

RESOURCE DOCUMENT

Sixth Protocol Writing Workshop for first year postgraduate students

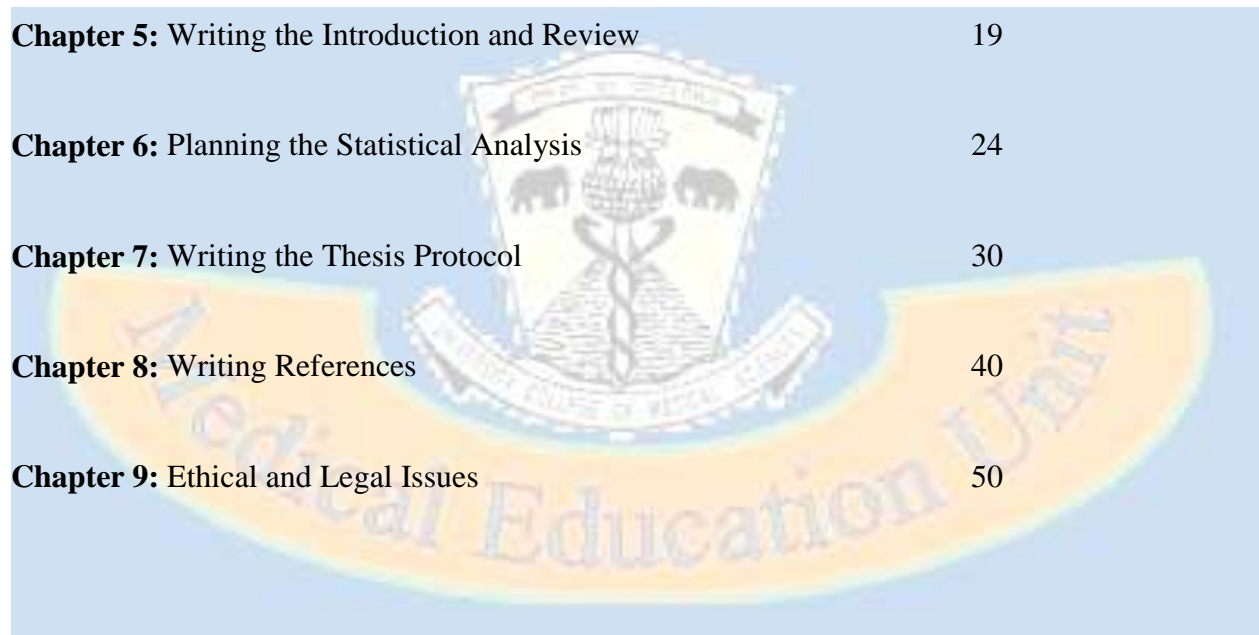
Conducted by the **Medical Education Unit**

UCMS and GTBH Delhi

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Chapter 1

Rationale for Thesis in Post Graduate Courses: A Singular Experience

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In 1974, the All India Institute of Medical Sciences (AIIMS), New Delhi, and the Post Graduate Institute of Medical Research (PGI), Chandigarh, reduced the duration of post graduate medical degree courses from 3 to 2 years. This they achieved by eliminating the writing of thesis. The rationale for this was that more qualified MD/MS could be produced over the next 10 years.

I joined MD Pathology at AIIMS in 1974 for a 2-year course, without thesis. Interestingly, the student instruction manual given to each post graduate student in Pathology, at the time of admission stated: ‘Active participation in research is compulsory for every trainee. Writing a thesis is an essential requirement for the MD degree’.

There were positive and negative aspects to this experiment. I sailed through MD in two years. It was hassle free, and I maintained my independence. The time spent in the library was used productively to gather knowledge rather than to write and re-write the thesis. All in all, it was a fruitful two years.

The negative aspects of not writing a thesis became apparent when I went looking for a job. I had little idea of research or of paper writing. I had no mentor, no one to write that extra line as a recommendation that would ensure a placement in the US. All this was because I had no thesis, so had not dedicated one year as an assistant to any one faculty member in Pathology.

I joined UCMS as a permanent demonstrator in 1976. This ensured a teaching position but I struggled when I was asked to become supervisor for a thesis.

Interestingly, three years later AIIMS and PGI reverted back to 3 years MD with thesis. The impact of the ‘no thesis’ on these institutions of higher learning was reflected by a decrease in

the numbers of research publications, uniformly, for every department.¹ In other words thesis contributed to research. It was beneficial to both post graduate student as well as faculty.

Although research experience can never replace solid medical training, it is a mandatory additional requirement, needed when the merits of a candidate are being assessed for a job particularly in the teaching fraternity. The quality of a research publication helps discriminate between candidates.

Thesis writing is a record of your research endeavor. It fine tunes your thinking, organizational, and problem solving skills. These, along with a systematic approach to a problem, keenness of observations and ability of expression are useful attributes, even if the career aim is private practice.

What had other post graduates endured while writing a thesis? One publication that was insightful felt that not too much was gained by writing thesis.² The study showed that some supervisors had poor understanding of research methodology, spent no time with the student, and were unable to provide infrastructure or finances for research. Students felt that the thesis was a mere formality and they could get by with data fabrication and plagiarism. The authors of that study suggest methods to improve student interest in thesis: by standardizing the work, time frame for submission, ensure one publication at the time of completion of PG course, and awards for best thesis both at the institutional and national level.

References and further reading:

1. Kabra SK, Verma IC. Thesis during MD: Must or bust? Indian J Pediatr 2007;74:72-3.
2. Hyderi A, Ravikiran. PG thesis: Idealistic Vs Realistic. Indian J Pediatr 2006;73:373-4.

Chapter 2

Relevance of Research in Medical Practice

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As a doctor, the following questions will haunt you where ever you go: What? Where? Why? How? When? How much? How often?

The answers to these questions can be found only through RESEARCH.

What is Research?

Research is a systematic process of organized, scientific enquiry into etiology, patho-physiology, diagnosis, therapy, and prognosis of disease.

The **essence of research** is to recognize a problem, formulate an approach to the study of the problem, and apply your findings to medical practice. In other words, research is *thought in action*.

It should:

Be systematic- follow a definite set of procedures and steps to make the results accurate, reliable, and thus, widely applicable.

Be organized- Plan well (the procedures should not be spontaneous, hurriedly thought out); this will ensure that the results are reportable and not a complete waste of time.

Ask a question and search for the answer- Even NO is an answer. Ask a simple focused question.

How research helps:

- Advances the cause of Science
- Enhances our knowledge of disease
- Improves our understanding of health
- Solves health problems
- Helps in achieving economic growth

How Research can help you:

The achievement of a scientist is measured by volume and quality of research contribution. Thus, all completed research works, including your thesis, should be published in a good Journal, otherwise they are a waste of time and resources.

When should research begin?

Ideally, research should begin as soon as you ask the first question, especially during undergraduate medical education. *How can you improve the quality of life in schizophrenia? How can cataract be entirely prevented? Why are some patients more difficult to satisfy?* Studies have shown that research experience as a medical student is strongly associated with later research. Nothing can be more motivating for a student than to get published; studentship research contributes to the published output of an institution. As postgraduate students, if you have not participated in research as yet, you have already delayed it!

Why do Research during PG?

Writing a Thesis is a teaching-learning method. It teaches you research methodology and biomedical communication.

Your research career should NOT end with your thesis. Publish your findings!

Chapter 3

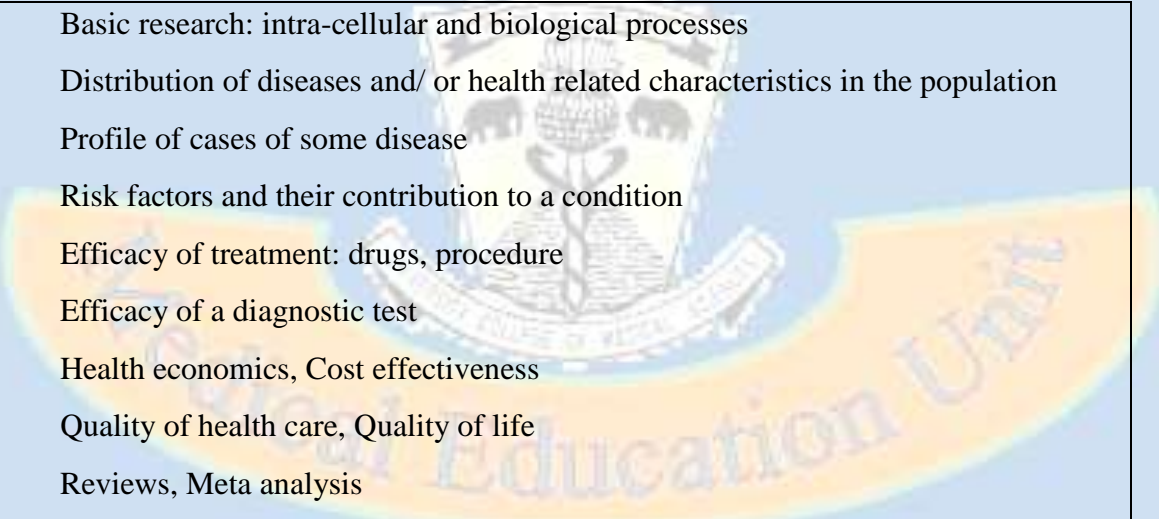
Research Question and Title of the Thesis

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Selecting a good research topic/question for your thesis is the first and one of the important steps towards thesis writing. For a PG student, who has joined the course only a few weeks back, it is an unfamiliar and onerous task. A large number of fields are available from which you can choose a topic relevant to your discipline. Awareness of the list (Box 1) would be of great help.

Box 1. Fields for research



- Basic research: intra-cellular and biological processes
- Distribution of diseases and/ or health related characteristics in the population
- Profile of cases of some disease
- Risk factors and their contribution to a condition
- Efficacy of treatment: drugs, procedure
- Efficacy of a diagnostic test
- Health economics, Cost effectiveness
- Quality of health care, Quality of life
- Reviews, Meta analysis

The success of your thesis project and the degree its contribution to your career development will depend on the goodness of your research topic/ question. Some characteristics of a good thesis topic are shown in Box 2. You must evaluate the tentative topics on goodness parameters before finalizing the topic.

Box 2. The characteristics of a good thesis topic

Addresses a defined gap in knowledge
Original and relevant
Well defined, focused, and narrow
Neither very ambitious nor very simple
Acceptability to study population
Ethically sound
Interesting to student, supervisor, research community
Well suited to caliber/ commitment
Can be completed using available resources: time, subjects/ material, tools

Ways to Formulate a Research Topic/Question

It would be good strategy to first choose a broad topic and then narrow down to a more specific topic. You must jot down what you already know and what you would like to know about the topic. You must further increase your knowledge about the subject by reading coursework, journals, and information on internet. Interviewing peers, adviser, and research workers interested in the topic may provide useful information. It is also useful to examine case records pertaining to the topic. A pilot study can provide you insight regarding feasibility of the proposed study and the difficulties likely to be faced. You should work on a few topics in this manner, and then select the most appropriate topic.

