannot reproduce the results. The form used in the study should be designed so that there is no confusion about what information is required, how it is to be obtained, and how it is to be reported.

Statistical methods are not infallible. They do not determine the success or failure of a study. Some clinical results can never be statistically proven because of a small sample size, the study design was inappropriate, extraneous factors interfered, or the wrong statistical method was used. Nevertheless, observed changes may be clinically important.

Step 9: Interpreting results

The basis for interpretation of results

1. Validity and reliability of the research method
2. Statistical significance of the findings
3. Clinical significance of the findings and conclusions.

Validity and reliability of the research method

- Is 'valid' when it measures what it set out to measure with acceptable accuracy
- Is 'reliable' when it produces consistent results

'Validity' and 'reliability' of a research project have to be checked at two main junctures of the research sequence. The first is the point at which information is collected and recorded, and the second is the point at which it is classified and coded.

Check validity and reliability at two levels

a. Point at which information is collected and recorded.
b. Point at which information is classified and coded.

Statistical significance

This is a comment on the degree of probability that observed associations may have arisen through chance?

- By convention, a probability (P) of findings occurring by chance not more than once in twenty (P<0.05 or 'significant at the 5% level") is normally accepted as 'statistically significant'. A probability of findings occurring not more than once in a hundred (P <0.01 or 'significant at the 1% level') indicates that the findings are statistically highly 'significant'.
- The choice of which statistical test should or should not be applied depends on many factors including the number of observations made, the distribution of observations around the average value and whether, for example, numerical or verbal information forms the original basis for the numbers being analyzed.
- The pitfalls of the application of statistical tests are many. Whenever possible, professional statistical advice should be sought.
- Two of the common statistical tests applied are :
  a. The t-test.
  b. The X2 test (Chi-Square).

Clinical significance

Even after good quality information has been submitted to the correct tests of statistical significance there remain two possible weaknesses in the fact that statistical significance only mirrors probability of chance. One is incorrectly attributing significance when none exists; and the other is failing to recognize real differences, which are present. The first weakness is especially likely to arise when multiple analyses are undertaken.

Statistical significance does not automatically imply clinical significance. Also, a clinically important difference between two sets of observations may fail to reach the conventional level of statistical significance either by chance or because the size of the study has been too small.

It is the balancing of the concepts of statistical and clinical significance that provides the art of research interpretation, in particular in the more behavioral areas of research that general practice research inevitably involves.

Step 10: Advocating the work

It is responsibility of the research worker to write about the project and publicize the findings.

The responsibility may include writing

- A final report of the project or
- A Thesis

A. Final report of a project

A report will normally be between 1,500 and 2000 words in length and comprise of the following sectors:

a. Introduction (around 300 words)
b. Methods used for the study (around 500 words)
c. Results (around 500 words)
d. Discussion (around 500 words)
e. Summary (often attached as the front page)
f. Acknowledgements
g. References (quoted in the text)

B. A Thesis

In contrast to a published paper where only selected references and results are normally presented and the discussion is restricted in its depth, the thesis requires extensive review of literature, detailed presentation and defense of the experimental design and method, and a through discussion of the findings and their implications. A Thesis may comprise of about 100 pages (20,000 - 25,000 words), 100 references and perhaps 25 tables and illustrations.

Step 11: Speaking about the research

All satisfactory communications given to any audience depend on the care given to the preparation - preparation from the time thinking about the project to explaining it to others.

Key Point

The process of research starts with asking questions and ends with publishing results. Each step depends on the one before and should be influenced by anticipation of later stages of the process. Each of the steps is vital to the success and significance of the work and none must be sacrificed for the sake of the other.

Reading List

1. Gehlbach SH. Interpreting the medical literature. New York, Macmillan, 1988.
2. Hogg WE. Family Medicine: the challenge of maturity. Can Fam Physician 1989;35:823.
3. McWhinney IR. A textbook of family medicine. New York: Oxford University Press, 1989; 363.