Finally, define a clear, achievable, worthwhile, and specific research question. In practice, well-built analytic research questions usually contain four elements, represented by PICO - an acronym which stands for:

- **P**atient or **P**roblem
- **I**ntervention
- **C**omparator
- **O**utcome

Suppose you want to find out *effect of specific operative procedure on the outcome of the treatment of anal fistula*, you may use the PICO structure to translate the clinical problem into a structured research question which identifies specific key concepts. (See Box 3)

Box 3: PICO Structure for translating clinical problem into a research question

	Patient/ Problem	Intervention: Cause, prognostic factor, treatment	Comparison intervention	Outcome
Tips for formulating	How to describe the study population?	Which main intervention is considered?	What is the main alternative for comparison with intervention?	What could this intervention really affect?
Example	In patients with simple anal fistula	Fistulotomy with marsupialization	When compared with fistulectomy	Results in less postoperative pain and faster wound healing.

Do not be afraid to change the topic if it is not working.

Research Design

Once you have made up your mind about the research topic/ question, you will have to choose an appropriate research design for your thesis. The research studies are broadly classified as **descriptive** and **analytic** studies.

- **Descriptive studies** are conducted to ascertain current status of a problem or phenomenon: for example, *study of mortality and morbidity following typhoid fever, study of level of blood pressure in school children.*
- **Analytic studies** are conducted to find out relationship among various factors associated with a condition/ phenomenon, difference between groups or effects of an intervention. Analytic studies may be **observational** or **experimental**.

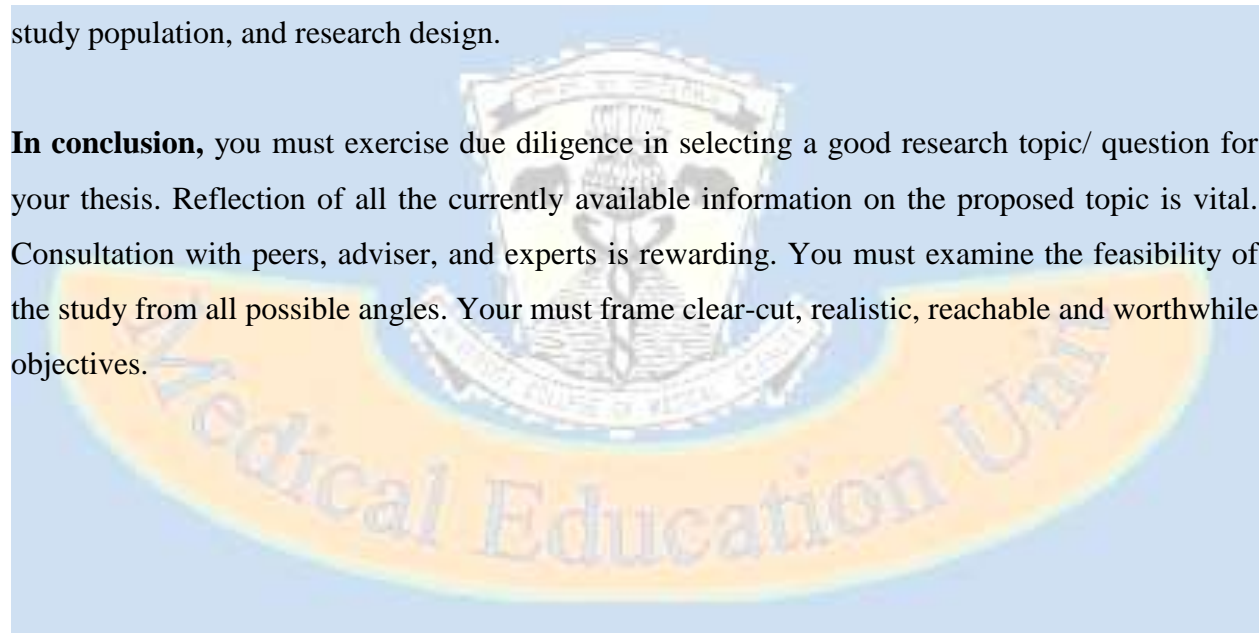
Observational studies are based on naturally occurring events and do not involve any human intervention as a part of research protocol. For example: *Effect of pre-existing maternal anemia on birth weight of babies; Factors affecting mortality in diarrhea.*

Experimental studies ascertain the effects of an intervention undertaken as a part of research protocol. For example: *Comparison of fistulotomy and fistulectomy in the treatment of simple anal fistula; Comparison of Prostate Specific Antigen and Ultrasound for diagnosis of carcinoma prostate.*

Title for the Research Project

The next step is to select an appropriate title for your thesis project. The title should be brief and informative; it should neither be too short nor too long. Important words should be placed towards the beginning of the title. Name of the institution or the number of cases to be studied should not be included. The title may include the following: hypothesis/ problem to be studied, study population, and research design.

In conclusion, you must exercise due diligence in selecting a good research topic/ question for your thesis. Reflection of all the currently available information on the proposed topic is vital. Consultation with peers, adviser, and experts is rewarding. You must examine the feasibility of the study from all possible angles. You must frame clear-cut, realistic, reachable and worthwhile objectives.



Chapter 4

Searching the Literature

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Knowledge is of two kinds: we know a subject ourselves or we know where we can find the information pertaining to it. This becomes far more important with the increasing volume of scientific literature particularly in the field of medicine and life sciences which is referred to as 'Information Explosion'. Thus a new research worker should be aware of the best way to acquire information and to record it. Fortunately, the scientific literature of medicine and the life sciences is well organized and many indexes, catalogues and on-line libraries exist to serve as access points to vast stores of literature.

The information could be in the form of textbooks, individual study/studies, the systematic review of all the available studies, a synopsis of individual studies and systems of information. Most of these resources are now electronically available. To find answers to general background medical questions (such as physiology, mechanism of action of an intervention or diagnostic approach to a clinical condition), referring to a textbook that is well referenced and updated frequently is likely to be faster and more rewarding. For questions dealing with clinical problems (foreground questions), searching good review articles on your topic can often give you an idea about the lacunae in the existing knowledge and the need of conducting a study. Carefully modifying your search strategy by limiting the search to desired sections such as diagnostics or therapeutics would help to deal with the problem of 'too much material'. In this section, we focus on online rather than print products because they are generally easier to search and more current than print products.

The main sources of information that are useful for retrieval of literature are discussed below:

1. MEDLINE

It is an attractive database for finding the information because of its comprehensiveness and free accessibility. The U.S. National Library of Medicine maintains this impressive bibliographic database, which includes over 12 million citations of both clinical and preclinical studies.

Anyone with Internet access can search MEDLINE free of charge using PubMed (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>). In addition, most health sciences or hospital libraries provide access to MEDLINE through a commercial vendor such as OVID, Knowledge Finder, or Silver Platter and most medical websites provide a link to MEDLINE.

These positive features are balanced with a disadvantage that relates to the size of the MEDLINE and to the range of publications that it encompasses. Searching MEDLINE effectively often requires careful thought, along with a thorough knowledge of how the database is structured and how publications are indexed. Understanding how to use Medical Subject Headings is essential, as is text word searching and exploding and use of the logical operators AND and OR to combine different search results. In this section, we present only the most crucial and basic MEDLINE searching advice. Readers are encouraged to consult various on-line tutorials for MEDLINE search and go through the help file at the PubMed site for more details.

Boolean operators:

PubMed searching is easy, you may just enter search terms in the query box, and press the Enter Go or click Go. You may enter one or more terms (e.g., preterm zinc iron) in the query box and PubMed automatically combines (ANDs) significant terms together using automatic term mapping. The terms are searched in various fields of the citation. If your search includes 'Boolean' operators AND, OR, NOT, they must be in upper case. PubMed processes all Boolean connectors in a left-to-right sequence. You can change the order that PubMed processes a search statement by enclosing individual concepts in parentheses. The terms inside the set of parentheses will be processed as a unit and then incorporated into the overall strategy, e.g. "preterm AND (iron OR zinc)".

Once you click Go, PubMed will display your search results. The query box displays your search terms as you entered them. You can modify your current search by adding or eliminating terms in the query box or in 'Details'.

Limits:

To make the search more specific, click 'Limits' from the Features bar to limit your search to specific age group, gender, or human or animal studies. 'Limits' also allows you to restrict to articles published in a specific language, and to specific types of articles such as review articles. You can limit by either Entrez or Publication Date. And lastly, you may limit your retrieval to a specific subset of citations within PubMed, such as AIDS-related citations or nursing journals. If you select a limit and either run a search or move to another screen, a check will appear in a box next to Limits on the Features bar to indicate that limits have been selected. If you then run a search, the limits in effect will appear in the yellow bar above the Display button. To turn off the limits before you run your next search, click on the box to remove the check. To turn off the existing limits, click on the check box to remove the check before running your next search.

Search Field Tags:

To search by an author's name enter the name in the format of last name plus initials (no punctuation), e.g., Agrawal kn, Shah d. A name entered using this format will search in the author field. To search for an author in the author field when only the last name is available, enter the name with the author search field tag [au], e.g., Shah [au].

You can also search for an article in a specific journal. You may search by the full journal title, e.g., Indian Pediatrics or the MEDLINE abbreviation, e.g., Indian Pediatr. If a journal is also a MeSH term (e.g., *Gene Therapy*, or *Circulation*), PubMed will search the unqualified term as MeSH. Qualify the journal title with the Journal Title search field tag, e.g., gene therapy [ta], to search for the journal. Qualify single word journal titles using the 'Journal Title search field tag', e.g., circulation [ta], since PubMed will search unqualified single journal titles in All Fields.

Medical Subject Headings (MeSH):

The MEDLINE indexers choose Medical Subject Headings (MeSH) for each article. These headings provide one strategy for searching. Unqualified terms that are entered in the query box are matched first against a MeSH (Medical Subject Headings) Translation Table. If a match is found in this translation table, the term will be searched as MeSH and as a 'Text Word'. For example, if you enter vitamin h in the query box, PubMed will translate this search to:

("Biotin"[MeSH Terms] OR vitamin h[Text Word]) - vitamin h is an entry term for the MeSH term Biotin. Note, however, that indexers reference articles under the most specific subject heading available (for example, "ventricular dysfunction, left" rather than the more general term "ventricular dysfunction"). As a result, if you choose the more general heading ("ventricular dysfunction") you risk missing out on many articles of interest. To deal with this problem, use a command known as *'explode'*. This command identifies all articles that have been indexed using a given MeSH term, as well as articles indexed using more specific terms. For example, in the PubMed MEDLINE system for the 1966 to 2000 file, the MeSH heading "sports" contains 10,806 indexed articles, whereas "explode sports," which picks up more than 20 specific sports from baseball and basketball through weight lifting and wrestling, contains 37,043 indexed articles.

Text Word Searching:

Another fundamental search strategy substitutes reliance on the decisions made by MEDLINE indexers with the choices of study authors regarding terminology. Using "text word" searching makes it possible to identify all articles in which either the study title or abstract includes a certain term. Experience with MEDLINE allows a clinician to develop preferred search strategies. Comprehensive searches will usually utilize both MeSH headings and text words.

Sensitive search strategies have comprehensive retrieval with some irrelevant citations, whereas a specific search strategy is not as comprehensive but is less likely to retrieve irrelevant citations. Although the strategies tend to be complex, PubMed searching system now have them automatically available for use. The PubMed system has a special section with these strategies entitled "Clinical Queries." Access to this option is on the left side of the main searching screen.

2. JOURNALS

Once, we have a list of abstracts from MedLine search, the next step is to go through these and identify the relevant journal articles. Journals are the principal vehicle for the communication of scientific information and have two main advantages over other forms of literature: firstly, they provide more recent information which is an important factor in rapidly developing areas such as

immunology. Secondly, they contain the latest and often very specific accounts of current research work, new techniques and unusual but interesting cases.

The PubMed system maintains a list of the journals indexed by MedLine. Use the Journal Browser to search for journals by journal title or title abbreviation. The list of journals with links to full-text (websites) is also included in the browser. The search results of PubMed also provide links to the website of the related journal and also indicate whether full-text is freely available or not.

Searching for an article from a journal in any library may be a tedious job. However, this task may become interesting and also a social activity if the environment of the library is supportive and the student has developed the skills of searching. It is important to make a list of all the desired articles in an alphabetical order (according to the journal name) as most libraries arrange the journals in this way. The National Medical Library at New Delhi is the most comprehensive library of its type in India. Every library has a catalogue or list of journal holdings, consisting of an alphabetical list of titles held, together with details of the particular volumes carried.

3. COCHRANE LIBRARY

The Cochrane Collaboration, an international organization that prepares, maintains, and disseminates systematic reviews of health care interventions, offers another electronic resource for locating high-quality information quickly. They publish the Cochrane Library, which focuses primarily on systematic reviews of controlled trials of therapeutic interventions. Updated quarterly, the Cochrane Library is available in CD-ROM format or over the Internet. It contains three main sections.

The first of these, the Cochrane Database of Systematic Reviews (CDSR), includes the complete reports for all of the systematic reviews that have been prepared by members of the Cochrane Collaboration and the protocols for Cochrane systematic reviews that are under way.

A second part of the Cochrane Library, the Database of Reviews of Effectiveness (DARE), includes systematic reviews that have been published outside of the collaboration.

The third section of the Library, the Cochrane Controlled Trials Registry (CCTR), contains a growing list of over 268,000 references to clinical trials that Cochrane investigators have found by searching a wide range of sources. The sources include the MEDLINE and EMBASE (Excerpta Medica) bibliographic databases, hand searches, and the reference lists of potentially relevant original studies and reviews. Although most citations refer to randomized trials, the database also includes a small number of observational studies.

To search the Cochrane Library, you can enter terms in the first screen that appears after selecting "Search". If you have access to the CD-ROM version, using the Advanced Search option you can create more complex search strategies that include Medical Subject Headings and logical operators.

4. IND MED

The purpose of IndMED is to index selected peer reviewed medical journals published from India. It supplements international indexing services like PubMed. It covers about 77 journals indexed from 1985 onwards.

5. WORLD WIDE WEB (INTERNET)

Online libraries are rapidly becoming important sources of medical information, some for a fee, others free of charge. To make these resources more accessible, certain web sites provide links to medical information locations. Examples of such Web sites include Medical Matrix, Medscape, ScHARR, MD Consult (www.mdconsult.com) and Medical World Search. Clinicians can also use the Internet to access medical journals and clinical practice guidelines. We must, however, issue a user beware caveat: some of this information may be unreliable. Searching for reliable information on internet requires expertise and knowledge of reliable sites. Besides MedLine and journals' official websites, some of the sites of reliable information are maintained by reputed organizations such as WHO, UNICEF and ICMR.

6. BOOKS

Library catalogues enable you to find books according to authors, subjects and occasionally titles. A type of catalogue that is commonly used is known as a 'Dictionary Catalogue' where

entries for both author's name and subjects are listed in a single alphabetical sequence. A more popular type of catalogue is a 'Classified Catalogue' which replaces the alphabetically arranged subject catalogued. The classification scheme widely used throughout the world is the Dewey Decimal Classification. It employs a numerical notation (000 to 999) and divides the whole field of knowledge into 10 main classes e.g. the numbers 610 to 619 are allocated to medicine and all medical books will therefore be found within this range. Individual classmarks for specific subjects are build up from these classmarks by the addition of extra numbers e.g.:

616	-	Internal Medicine
616.4	-	Endocrinology
616.462	-	Diabetes.

7. INDEXES AND ABSTRACTS

An indexing journal is one which, simply by means of author and subject indexes, lists the contents of a number of other journals, e.g. : Index Medicus. An abstracting journal performs the same function but in addition provides an abstract or brief summary of the paper indexed e.g. Biological Abstracts. To search literature by means of indexes and abstracts, you should first select the paper most relevant to your search interest (recommended by our supervisor/librarian). Then begin with the most recent issue available, search under the subject headings of interest and continue backwards as far as you wish to go, making a note of every article which seems to be interest. With the easy availability of computerized indexes such as 'MedLine', the utility of print indexes is very little. The main indexing and abstracting journals are listed below.

- A. **Index Medicus** published by the National Library of Medicine indexes the contents of thousands of the world's important medical journals. It is the print version of MedLine. Each monthly issue consists of articles indexed for both subject and authors. At the end of the year these issues are combined to form the Cummulated Index Medicus. Each topic is divided into various sub-headings such as etiology, metabolism, occurrence, toxicity etc. These are called medical subject headings (MeSH) which are constantly under review.
- B. **Excerpta Medica** is published from the Netherlands and provides abstracts from medical and scientific journals, excluding nursing, dentistry and the veterinary sciences. Each issue consists

of a number of abstracts arranged under broad subject groups followed by an index of authors and subjects. The subject index is based on the title of the paper, as well as its content; thus a paper would appear in the index more than once, depending upon the number of primary indexing terms selected, which indicate the substance of that paper.

C. Biological abstracts: It covers reports, reviews, meetings and abstracts from journals, books, monographs and conference proceedings. It appears fortnightly and each issue consists of abstracts arranged under very broad subject group such as enzymes, muscles, Radiation Biology etc. The references in each volume are numbered consecutively and include the authors' complete address and an abstract of the paper.

D. Science citation index: The reference list at the end of a scientific paper is there to substantiate a statement made in the text, or to show the original description of a method used. Many readers refer to these earlier papers for more information. The Science citation index enables this process to be reversed i.e. the reader can take an earlier reference of interest, and locate later papers which have cited it. It appears 6-times a year with an annual cummulation and consists of 3 separate but related indexes: the citation index, source index and permuter subject index.

8. REVIEWS

For a more selective approach to the literature, you need to consult a review paper. Such papers are usually written by an expert who surveys and critically analyses the literature on a subject. They carry a personal evaluation from the author and have a list of recommended references and are therefore an excellent starting point for anyone unfamiliar with the literature in that field. Review papers appear usually in journals designed for this purpose, such as 'Pediatrics in Review', 'Nutrition Reviews' etc.

9. OTHER CATEGORIES (theses and conference proceedings)

A journal called 'Dissertation Abstracts International' provides complete details, including abstracts of theses accepted in United States and many European countries. The association of Indian Universities also brings out a list of accepted theses.

Chapter 5

Writing the Introduction and Review

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The review traditionally provides a historical overview of the research literature, with a special emphasis on literature specific to the thesis topic. It should be selective. A common mistake is to comment on everything related to the topic regardless of its relevance. The review is like an inverted pyramid- widest to start with (an overview), and narrowest in the end (discussing the research that relates to your specific topic).

Another way of looking at it is to imagine you are a film director (Rudestam and Newton, 1992). Provide your audience with: long shots (giving a solid sense of the background); middle distance shots (the key figures and elements are brought clearly into view); and, close-up shots (the precise focus of your work is pinpointed).

For the Master's thesis submitted to Delhi University, the review of the literature is stand-alone, rather than embedded in the discussion, or segmented into a series of chapters on several topics.

Why do you need to review the literature for your thesis or project?

A review of the literature has the following functions:

1. To justify your choice of research question, theoretical or conceptual framework, and method
2. To establish the importance of the topic
3. To provide background information needed to understand the study
4. To show readers you are familiar with significant and/or up-to-date research relevant to the topic
5. To establish your study as a link in a chain of research that is developing knowledge in your field

What are the Reviewers looking for?

It should be evident to the reader that you:

- a) have a clear understanding of the key concepts/ideas/studies/ models related to your topic,
- b) know about the history of your research area and any related controversies

- c) can discuss these ideas in a context appropriate for your own investigation, can evaluate the work of others
- d) can clarify important definitions/terminology
- e) can narrow the problem; make the study feasible

Questions you need to ask yourself when planning and drafting your Literature Review:

1. What has been done in your field of research? What principles of selection are you going to use?
2. How are you going to order your discussion? Chronological, thematic, conceptual, methodological, or a combination? What section headings will you use?
3. How do the various studies relate to each other? What precise contribution do they make to the field? What are their limitations?
4. How does your own research fit into what has already been done?

'Literature' can include a range of sources:

Journal articles, monographs, computerized databases, conferences proceedings, dissertations, empirical studies, government reports and reports from other bodies, historical records, and statistical handbooks.

The review should have an introduction, a body, and a conclusion

The introduction is like a map that provides the scale and structure of your review.

The body of the review is evaluative and not merely descriptive.

The conclusion sums up the main findings of your research into the literature, in relation to the aims of the study you are proposing. The reader is given a coherent background to your study.

Introduction

The introduction should define the topic and purpose of the review and describe its relevance to your research. It should be written so that your research question is interesting and seems logical. Figure out and expand on the special angle of your study. It may be that the kind of population you are studying has not been studied before; the instrument you propose to study has not been used in this kind of study. It should be clear to the reader that there is something new and important about your study.

Body of Review

Start with a very brief outline. The outline should go from the general to the particular. The start is usually a general statement that anyone can be interested in and agree with, eg: “it is well known that malnourished children are at greater risk for pneumonia than well nourished ones.” Then you narrow in on the current state of knowledge in a specific area of that field; finally a controversy or question that hasn’t been solved.

The starting outline should consist of sub topics that follow logically. Remain focused; delete anything that is not necessary to your outline. After writing the outline, identify sub-topics or sub headings and write a paragraph for each.

Each paragraph should begin with a topic sentence. Topic sentences make the organization of the paper clear to the reader, and they help the writer stay focussed. Within the paragraph, move from the general to the particular. Put important things early in the paragraph and early in the sentence. If an idea is not tightly related to the topic sentence of the paragraph, be ruthless and delete it; if the information is not central to your point, it will distract the reader.

When searching the literature on your topic, consult several sources of evidence-based reviews. Use high-quality recommendations that are relevant to the topic; they should be based on the highest level of evidence available. If you are not sure about the source or strength of the recommendation, return to the literature, seeking out the basis for the recommendation, preferably in an authoritative compendium of evidence based reviews, or at least try to find a meta analysis or well-designed randomized controlled trial (RCT) to support it. If no strong evidence exists to an approach, point this out in the text.

Patient-Oriented vs. Disease-Oriented Evidence

Shaughnessy and Slawson developed the concept of Patient-Oriented Evidence that Matters (POEM), in distinction to Disease-Oriented Evidence (DOE). POEM deals with outcomes of importance to patients, such as changes in morbidity, mortality, or quality of life. DOE deals

with surrogate end points, such as changes in laboratory values or other measures of response. Use POEM-type evidence rather than DOE. When DOE is the only guidance available, indicate that key clinical recommendations lack the support of outcomes evidence. For example: “Although prostate-specific antigen (PSA) testing identifies prostate cancer at an early stage, it has not yet been proved that PSA screening improves patient survival.” (PSA testing is an example of DOE).

Evaluating the Literature

Evaluate the strength and validity of the literature that supports the discussion. Prefer meta-analyses, high-quality, randomized clinical trials with important outcomes, or well-designed, nonrandomized clinical trials, clinical cohort studies, or case-controlled studies. Avoid anecdotal reports or repeating the hearsay of conventional wisdom, which may not stand up to the scrutiny of scientific study (e.g., prescribing prolonged bed rest for low back pain).

Rating the quality of studies:

Level A: High-quality randomized controlled trial (RCT) that considers all important outcomes; high-quality meta-analysis using comprehensive search strategies.

Level B: Includes lower quality RCTs, clinical cohort studies, and case-controlled studies with nonbiased selection of study participants and consistent findings. Other evidence, such as high quality, historical, uncontrolled studies, or well-designed epidemiologic studies with compelling findings, is also included.

Level C: Consensus viewpoint or expert opinion.

Rate each recommendation including the letter rating (A, B, C), followed by the specific type of study for that reference. For example:

- “To improve morbidity and mortality, most patients in congestive heart failure should be treated with an angiotensin-converting enzyme inhibitor. [Evidence level A, RCT]”
- “The American Diabetes Association recommends screening for diabetes every three years in all patients at high risk of the disease, including all adults 45 years and older. [Evidence level C, expert opinion]”

When scientifically strong evidence does not exist to support a given clinical recommendation, point it out. For example:

- “Physical therapy is traditionally prescribed for the treatment of frozen shoulder, although there are no randomized outcomes studies of this approach.”

Your literature review should end with a compelling rationale paragraph. This is where you state the lacunae in the literature that you will address, and how your study will seek to fill it.

Some useful tips

Read other literature reviews

Quotations: quotations should only be used if exact wording or terminology has to be included.

Voice: Avoid 1st person

Example: In this review, I will show that the literature on treating is sparse.

Unfortunately, I have found that most of the treatment results are

Instead, use: ‘The literature on treating is sparse Most of the treatment results are ...’

Avoid slang. Use scientific language. Say ‘conducted a study’ instead of ‘did a study’; ‘examined’ instead of ‘looked at’.

Arrange by topics, not chronologically.

Be concise: Delete unnecessary words, phrases, and sentences.

References: develop the habit of citation. It is plagiarism to use other writers’ words and ideas.

Read and reread your draft. Write multiple drafts. Reread several times to identify repetitious or confusing sentences. If a paragraph seems long or wordy, recall the main ideas of the paragraph, and try to convey only those. If the paragraph has no theme, delete it. If you describe something in one paragraph, and then reiterate it a page later, it usually means that the intervening paragraphs are not relevant and could be deleted or moved.

Some Sources of Evidence-Based Medicine

- Centre for Evidence Based Medicine (CEBM) <http://cebm.jr2.ox.ac.uk/>
- Cochrane Database of Systematic Reviews <http://www.cochrane.org/>
- Database of Abstracts of Reviews of Effectiveness (DARE) <http://agatha.york.ac.uk/darehp.htm>
- Abstract summaries *Clinical Evidence*, BMJ Publishing Group www.clinicalevidence.org

Chapter 6

Planning the Statistical Analysis

Dr Pankaj Kumar Garg, Dr. Khan Amir Maroof

MEU, UCMS and GTBH, Delhi

Many medical researchers would wonder why they need to know about statistics. Statistics is the base on which data analysis of all clinical, basic, and epidemiological research stands. Doctors who are not researchers also need to understand statistics; it helps to analyze strengths and weaknesses of published data, and to decide whether to apply the results to their practice. With the availability of user friendly software, statistics has become a reality for busy researchers; all they need is to be computer friendly and understand basic principles of statistical analysis.

Data vs Variable

A variable is something whose value can vary. Example: age, sex and blood type.

Data are the values you get when you measure a variable. Example: 18 years (for the variable age), or male (for the variable sex).

Types of data

There are basically two types of data: (a) categorical or qualitative data (b) Numerical or quantitative data.

1. Categorical data is one which can be divided into categories or groups. Examples: result-pass/fail, blood groups (O,A,B,AB), severity of disease (mild, moderate, severe)
2. Numerical data is one which can be measured in whole numbers and fractions. Example: height, weight, blood pressure.

Properties of data

Any data is usually summarized by its two properties: **Central Tendency** and **Dispersion**

Measure of central tendency

Central tendency is defined as the middle, or typical, value of data which represents the whole data. It gives an idea of the value around which all observations in the data set appear to concentrate.

For quantitative data, the three common types of measures of central tendency are:

Mean

- Sum of observed values divided by number of observations
- Most common measure of centrality
- Most informative when data follow normal distribution (bell-shaped curve)

Median

- “Middle” value when observations are arranged in either ascending or descending manner; half of all observed values are smaller, half are larger
- Best centrality measure when data is non uniform

Mode

- Most frequently observed value; it is rarely used.

For qualitative data, we use proportions or percentage.

Measure of dispersion

Measure of dispersion of a data gives an idea of the extent to which the vales are clustered or spread out. Most common measures to describe variability are **standard deviation** and **interquartile range**.

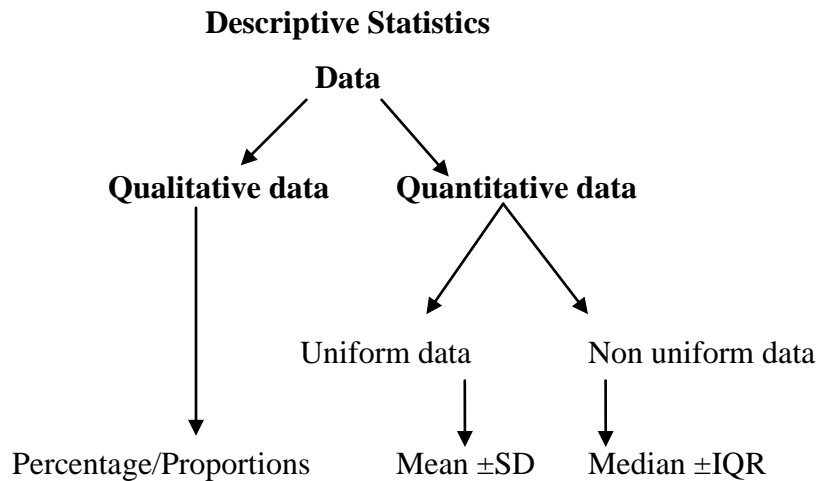
- **Standard deviation (SD)** provides information how much the data vary around the mean. It is a function of the squared differences of each observation from the mean. 1 SD includes 68% of values while 2 SD includes 95% of values around the mean.
- **Interquartile range (IQR)** provides information how much the data vary around the median when observations are arranged in either ascending or descending manner. It includes middle 50% of values from 1st quartile to 3rd quartile.

It is important to find out whether the data is uniform or not.

Uniform data (parametric data) do not have extreme values; the frequency distribution graph is symmetrical.

Non uniform data (non parametric data) has outlier values; the frequency distribution graph is asymmetrical.

The following algorithm will help in deciding how available data should be presented



Concepts of Confidence interval and standard error of mean

Confidence intervals (CI) are typically used when, instead of simply wanting the mean value of a sample, we want a range that is likely to contain the true population value. This “true value” is another tough concept – it is the mean value that we would get if we had data for the whole population. We can calculate a range (interval) in which we can be fairly sure (confident) that the “true value” lies.

Example: we may be interested in blood pressure (BP) reduction with antihypertensive treatment. From a sample of treated patients we can work out the mean change in BP. However, this will only be the mean for our particular sample. If we took another group of patients we would not expect to get exactly the same value, because chance can also affect the change in BP. The CI gives the range in which the true value (i.e. the mean change in BP if we treated an infinite number of patients) is likely to be. The average systolic BP before treatment in study A, of a group of 100 hypertensive patients, was 160 mmHg. After treatment with the new drug the mean BP dropped by 20 mmHg. If the 95% CI is 15–25, this means we can be 95% confident that the true effect of treatment is to lower the BP by 15–25 mmHg.

$$95\% \text{ CI} = \text{Mean} \pm 2 \times \text{SD}/\sqrt{n}$$

$$95\% \text{ CI} = \text{Mean} \pm 2 \times \text{SEM}$$

Standard deviation is used for a given sample, while SEM is used for population.

Concept of hypothesis testing

Hypothesis testing is to quantify our belief against a particular hypothesis. Example: in a clinical trial for testing a new drug for reduction in blood pressure, we start with null hypothesis i.e. this drug is ineffective in reducing the blood pressure. The alternate hypothesis is that this drug is effective in reducing the blood pressure. We apply statistical tests to find out the probability (p-value) of null hypothesis being true. If probability of null hypothesis being true is less than significant, we reject it; the alternate hypothesis is accepted. Conventionally, significant probability (p value) is taken as > 0.05 or 5%, but this may be any value for a particular research. P value may range from 0 to 1.

Paired vs unpaired data

When a variable is measured in the same group of people before and after an intervention, data we get is known as paired data.

Example: hemoglobin value in 100 pregnant women before and after iron supplementation.

When a variable is measured in different groups of people, we get unpaired data.

Example: hemoglobin value in 100 pregnant women without iron supplementation and another 100 pregnant women with iron supplementation

Concept of type I and type II errors

Type I error occurs when we reject the hypothesis considering that it is false, but it is true in reality. This is also known as alpha (α) error.

Type II error occurs when we accept the hypothesis considering that it is true, but is false in reality. This is also known as beta (β) error.

Type I error is more dangerous than type II; type I error will lead to acceptance of hypothesis when it is actually wrong. So, conventionally we set type I error as 5% in our research design.

Concept of power

The power of a statistical hypothesis test measures the test ability to reject the null hypothesis when it is false in reality- that is, to make a correct decision.

So, power of a test = $1 - \beta$

The power can be any value between 0-1. Ideally we want a power of 1 (100%). Larger the sample size, higher is the power. Conventionally, we set power of a test as 0.8 or 80%.

		Truth \longrightarrow	
Conclusion \downarrow		No difference	Difference
	No difference		Type II
	Difference	Type I	Power

Sample size

Determining sample size is a very critical issue as large samples may waste time, resources and money while small samples may lead to inaccurate results. Sample size calculation will depend upon the research design.

For a **prevalence study**, sample size may be calculated based on expected prevalence, standard deviation and 95% confidence interval.

For **hypothesis testing** for population proportion, following information will be required

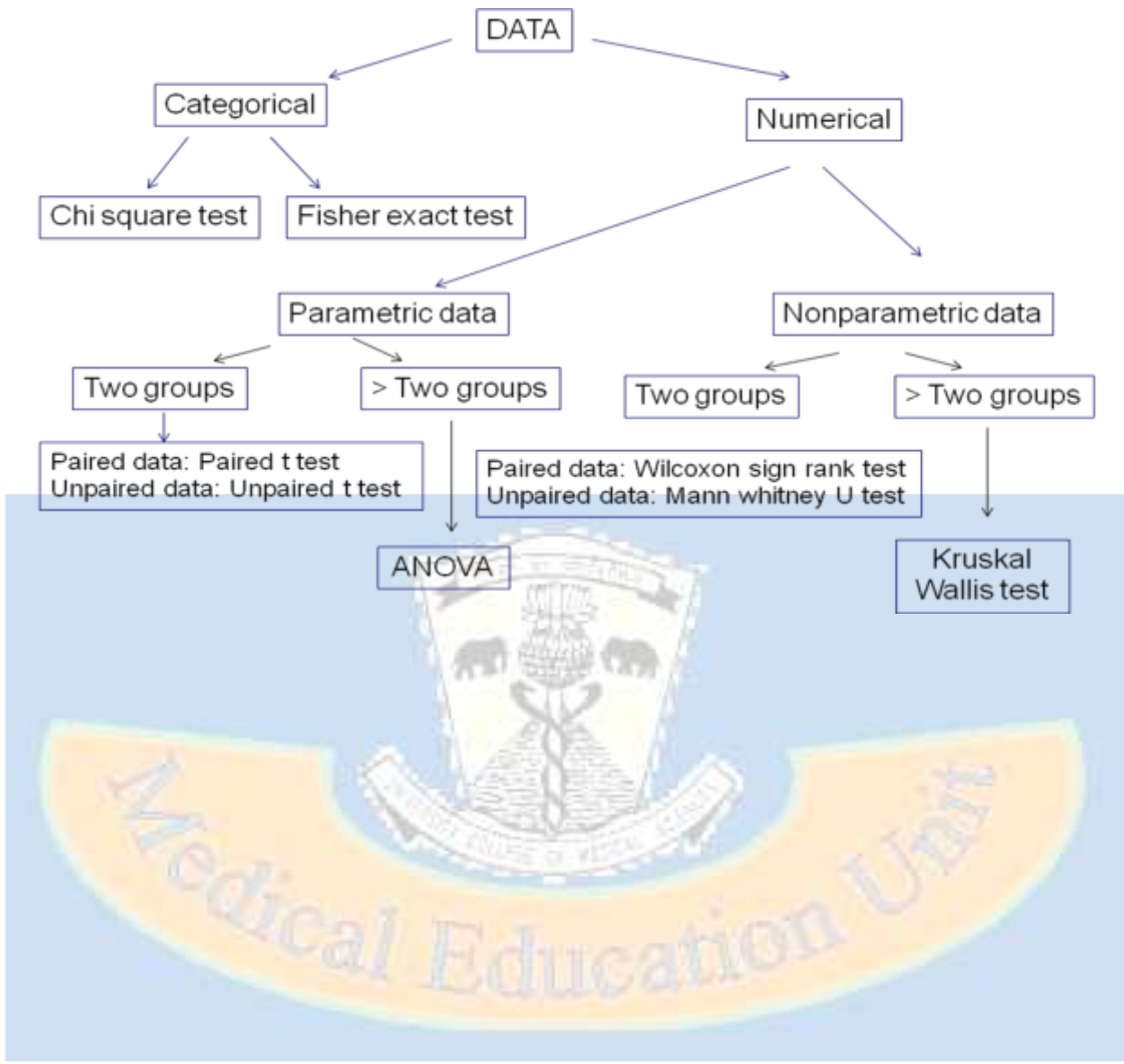
1. Test value of population proportion under null hypothesis
2. Anticipated value of population proportion
3. Level of significance or type I error, conventionally taken as 5%
4. Power of the study, conventionally taken as 80%

Sample size may not be calculated if prior information is lacking. This situation calls for the pilot study to be undertaken.

Choosing a statistical test for a database: Our choice will depend upon the following factors

1. Whether the variable is categorical or continuous
2. Whether the data in that variable is normally distributed or not; and
3. Whether the data is paired or unpaired.

The following algorithm shows how an appropriate statistical test may be selected based on the above parameters.



Chapter 7
Writing the Thesis Protocol
Dr. Dheeraj Shah
MEU, UCMS and GTBH, Delhi

The first step towards acquiring a post graduate thesis is the writing of a thesis protocol and the presentation of the same to the research/thesis committee for a critical appraisal. The protocol needs to be corrected according to the suggestions given by the committee. Finally, it needs to be approved by the University. The thesis protocol is then considered an official document and the thesis work needs to conform to the same.

General Guidelines

The recommended format of Thesis-Protocol for the University of Delhi is as follows:
AMENDMENT TO APPENDIX -II TO ORDINANCE V AND VII OF THE ORDINANCES OF THE UNIVERSITY RELATING TO POST-GRADUATE, SUPER-SPECIALTY (D.M.-M.Ch) AND Ph.D COURSES

Title Page	Page- 1
Certificate from Institution	Page-2
Summary of Protocol	Page-3
Introduction/ background including lacunae in existing knowledge	Page-4
Brief review of literature	Page-5-7
Objectives of research project	Page-8
Patients/ Subjects/ Materials and Methods including plan of statistical evaluation	Page-9-11
Index of references (Vancouver system of references)	Page-12-13
Appendix, if any (Data Sheet, Consent form, etc.)	

Other technicalities:

- Four copies to be submitted
- Pages: Generally should not exceed 13 (appendices extra)
- Font size:12
- A4 size paper
- Line spacing: Double space
- Margins: At least 2.5 cm on both sides
- Margins: Justified

HOW TO USE THIS TEMPLATE

This protocol template can be used to develop a thesis protocol for the MD / MS courses of Delhi University.

It contains sections “A” TO “H” defined in the University Calendar, and amplifies them for ease of use. However, there are some sections which will not be needed in every study. When you identify such a section (e.g. the one on interventional studies, and your study does not have an intervention) you should delete it.

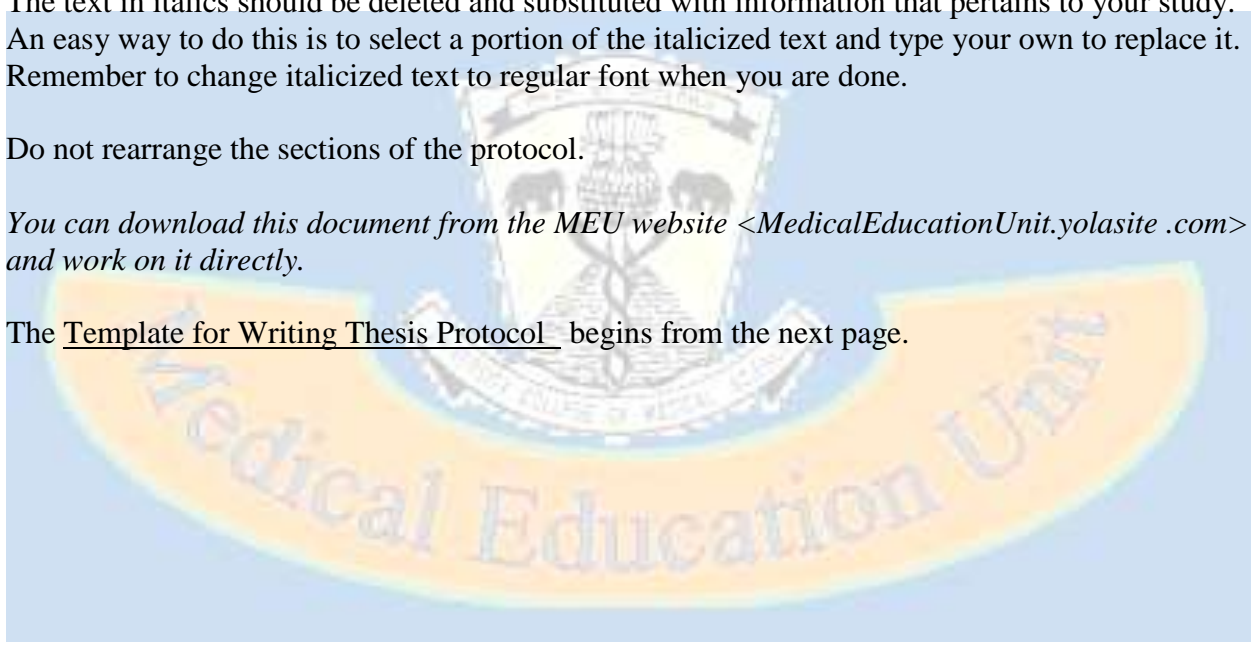
*Instructions and / or sample text is provided in italics to generate ideas of what should be included in some of the sections. The **key-words** are in bold italics to ensure that you do not miss putting in essential information.*

The text in italics should be deleted and substituted with information that pertains to your study. An easy way to do this is to select a portion of the italicized text and type your own to replace it. Remember to change italicized text to regular font when you are done.

Do not rearrange the sections of the protocol.

You can download this document from the MEU website <MedicalEducationUnit.yolasite .com> and work on it directly.

The Template for Writing Thesis Protocol begins from the next page.



A. TITLE PAGE (*Annexure I*)

This page carries:

- **Title of thesis** (*Write in title case or capital letters*)
- **Name of the University**
- **Degree (with discipline)** *for which the thesis is being submitted*
- **Years of the batch**
- **Name and Signature of Candidate**
- **Names and Signature(s) of Supervisor and Co-supervisor(s)**

B. SUMMARY OF PROTOCOL

The protocol summary should be no more than 300 words and at the most a page long (font size 12, single spacing). The summary should be able to stand on its own. Fragment/phrases can be used instead of complete sentences. Provided on a separate page, it should summarize all the central elements of the protocol in a STRUCTURED manner as given below:

Study title: *Enter the full title*

Rationale: *Specify the reason for conducting this research in light of current knowledge i.e. why the research needs to be done and its relevance.*

Objective: *State the research question.*

Setting: *Place where the study will be conducted eg. outpatients, community, school, tertiary care hospital, dispensary, etc.*

Study design: *Observational/interventional; if observational, descriptive or analytical; if analytical, cross sectional or longitudinal. If interventional, whether controlled or non-controlled (randomized control trial, cohort, case-control) etc.*

Time frame: *Time during which the study will be conducted (from inception to submission)*

Population/ participants: *List the nature (age, sex, characteristics etc.), inclusion/exclusion criteria, method of enrollment.*

Sample size: *State the total number of patients for the study*

Methods: *List of procedures/Intervention*

Outcome measures: *List primary and secondary outcome measures*

Statistical analysis: *Statistical methods proposed to be used for data analysis.*

C. INTRODUCTION

*It should include a well documented **statement of the need/problem** that is the basis of the project, the **cause** of this problem and its **possible solutions**. It should answer the question of why and what: **why the research needs to be done** and **what will be its relevance**. Organize the information to present the more general aspects of the topic early in the introduction, then*

narrow toward the more specific topical information that provides context, finally arriving at your **statement of purpose and rationale**. Provide a clear statement of the **lacunae** in the current status of knowledge and state the purpose and /or **hypothesis** that you will investigate.

D. REVIEW OF LITERATURE

The **magnitude, frequency, affected geographical areas, ethnic and gender considerations**; etc of the problem should be followed by a brief description of the most relevant studies published on the subject. This section should answer the questions of: what is the **current knowledge** about the subject of study? In what ways the problem has been approached by others, and what are the results? Are the reported studies contradictory? What are the **lacunae** in the existing knowledge?

E. AIMS AND OBJECTIVES

Aims are broad statements of what the proposal hopes to accomplish. They create a setting for the proposal. Specific **objectives** are statements of the **research question(s)**. Objectives should be simple (not complex), specific (not vague), and stated in advance (not after the research is done). After statement of the **primary objective**, **secondary objectives** may be mentioned.

F. MATERIAL AND METHODS

A checklist for 'Materials and Methods' is enclosed as Annexure II.

This section is the most important part of the protocol. The **design** of the study should include information on the **type of study**, the **research population** or the sampling frame, **inclusion and exclusion criteria**, withdrawal criteria (e.g. who can take part etc.), and the expected **duration** of the study

It should include detailed information on the **interventions** to be made, **procedures** to be used, **measurements** to be taken, **observations** to be made, **laboratory investigations** to be done etc. Interventions should be described in detail, including a description of the **drug/device/vaccine** that is being tested. Interventions could also be in the realm of social sciences for example providing training or information to groups of individuals. Procedures could be biomedical (collection of blood or sputum samples to develop a **diagnostic test**), or in the realm of social sciences (doing a **questionnaire** survey, carrying out a focus group discussion as part of formative research, observation of the participant's environment, etc.).

Standardized and/or documented procedures/techniques should be described and **bibliographic references**, if not provided earlier should be provided. **Instruments** which are to be used to collect information (questionnaires, FGD guides, observation recording form, case report forms etc.) must also be provided.

In the case of a randomized controlled trial additional information on the **process of randomization and blinding**, description of **stopping rules** for individuals, for part of the study or entire study, the **procedures and conditions for breaking the codes** etc. should also be described.

A graphic outline of the study design and procedures using a **flow diagram** must be provided. This should include the timing of assessments.

G. DATA MANAGEMENT AND STATISTICAL ANALYSIS

The protocol should provide information on how the data will be managed, including **data handling** and **coding** for computer analysis, monitoring and verification. The **statistical methods** proposed to be used for the analysis of data should be clearly outlined, including **reasons for the sample size** selected, **power of the study**, **level of significance** to be used, procedures for accounting for any missing or spurious data etc. For projects involving qualitative approaches, specify in sufficient detail **how the data will be analysed**.

H. REFERENCES

References should be **cited in the text** of the protocol. In this section, a list of references cited in the text should be listed in their **order of appearance** in the text. Standard **Vancouver method** should be used to cite references.

ANNEXURES

CASE RECORD FORM (Clinical Data Sheet) A sample case record form is enclosed as Annexure III

The data sheet will have information about

- The **subject** (patient)
- The **procedure** carried out
- **Outcome measure(s)** at predefined interval
- Observations and comments about that very particular case

Must capture required, relevant, accurate and analyzable data.

INFORMED CONSENT (Annexure IV)

Before requesting an individual's consent to participate in research, the investigator must provide the individual with the information about the **purpose of the study**, the **expectations from the participant**, the **responsibility of the investigators**, **risks and benefits** of the intervention/method, the **alternatives** available (if interventional study), and the **options to withdraw** from the study.

Annexure I: Sample Title Page

Protocol of Thesis to be submitted to the (Name of University) towards the partial fulfillment of the requirement for the Degree of MD/MS (Discipline) (Batch Year-Year)

Title of Thesis:

Name of student:

Signature:

Name and Designation of Supervisor:

Signature:

Name and Designation of Co-Supervisor:

Signature:



Annexure II:
Checklist for 'Materials and Methods'

When (.....to) and **where** the study will be carried out.

Type of study- Prospective/Retrospective. Descriptive or analytical. If analytical, whether observational (cohort, case-control or cross-sectional) or interventional (RCT, cross-over)

Subjects: Target population (age group, sex)
Details about the **control group** if any

Sample size, and the basis of this number

Place where subjects will be recruited from

Inclusion criteria- Define ages, criteria for defining disease condition / normalcy

Exclusion criteria- Subjects **who fulfil inclusion criteria** BUT would be excluded because of other conditions that could possibly of introduce bias.

Method of Randomization (if Randomized Controlled Trial) – How will randomization be done?
How will allocation concealment or/and blinding be done.

Intervention/Procedure: Detail if using a new method; or else quote standard reference if anybody else has already described the method you are going to use.

Describe:

Modifications you have made to a standard or published method.

Quantitative aspects- masses, volumes, incubation times, concentrations, machine specifications (include manufacturer's name and address)

Who will make the assessments and using what tools.

Frequency and duration of intervention.

Procedures and *schedules* of examination / investigations / treatment, and observation of outcome measures.

Dosage, formulations, schedules, duration of drug treatments, if any

Withdrawal criteria

Rules for withdrawal must be pre-defined

Define procedures to handle protocol violators and dropouts, withdrawals, therapy failures

Outcome measures

Primary Outcome Measures: these are the outcomes on which study hypothesis is based; the main thrust of interest in the protocol.

Secondary Outcome Measures are other outcomes of possible interest

Data management and statistical analysis

Procedure for data handling/ statistical tests planned

Annexure IV
Informed consent form*

I _____ son/daughter/wife of _____ resident of _____ give my full, free and voluntary consent to be included as a subject in the study entitled _____.

I have been explained, in my own language, and to my full satisfaction, the aim and nature of the study and risks and benefits. I have also been explained that my confidentiality will be maintained and all the investigations/ interventions will be carried out only after my consent is obtained. I am aware of my right to opt out of the study at any point without giving any reason, and without penalty or loss of routine care benefits.

Signature/Thumb impression Date and time

Patient's Name

Or _____

Parent's / Guardian's name

Name of witness

Name of doctor

*From the ICMR document 'Ethical guidelines For Biomedical research On Human participants' available at http://icmr.nic.in/ethical_guidelines.pdf

Consent form in Hindi

अवगत सहमति फार्म

मैं _____ बेटा / बेटी / पत्नी _____ निवासी _____ अपनी पूर्ण, स्वतंत्र और स्वैच्छिक रूप से _____ नाम के अध्ययन में सम्मिलित होने की सहमती देती/देता हूँ। इलाज करने वाले चिकित्सक ने मुझे मेरी अपनी भाषा में, और मेरी पूर्ण संतुष्टि से, अध्ययन के उद्देश्य और विधियों के बारे में, तथा जोखिम और लाभ के बारे में, समझाया है। मुझे यह भी बताया गया है कि मेरी गोपनीयता बनाइ रखी जाएगी और सभी जांच और हस्तक्षेप मेरी राज़गी के बाद ही किये जायेंगे। मुझे समझाया गया है कि मैं किसी भी वक्त, कोई कारण दिये बिना, बिना जुर्माना के अध्ययन से बाहर निकल सकती/ सकता हूँ।

मरीज के हस्ताक्षर / अंगूठे का निशान

दिनांक और समय

डॉक्टर के हस्ताक्षर

दिनांक और समय

गवाह के हस्ताक्षर / अंगूठे का निशान

दिनांक और समय

Participant/Patient Information Sheet

In addition, the investigator must provide to the individual as much of the following information (in the language he/she is able to understand) as is feasible, depending on the type of study.

1. Title of the research project
2. Nature and purpose of study, stating that it is research
3. The identity of the research teams with address and phone number of contact person/s
4. Duration of participation with number of participants
5. Procedures to be followed
6. Investigations, if any, to be performed
7. The benefits that might reasonably be expected as an outcome of research: to the subject, community or medical profession as may be applicable
8. Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk
9. Policy on compensation for risk/injury
10. Availability of medical treatment for such injuries or risk management
11. Whether free treatment for research related injury by the investigator/institution will be provided
12. Whether any compensation/reimbursement/insurance cover for participation or risk involved
13. Any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment to which he/she is being subjected
14. Steps taken for ensuring confidentiality
15. Contact details of Chairman of the Institutional Ethics Committee for appeal against violation of rights
16. If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines
17. Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results
18. Responsibility of investigators
19. Freedom of the individual to participate and to withdraw from research any time without penalty or loss of benefits which the subject would otherwise be entitled to
20. No loss of benefits on withdrawal
21. Benefit sharing in the event of commercialization
22. Publication, if any, arising out of this research.

A copy of the participant/patient information sheet should be given to the participant for her/ his record.

Chapter 8

Writing References

Dr Pooja Dewan, Professor Upreet Dhaliwal
MEU, UCMS and GTBH, Delhi

Referencing is a standardized way of acknowledging the sources of information and ideas that you have used in your assignments and which allows the sources to be identified.

A) References Vs Bibliography

Reference list and bibliography are similar, but not the same.

Reference list is ONE particular aspect of bibliography: i.e. the list of sources actually used in preparing a work and which are cited in the text of that work. You will be including a reference list that appears at the end of your protocol/thesis; the entries are listed numerically and in the same order in which they have been cited in the text.

Bibliography, on the other hand, is an extensive list of all of the following

1. Sources consulted as one works on a project, though not necessarily cited in the text
2. Sources cited in the final work
3. It represents the research done in preparation for writing
4. Sources offered as suggestions for further reading on the topic

A bibliography is a separate list from the reference list and should be arranged alphabetically by author, or title (where no author is given), in the Vancouver style.

B) Why include a reference list?

1. Important resource for the person reading your thesis
 - Can assess credibility of your work and form opinion
 - Can learn what is already done in that field
 - Gets ideas for further work
 - Helps in retrieval of the cited and related articles

2. Tells the reader which parts of the thesis are descriptions of previous knowledge and which parts are your additions to that knowledge.

You must give references for all ideas, concepts, text, and data that are not your own but have been obtained from books, journals, and other sources. If not, the reader will infer that the data is your own. This amounts to **plagiarism**: unauthorized use or close imitation of the language and thoughts of another author and representing them as one's own. Plagiarism is academic dishonesty or academic fraud and offenders are subject to academic censure.

To be useful, references need to be cited accurately.

To ensure accuracy:

- Cite correctly and completely
- Cite exactly as given by authors
- Place the citation accurately in the text
- Check the reference from the Original Source (Journal/Book/Article) where ever possible
- Avoiding citing cross-references, unless you have read the complete article
- Avoid citing material in foreign languages

C) The need for a uniform method arose because the scientific community is global, and a system that is comparable across nations was required. Moreover, sufficient information must be provided for readers to find the books and papers in a library or a database.

Referencing Style:

- Vancouver Style
- Howard Style

To ensure uniformity in referencing, most journals refer to the International Committee of Medical Journal Editors (ICMJE); this is also known as the 'Vancouver system' (1978) and is available at: <http://www.icmje.org/> (updated April 2010).

D) How to indicate references in the text

Method 1: Use index numbers in parenthesis (as recommended by ICMJE).

You may use square [3,4] or rounded (3,4) brackets; remember to use the same type of brackets throughout your text.

Example: This has been demonstrated by other authors as well.[3,4]

Method 2: Use index numbers as superscript numerals (as recommended by many journals)

Example: This has been demonstrated by other authors as well.^{3,4}

Rules for using Index numbers

The Vancouver System assigns a number to each reference as soon as it is cited in the text. A number must be used even if the author is named in the sentence.

Example: Agarwal, 1999 [10] has reported that....

Number references consecutively in the order in which they first appear in text. Thus, the first reference you cite will be given number 1, and so on.

This number will be the same where ever that reference reappears later

When one statement has several sources, indicate in the text as follows

- Consecutive references

Younger people are more inclined to multitask.[2-9]

- Do not use a hyphen if there are no citation numbers in between two references

Younger people are more inclined to multitask.[1,2]

- Non-consecutive references

Younger people are more inclined to multitask.[2,3,5,7,9]

- Some references consecutive, others not

Younger people are more inclined to multitask.[2-4,9]

Use commas (without spaces) to separate non-inclusive numbers in a multiple citation.

Example: [2,3,4,5,7,10] is abbreviated to [2-5,7,10].

▪ **References in tables and figures**

References cited only in tables or figure legends should be numbered according to the first identification *in the text* of that table or figure.

Example: In the past, the time taken to obtain a consultant's post was highly variable in the UK.[10] It was much longer than in other countries (Table 2). In the mid-1990s, British reforms to postgraduate medical training shortened the expected time of training; thus, now, progression to first consultant appointment takes around 8 years.[19]

From this example we see that studies 11 to 18 are used in Table 2; thus, even though the table is placed elsewhere (say on the next page, or at the end of the protocol/thesis), any references it contains must follow the sequence that is running in the text where the table is first mentioned.

DO REMEMBER

- **When referring to other works** *do not copy text written by other authors*. Summarize the information you need and rewrite it in your own words.
- Check that all material referred to in the *main text* is also available in the *reference list* at the end of the thesis. However, do not over-inflate the thesis with too many references. Conversely, all **references** listed at the end of the thesis should have been used in the **main text**.
- Verify references against the original documents, not from the reference list of some other article.

DON'T

- Don't use conference abstracts as references. Try to avoid this as far as possible; instead, use the full version of the paper published in conference proceedings.
- Don't give reference number to papers **submitted** to a journal but **not accepted**. These should be cited in the text as "unpublished observations"; take written permission to cite.

Example: An earlier study from this institution found that patients who had undergone surgery in government hospitals were more likely to achieve better outcomes (unpublished observations).

- Try not to include papers **accepted** for publication by journals but **not yet published**. If, however, they are important for your protocol/thesis, you may cite in the text and write “forthcoming”; obtain written permission to cite them, as well as verification that they have been accepted for publication.

Example: *An earlier study found that patients who had undergone surgery in government hospitals were more likely to achieve better outcomes (Singh S, forthcoming).*

- Don't cite a “personal communication” unless it provides essential information that is not available from a public source. You should cite the name of the person and date of communication in parentheses in the text.

- Don't cite retracted articles except in the context of referring to the retraction. You should identify retracted articles by using the following search term ‘Retracted publication [pt]’ in PubMed

E) How to list references in your reference list (the reference list is usually located at the end of the protocol/thesis)

- List them in the same order as they appear in the text; the index number now serves as the serial number. Take special care of capitals, punctuation and spacing
- List the first six authors followed by *et al.* The use of ‘*et al.*’ saves space; however, NLM now recommends listing all authors.

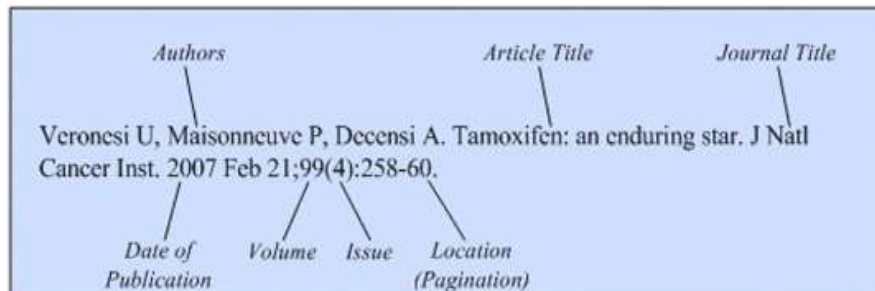
Greater detail is available online at

<http://www.icmje.org/> or <http://www.nlm.nih.gov/citingmedicine>

SPECIFIC EXAMPLES

1. PRINT JOURNALS

How to refer to articles from print journals



a. Standard journal article

Dhaon S, Jain P. Blood pressure levels before dementia. *Arch Neurol.* 2005;62(1):112-6.

b. Journal article with many authors

Jain P, Rattan JK, Bhutta Z, Gupta P, Sharma S, Sharma K, Sharma N, Jain JK. Towards a mutant map of the mouse: new models of neurological, behavioural, deafness, bone, renal and blood disorders. *Genetica.* 2004;122(1):47-9.

Or, restrict yourself to the first six authors, to save space

Jain P, Rattan JK, Bhutta Z, Gupta P, Sharma S, Sharma K, *et al.* Towards a mutant map of the mouse: new models of neurological, behavioural, deafness, bone, renal and blood disorders. *Genetica.* 2004;122(1):47-9.

c. Journal article with organization as author

American Diabetes Association. Diabetes update. *Nursing.* 2003 Nov;Suppl:s19-20, 24.

d. Journal article with governmental body as author

National Institutes of Health (US). End-of-life care. National Institutes of Health statement on the state of the science. *AWHONN Lifelines.* 2005;9(1):15-22.

e. Journal article with year having a supplement

Nair MK, Prasanna GL, Jeyaseelan L, George B, Resmi VR, Sunitha RM. Validation of Home Screening Questionnaire (HSQ) against Home Observation for the Measurement of Environment (HOME). Indian Pediatr. 2009;46 Suppl:s55-8.

f. Journal article having an erratum

Last P Amnioserosa is required for dorsal closure in Drosophila. Dev Dyn. 2005 Mar;232(3):791-800. Erratum in Dev Dyn 2005;233(1):245.

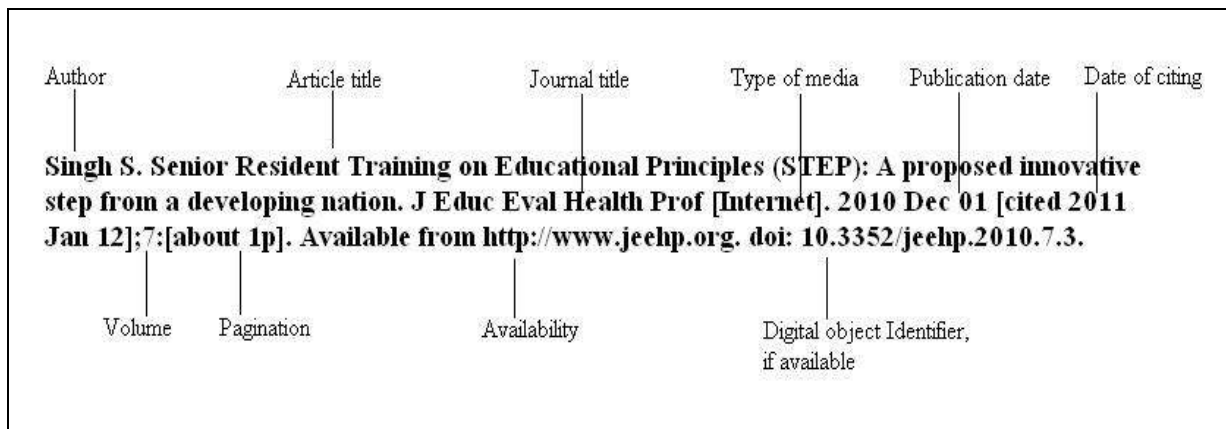
2. ONLINE JOURNALS

Referencing articles from online journals

a. standard journal article on the Internet

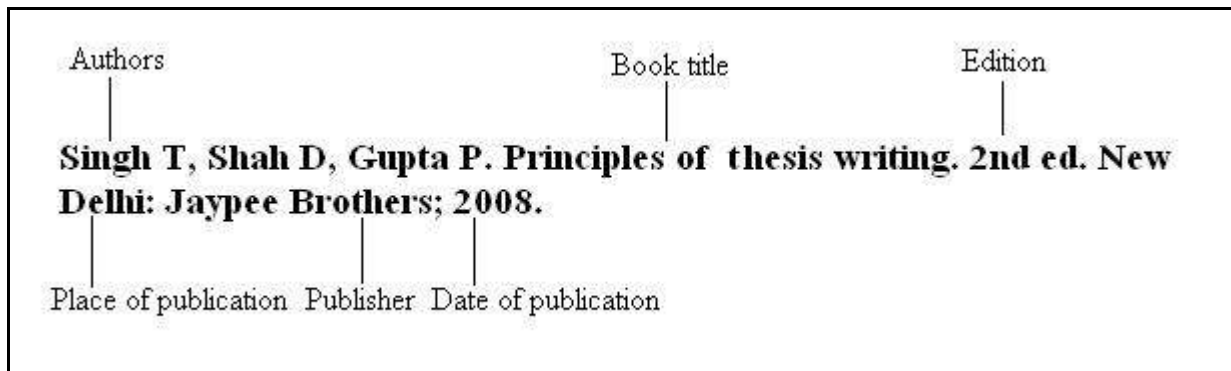
Polgreen PM, Diekema DJ, Vandenberg J. Risk factors for groin wound infection after femoral artery catheterization: a case-control study. Infect Control Hosp Epidemiol [Internet]. 2006 Jan [cited 2007 Jan 5];27(1):34-7. Epub 2006 Jan 6. Available from: <http://www.journals.uchicago.edu/ICHE/journal/issues/v27n1/2004069/2004069.web.pdf>

b. Journal article with DOI provided



3. BOOKS

a. Personal author



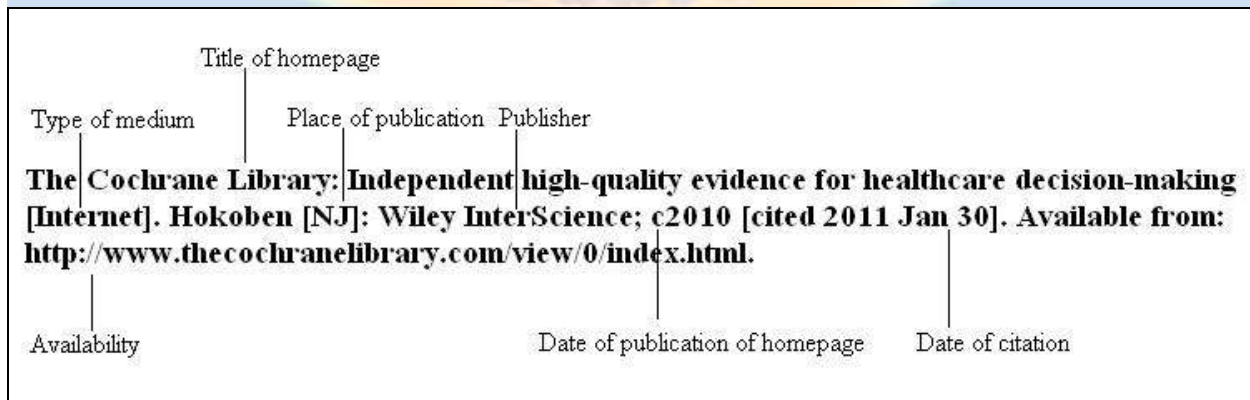
b. chapter in a book

Dewan P. Examination of the Nervous System. In: Gupta P, editor. Clinical Methods in Pediatrics. CBS Publishers: Delhi; 2009. P. 285-343.

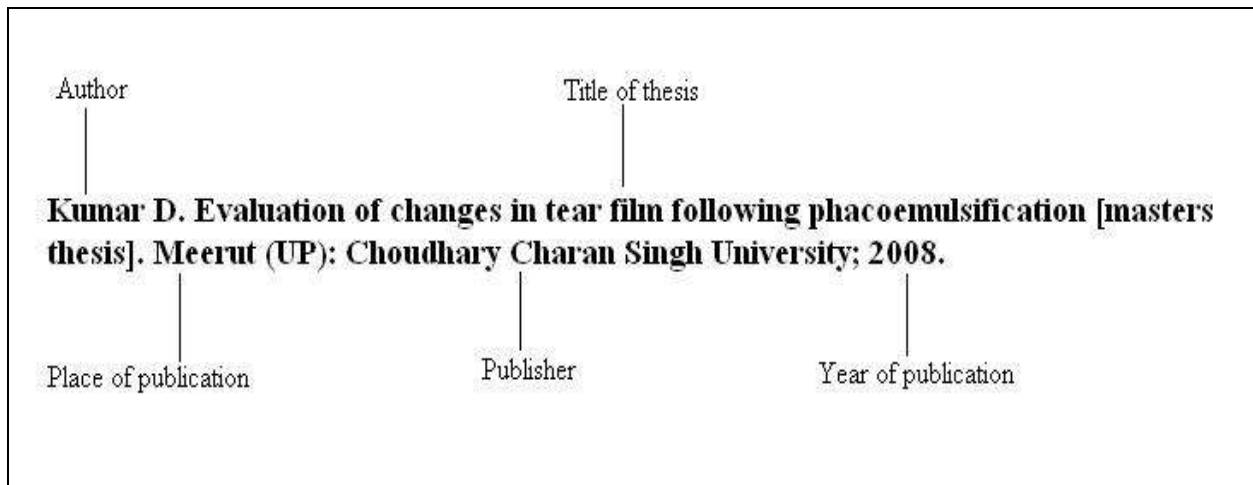
c. Contributed chapter in one volume of a multivolume book

Robinson A, Fridovich-Keil JL, Fridovich I. The principles of genetics and heredity. In: The new encyclopaedia Britannica. 15th ed. Vol 19. Chicago: Encyclopaedia Britannica, Inc.; c2002. p. 699-740.

4. WEBSITE



5. THESES



6. PAPER PUBLISHED IN CONFERENCE PROCEEDINGS

Christensen S, Oppacher F. An analysis of computational effort statistic for programming. In: Foster JA, Lutton E, editors. Genetic programming. EuroGP 2002: Proceedings of the 5th European Conference on Genetic Programming; 2002 Apr 3-5; Kinsdale, Ireland. Berlin: Springer; 2002. p. 182-91.

7. SCIENTIFIC & TECHNICAL REPORT

Page E, Harney JM. Health hazard evaluation report. Cincinnati (OH): National Institute for Occupational Safety and Health (US); 2001 Feb. Report No.: HETA2000-0139-2824. 24 p.

CITING MEDICINE

Citing Medicine: The NLM Style Guide for Authors, Editors, and Publishers, is recommended by the ICMJE

This is an online resource that details referencing methods for many other media like:

- Newspaper articles
- Maps
- Conference proceedings
- Scientific and Technical reports

- Audiovisual material
- Websites

It is available from: <http://www.nlm.nih.gov/citingmedicine>

Reference management software packages

The following free software can help you organize your references:

- [Aigaion](#)
- [BibDesk](#)
- [Connotea](#)
- [JabRef](#)
- [Pybliographer](#)
- [Rebase](#)
- [Referencer](#)
- [Zotero](#)

EndNote (Thomson Scientific; EndNote X2 (12) for Windows) is popular but not free!

Software can help you:

- Extract literature cited within a text and build an appropriate reference list
- Export and import references
- Search within lists
- Use Newer resources: Abstract, Conference, Magazine, Manual, Newspaper, Patent, Report,

Software

- Provide output in Vancouver, AMA, APA, Chicago, Harvard, or MLA style.

Chapter 9

Ethical and Legal Issues, Informed Consent

Dr Satendra Singh, Professor Upreet Dhaliwal

MEU, UCMS and GTBH, Delhi

1. Plagiarism

Definition: Using other peoples' ideas and words without clearly acknowledging the source of that information.

How to avoid plagiarism

Give credit whenever you use another person's

- idea, opinion, or theory
- statistics, graphs, drawings
- quotation of or paraphrase of spoken or written words

If you want to quote somebody verbatim, put the original words in “quotation marks” and give reference to the original source. Quotations are seldom used in a medical thesis. Rather, you should paraphrase: write out the idea in your own words. Do not just rearrange or replace a few words. Also, check your paraphrase to be sure that the information is accurate and you have not changed the meaning during paraphrasing. Give reference to the original source.

2. Copyright infringement

Copyright: The creator of a creative effort has the right to control who can make copies, or make works derived from the original. Every creative work is copyrighted the moment it is fixed in tangible form. No notice or registration is necessary, though it helps legal cases.

Does that mean we should seek permission every time we want to use material from another author's work?

No. Not if you use less than a substantial part of a copyright protected work and give sufficient acknowledgement. In addition, there are exceptions that allow limited use of copyright works without permission:

- Non-commercial research and private study

- Criticism, review and reporting current events
- Teaching in educational establishments

3. Fictitious data in thesis

Documentation of thesis research and results must respect the principles of academic integrity. Do not cook up data. Dishonesty discovered in the research conduct or reporting will merit disciplinary action. Remember that you have to sign a declaration that the material presented in the thesis is your own work. Your supervisor and co-supervisors will vouch for the truth of your declaration. Do remember to declare the contributions of co-workers.

4. Authorship

An “author” is generally considered to be someone who has made substantive intellectual contributions to a published study.

The ICJME recommends the following:

Authorship credit should be based on ALL three of the following:

- 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- 2) drafting the article or revising it critically for important intellectual content, and
- 3) final approval of the version to be published.

Moreover, all persons designated as authors should qualify for authorship, and all those who qualify should be listed

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.

Examples of persons who may be acknowledged

- Provided purely technical help
- Writing assistance
- A department chairperson who provided only general support

- Assistance with study design, data collection, data analysis, or manuscript preparation
- Financial and material support

Authorship order

- Order of authorship credit is determined by degree of scientific or professional contribution
- Authorship issues are best settled prior to writing the paper
- The student rarely has the skills or knowledge necessary to conceptualize and design a study, so the supervisor may earn first authorship

5. Participant Protection

Patient protection

When conducting experiments on human subjects follow the ethical standards of your Institutional Committee on human experimentation and the Helsinki Declaration of 1975, as revised in 2000

Patients have a right to privacy that should not be violated without informed consent. Identifying information (name, initials, hospital numbers) should not be published unless essential for scientific purposes. The patient (or guardian) must give written informed consent for publication

Animal protection

When conducting experiments on animals follow guidelines of your Institutional Ethical Committee for the care and use of laboratory animals

Informed consent

Before requesting an individual's consent to participate in research, the investigator must take the participant's consent. In addition, the investigator must provide to the individual as much of the following information (in the language he/she is able to understand) as is feasible, depending on the type of study.

A sample **consent form** and **Participant information sheet** is appended in Chapter 7 'Writing the Thesis Protocol'.